

VIA EMAIL ONLY

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Mail Stop Comments - Patents
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Re: Comments on *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena & Natural Products*

The following comments are submitted in response to the USPTO's request by the United States Patent and Trademark Office ("Patent Office") for public comments on the *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* ("Guidance") issued by the Patent Office to the Examining Corps on March 4, 2014.

The Guidance makes a number of errors in interpreting the relevant cases and synthesizing rules. These errors include:

(1) Failing to see the law of patent eligibility as only protecting against claiming a law of nature, natural phenomenon, or an abstract idea itself. Combination of one of these "judicial exceptions" with almost any other subject matter, including another judicial exception, should be sufficient for patent eligibility. The Guidance tends to treat each judicial exception in a claim in isolation for patent eligibility. This error is especially prominent in the examples relating to products of nature.

(2) Mixing and confusing the standards for, and analysis of, claims to methods involving laws of nature and claims involving products of nature. The cases show different concerns and different standards, as is appropriate, for methods versus manufactures and compositions of matter. The cases also show different concerns and different standards for laws of nature versus natural products.

(3) Analyzing patent eligibility using a balancing test, which is incompatible with the fact that patent eligibility is a threshold. Balancing of the many factors presented in the Guidance can lead to finding a claim patent ineligible when the claim is over the threshold of patent eligibility. A line drawing test is more appropriate for analyzing the threshold of patent eligibility.

(4) Failing to correctly understand the scope and meaning of claims involved in the relevant cases and, as a result, misinterpreting the holdings and their scope and meaning. The claims in the cases are more specific than the Guidance assumes with the result that the Guidance derives the wrong standard for the line between patent eligibility and ineligibility.

This comment analyzes the relevant cases, shows how the correct rule and analysis is derived from them, and then shows how the Guidance is incompatible with the cases.

The Law of Patent Eligibility

In its cases on patent eligibility, the Supreme Court starts with the relevant statute, 35 U.S.C. § 101, and then recounts the limited exceptions to patent eligibility. The recounting in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __ (2013), is typical, comprehensive, concise, and useful:

Section 101 of the Patent Act provides:

“Whoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

35 U.S.C. § 101.

We have “long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.” [*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 10 (2012)] (slip op., at 1) (internal quotation marks and brackets omitted). Rather, “they are the basic tools of scientific and technological work” that lie beyond the domain of patent protection. *Id.*, at __ (slip op., at 2). As the Court has explained, without this exception, there would be considerable danger that the grant of patents would “tie up” the use of such tools and thereby “inhibit future innovation premised upon them.” *Id.*, at __ (slip op., at 17). This would be at odds with the very point of patents, which exist to promote creation. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (Products of nature are not created, and “manifestations . . . of nature [are] free to all men and reserved exclusively to none”).

The rule against patents on naturally occurring things is not without limits, however, for “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.” 566 U.S., at __ (slip op., at 2). As we have recognized before, patent protection strikes a delicate balance between creating “incentives that lead to creation, invention, and discovery” and “imped[ing] the flow of information that might permit, indeed spur, invention.” *Id.*, at __ (slip op., at 23).

Myriad, 569 U.S., at __ (slip op., at 10-11).

Thus, patent eligibility is controlled by 35 U.S.C. § 101, subject to very limited exceptions established by the Supreme Court. In effect, anything under the sun that is made by man is patent eligible with the exception of laws of nature, natural phenomena, and abstract ideas. Such “judicial exceptions” are not patent eligible when claimed per se. When laws of nature and abstract ideas are claimed as part of a method, the method is patent eligible unless the claim lacks sufficient additional elements such that it is not just a claim to the judicial exception itself. *See Mayo*, 566 U.S., at __, 132 S.Ct., at 1294; *Parker v. Flook*, 437 U.S. 584, 594 (1978);

Bilski v. Kappos, 561 U.S. 177, ___, 130 S.Ct. 3218, 3230 (2010). In contrast, a product of nature is patent eligible if it is a product of human ingenuity having a distinctive name, character, or use. *Chakrabarty*, 447 U.S., at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)); accord *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11-12 (1931) (a manufacture is something given “new forms, qualities, properties, or combinations” or that “possesses a new or distinctive form, quality, or property”).

The Judicial Exceptions Should be Applied Narrowly

The Supreme Court emphasizes that the exceptions to patent eligibility should be applied conservatively to avoid having the exceptions eviscerate patent rights. *Myriad*, 569 U.S., at ___ (slip op., at 12); *Mayo*, 566 U.S., at ___ (slip op., at 2).

The Supreme Court has also emphasized that it has decided the cases before it on their particular facts. “Rather than adopting categorical rules that might have wide-ranging and unforeseen impacts, the Court resolves this case narrowly on the basis of this Court’s decisions in *Benson*, *Flook*, and *Diehr*.” *Bilski*, 561 U.S., at ___, 130 S.Ct., at 3229-30. “Neither the dearth of precedent, nor this decision, should therefore be interpreted as reflecting a judgment that patent protection of certain novel and useful computer programs will not promote the progress of science and the useful arts, or that such protection is undesirable as a matter of policy.” *Flook*, 437 U.S., at 595.

We do not hold that that no process patent could ever qualify if it did not meet the requirements of our prior precedents. It is said that the decision precludes a patent for any program servicing a computer. We do not so hold. It is said that we have before us a program for a digital computer but extend our holding to programs for analog computers. We have, however, made clear from the start that we deal with a program only for digital computers. It is said we freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology. Such is not our purpose.

Gottshalk v. Benson, 409 U.S. 63, 71 (1972); see also *Myriad*, 569 U.S., at ___ (slip op., at 17-18).

As the Court has noted, broad application of general rules without due regard for the facts of particular cases can lead to unintended results. *Bilski*, 561 U.S., at ___, 130 S.Ct., at 3226 (2010) (“This Court has more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed.” (internal quotes and citations omitted)); *Diamond v. Diehr*, 450 U.S. 175, 182 (1981); accord, *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1073-74 (Fed. Cir. 2011) (rehearing) (Rader, C.J., additional views) (“The patent eligibility doctrine has always had significant unintended implications because patent eligibility is a “coarse filter” that excludes entire areas of human inventiveness from the patent system on the basis of judge-created standards.”).

Finally, the Court has recognized that granting of patents is intended to foster productive effort that “will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased

employment and better lives for our citizens.” *Chakrabarty*, 447 U.S., at 307 (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974)).

Thus, it is important for the Patent Office to apply court decisions conservatively in view of the facts in the cases decided rather than applying broad rules or principles.

Only Claims to a Judicial Exception Itself are Patent Ineligible

As the Supreme Court has emphasized, the concern with a law of nature, natural phenomenon, or abstract idea is that the law of nature, natural phenomenon, or abstract idea not be claimed as itself.

In *Myriad*, the Court noted that “Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes” and that:

“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.

Myriad, 569 U.S., at ___ (slip op., at 11-12, 14-15) (emphasis added). Thus, *Myriad* involved a claim to both the gene and genetic information itself.

In *Mayo*, the Court concerned itself with whether Mayo’s claims were to a law of nature itself.

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? We believe that the answer to this question is no.

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.

Mayo, 566 U.S., at ___ (slip op., at 8-9) (emphasis added). Thus, *Mayo* involved a claim to a law of nature itself.

The Court in *Bilski* simply held that “petitioners’ application is not a patentable ‘process,’” concluding that:

The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.

Bilski, 561 U.S., at ___, 130 S.Ct., at 3231 (emphasis added). Thus, *Bilski* involved claims to an abstract idea itself.

The Court in *Diehr* held claims to a method of curing rubber was patent eligible despite it involving a mathematical equation and a computer. *Diehr*, 450 U.S., at 185 (“Our conclusion is not altered by the fact that in several steps of the process a mathematical equation and a programmed digital computer are used”). Significantly, the Court distinguished *Benson* and *Flook* by focusing on the mathematical formula itself: “In contrast [to *Benson* and *Flook*], the respondents here do not seek to patent a mathematical formula.” *Id.*, at 187 (emphasis added). Thus, *Diehr* involved a claim to more than an abstract idea itself.

The Court in *Chakrabarty* held claims to a bacterium with added energy-generating plasmids patent eligible despite that both the bacterium and the plasmids are natural products. *Chakrabarty* added naturally occurring plasmids to a naturally occurring bacterium to create a new combination of natural products. Importantly, *Chakrabarty* did not alter the plasmids or the bacterium (other than by combining them). The plasmids retained their natural structure and function. The bacterium was also structurally unaltered except for the added plasmids.

Chakrabarty held that *Chakrabarty'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 . . .” *Chakrabarty*, 447 U.S., at 309-10. Thus, *Chakrabarty* involved a claim to more than a product of nature itself.

The Test of Patent Eligibility is a Line Drawing Test, Not a Balancing Test

The Guidance provides three questions to be asked and answered sequentially in order to determine if a claim is patent eligible or not. Question 1 is: Is the claimed invention directed to one or more of the four statutory patent eligible subject matter categories: process, machine, manufacture, or composition of matter? If it is, the analysis moves on to Question 2: Does the claim recite or involve one or more judicial exceptions?¹ If so, the analysis moves to the final question, Question 3: Does the claim as a whole recite something significantly different than the judicial exception(s)?²

¹ As the Guidance notes, judicial exceptions include abstract ideas, laws of nature/natural principles, natural phenomena, and natural products.

² *Mayo and Alice Corp. v. CLS Bank Int'l.*, 573 U.S. ___ (2014) (slip op., at 7) both analyze patent eligibility in a two-part test that is similar to Questions 2 and 3 in the Guidance. *Mayo* and *Alice* both involved claims to methods involving a law of nature (*Mayo*) or an abstract idea (*Alice*). Significantly, the intervening *Myriad* case, involving claims to products of nature per se, not methods, did not use the two-step analysis of *Mayo*.

Why must the claim be “significantly different” (more than an incidental or trivial difference) from the judicial exception? The apparent source is some of the Supreme Court cases on patent eligibility:

The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. *Flook*, 437 U.S., at 590 (emphasis added).

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. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101. *Chakrabarty*, 447 U.S. 303, 310 (emphasis added).

Similarly, insignificant post-solution activity will not transform an unpatentable principle into a patentable process. *Diehr*, 450 U.S., at 191-192 (citing *Flook*) (emphasis added).

And they 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*, 566 U.S., at ___, 132 S.Ct., at 1294 (citing *Flook*, 437 U.S. 584, 594) (emphasis added).

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? *Mayo*, 566 U.S., at ___, 132 S.Ct., at 1297 (underlining added; italics in original).

But these are just statements of a standard from which a bare conclusion is drawn, using indefinite terms such as “conventional,” “markedly,” and “significant.” To understand what the Court’s rule is (when is the claim significantly different from the judicial exception), we need to closely examine the claims at issue in these cases.

First, it is important to recognize the distinct analysis the Court uses when assessing method claims involving a law or nature or abstract idea compared to the analysis the Court uses when assessing claims to alleged products of nature. The Guidance errs by mixing and confusing these distinct standards. The cases show different concerns and different standards, as is appropriate, for methods versus manufactures and compositions of matter. The cases also show different concerns and different standards for laws of nature versus natural products.

Supreme Court Analysis of Method Claims Involving Laws of Nature or Abstract Ideas

The claim at issue in *Mayo* involved very specific facts. As the Supreme Court emphasized, the treatment of patients with thiopurine drugs, the measurement of the metabolites of thiopurine drugs, and the general correlation of the blood concentrations of the metabolites of thiopurine drugs with the likelihood that a particular dosage of a thiopurine drug could cause

harm or prove ineffective were all well known and conventional at the time the invention was made. *Mayo*, 566 U.S., at ___ (slip op., at 5-6). Significantly, the Court also accepted that a doctor would infringe the method even if he did not take any action or alter his conduct based on the results of the metabolite measurement. *Id.*, at ___ (slip op., at 6-7). The Court also limited the holding to the facts at issue, noting that:

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. 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 ___ (slip op., at 18) (emphasis added).

Thus, the presence of nonconventional steps or elements or of nonconventional combinations of steps or elements in a claim involving a law of nature can add something significant beyond the law of nature and make the claim patent eligible. *Cf. Mayo*, at ___ (slip op., at 11). At the least, the holding in *Mayo* does not support patent ineligibility of a process that includes new or nonconventional steps or materials in combination with a law of nature.

The claim at issue in *Flook* was a method for adjusting alarm limits in the catalytic conversion of hydrocarbons using a mathematical formula. As the Supreme Court noted, the chemical processes involved in catalytic conversion of hydrocarbons, the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for automatic monitoring were all well known. *Flook*, 437 U.S., at 594. The Court held the claim patent ineligible because there was nothing new or nonconventional about the process except for the mathematical formula, noting that post-solution activity that is purely conventional or obvious cannot transform an unpatentable principle into a patentable process. *Id.*, at 589-90.

As in *Mayo*, the key factor in *Flook* was the conventionality of the steps, including the conventionality of the combination of all of the other steps, to which the law of nature (the mathematical formula) was applied. By implication, the holding in *Flook* provides nothing that questions the patent eligibility of a process that includes new or nonconventional steps or materials in combination with a law of nature.

The claim at issue in *Diehr* was a method for molding raw, uncured rubber into cured, molded products. The process used a known mathematical equation to determine when to open the mold, depending on the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber. *Diehr*, 450 U.S., at 177-78. The method involved the steps of installing rubber in a mold, closing the mold, continuously monitoring the temperature on the inside of the mold, using the temperature measurements with the mathematical equation to continuously recalculate the mold opening time with a computer, and configuring the computer to signal when the mold should be opened. *Id.*, at 178-79, 187. The Court held the claim patent eligible because the steps of the process beyond the mathematical equation integrated the mathematical equation in to the process as a whole. The Court noted that “[o]bviously, one does not need a ‘computer’ to cure natural or synthetic rubber, but if the computer use incorporated into the process patent significantly lessens the possibility of ‘overcuring’ or ‘undercuring,’ the process as a whole does not thereby become unpatentable subject matter.” *Id.*, at 187 (emphasis

added). Significantly, the Court stated that the mathematical “equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold of § 101.” *Id.*, at 188. *Diehr* also clearly moderates the import of the conventionality of features, elements, and steps in a claim, stating that the claim must be considered as a whole because:

a new combination of steps in a process may be patentable even though all of the constituents of the combination were well known and in common use before the combination was made. The “novelty” of any element or steps in a process, or even the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter. *Diehr*, at 188-189 (emphasis added).

In the footnote to this passage, *Diehr* notes that the Court “did not hold in *Flook* that the mathematical algorithm could not be considered at all when making the § 101 determination,” referring to the idea that *Flook* had disregarded the mathematical algorithm by assuming it to be within the prior art.

Thus, the *Diehr* decision makes clear that new properties, features, steps, and combinations, along with the law of nature, are to be considered and given positive weight toward patent eligibility. As the Court recognized in *Mayo*, *Diehr* provides a counterpoint to the claims in both *Flook* and *Mayo*. *Mayo*, 566 U.S., at ___ (slip op., at 11-13). The Court in *Mayo* believed that the fact that the combination of steps in the method of *Diehr* added something that had significance was sufficient to make the *Diehr* process a patent eligible application of the mathematical equation. *Mayo*, at ___ (slip op., 12).

The cases involving computer implemented methods are consistent with new elements, steps, and combinations supporting patent eligibility. The Court in *Benson* did not discuss the significance or conventionality of anything added to the algorithm there. However, the claim included only the use of a computer beyond the algorithm itself, which is, of course, conventional for implementing an algorithm. Thus, the facts and holding in *Benson* are completely consistent with the rule apparent in *Flook*, *Diehr*, and *Mayo*.

The Court in *Bilski* did not discuss the significance or conventionality of anything added to the abstract method there. However, the claim did not include anything beyond the abstract method itself. Thus, the facts and holding in *Bilski* are completely consistent with the rule apparent in *Flook*, *Diehr*, and *Mayo*.

The Court in *Alice* emphasized the conventionality of the computer used to implement the abstract method there, finding that the claims did not include anything beyond the abstract method itself. Thus, the facts and holding in *Alice* are completely consistent with the rule apparent in *Flook*, *Diehr*, and *Mayo*.

Taken together, all of the relevant Supreme Court cases with method claims involving a law of nature or natural phenomenon (implicating the “significantly more” standard) show that claims involving new properties, features, steps, and combinations, in combination with a judicial exception, are patent eligible. **Only when the claim consists of only old, conventional,**

and well know elements beyond the law or nature or natural phenomenon is the claim patent ineligible.

Supreme Court Analysis of Claims Involving Products of Nature

The claim in *Chakrabarty* was to a bacterium containing energy-generating plasmids that each provide a separate hydrocarbon degradative pathway. Chakrabarty added naturally occurring plasmids to a naturally occurring bacterium to create a new combination and a bacterium with new properties and uses (degradation of hydrocarbons in an oil spill). Importantly, Chakrabarty did not alter the plasmids or the bacterium (other than by combining them). The plasmids retained their natural structure and ability to express a degradative pathway. The bacterium was also structurally unaltered except for the added plasmids.

Chakrabarty held that Chakrabarty'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.'" *Chakrabarty*, 447 U.S., at 309-10 (misquoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)) (brackets in original). Significantly, although the Court goes on to state that "the patentee has produced a new bacterium with markedly different characteristics from any found in nature," the Court did not hold that "markedly different" characteristics were required for patent eligibility, only that Chakrabarty's bacterium had markedly different characteristics. *Id.*, at 310. The Court also emphasized the new function of the bacterium, stating that Chakrabarty's "human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills." *Id.*, at 305.

Thus, the Court in *Chakrabarty* established that products of nature manipulated such that they have a new characteristic—a new structure, new property, new function, or new use—are not products of nature and are thus patent eligible.

The claims at issue in *Myriad* were to isolated DNA coding for a BRCA1 or BRCA2 polypeptide having a particular amino acid sequence. *Myriad*, 569 U.S., at 5 (slip op.). In analyzing this claim, the Court recognized that, as an isolated DNA, chemical bonds had been broken and associated other DNA had been separated from the isolated DNA. *Id.*, at 14 (slip op.). But the Court minimized the significance of this structural alteration of the natural gene by emphasizing the informational content of the isolated DNA:

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. *Id.*, at 11-12 (slip op.) (emphasis added).

* * *

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally

occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. 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. *Id.*, at 14-15 (slip op.) (underlining added; italics in original).

* * *

Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. ... 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. *Id.*, at 18 (slip op.) (emphasis added).

Thus, the Court in *Myriad* minimized the chemical structural differences between the natural gene and the isolated DNA by emphasizing their functional identity. In the Court's view, the information encoded in DNA, whether in the natural gene or the isolated DNA, functions to specify and direct the construction of specific proteins. *Id.*, at 2-3 (slip op.). This is significant because it limits the nature of the holding in *Myriad*.

In a converse way, the rationale and holding of *Myriad* emphasizes the significance of functional differences between a natural product and its isolated counterpart. The rationale and holding in *Myriad* allows that structural differences, functional differences, or the combination of both can distinguish a derivative of a natural product from the native natural product. Consider, for example, that cDNA--although it encodes an identical amino acid sequence (that is, has the same informational content) as the isolated DNA and the natural gene--is patent eligible according to the Court because it is sufficiently structurally different from the natural gene. *Id.*, at 16-17 (slip op.). Thus, the *Myriad* decision indicates that sufficient structural or functional differences from a natural product can support patent eligibility for a derivative of a natural product.

American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 283 U.S. 11 (1931), has very little relevance to judicial exceptions to patent eligible subject matter under § 101 because it was neither analyzed nor decided on the basis of a judicial exception. Rather, *American Fruit Growers* was decided on the basis that the claimed fruit there did not belong to any of the statutory classes of invention. Specifically, the Court held that the claimed fruit was not a "manufacture" under the patent statute. *American Fruit Growers*, 283 U.S., at 11-12.

"Manufacture," as well defined by the Century Dictionary, is "the production of articles for use from raw or prepared materials by giving to these materials new

forms, qualities, properties, or combinations, whether by hand labor or by machinery;” also “anything made for use from raw or prepared materials.” Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. *Id.*

To the extent that *American Fruit Growers* can inform whether a natural product itself is or is not being claimed, it is clear that a natural product altered such that it “possesses a new or distinctive form, quality, or property” is sufficient to make the altered natural product patent eligible. *Id.* (emphasis added).

The claim at issue in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) was a combination of unaltered natural bacterial strains. The Supreme Court’s decision in *Funk Brothers* rested on the fact that the combination of bacterial strains had no different property than the strains alone. Only one of the strains would work with any given plant and the other strains’ presence would have no effect on the function of the working strain:

Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of noninhibition. It is no more than the discovery of some of the handiwork of nature, and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root nodule bacteria contained in the 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. They serve the ends nature originally provided, and act quite independently of any effort of the patentee.

There is, of course, an advantage in the combination. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, as respondent says, the packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like. But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 314 U.S. 90-91, and cases cited.

Funk Brothers, at 131 (emphasis added). The combination of bacterial strains in *Funk Brothers* lacked both structural differences and functional differences from the natural strains. As the quote above makes clear, the absence of both was necessary to the holding in *Funk Brothers* (“Their use in combination does not improve in any way their natural functioning.”). Thus, *Funk Brothers* cannot be said to require a structural difference in combined natural products regardless of the presence of a new, non-natural function.

Taken together, all of the relevant Supreme Court cases with composition claims involving a potentially natural product (implicating the “markedly different” standard) show that claims involving any new structure or new function for the natural product or the combination of the natural product with other elements are patent eligible. **Only when the claim consists of only an unaltered natural product or a combination of unaltered natural products that do not have a new function is the claim patent ineligible.**

To summarize, the Supreme Court standard for patent eligibility of a method claim involving a law of nature is that **only when the claim consists of only old, conventional, and well know elements beyond the law or nature or natural phenomenon is the claim patent ineligible.** The Supreme Court standard for patent eligibility of a claim to a product of nature is that **only when the claim consists of only an unaltered natural product or a combination of unaltered natural products that do not have a new function or use is the claim patent ineligible.** These are the standards by which patent eligibility of claims should be assessed.

Neither of the true standards for patent eligibility are consistent with a balancing of factors as used in the Guidance.

Patent Eligibility Should Not be Assessed Using a Balancing of Factors

Although the various cases on patent eligibility discuss a variety of issues, effects, and rationales, the question of whether a claim that recites or involves a judicial exception is or is not patent eligible is an exercise in line drawing. That is, does a claim attempt to claim the judicial exception itself or does the claim fall on the other side of the line, requiring more than just the judicial exception. *Myriad*, 569 U.S., at ___ (slip op., at 11-12, 14-15) (judicial exception claimed: the genetic information of DNA is not altered in the isolated DNA and so is the same as the natural gene); *Mayo*, 566 U.S., at ___ (slip op., at 3) (judicial exception claimed: the claimed process has not transformed the natural laws and so the process is not patentable); *Bilski*, 561 U.S., at ___, 130 S.Ct., at 3229-20 (judicial exception claimed: the claims are attempts to patent abstract ideas and so are not patentable); *Diamond v. Diehr*, 450 U.S. 175, 192 (1981) (more than a judicial exception claimed: claim is not an attempt to patent a mathematical formula, but rather is drawn to an industrial process); *Chakrabarty*, 447 U.S., at 309-310 (more than a judicial exception claimed: claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter); *Flook*, 437 U.S., at 594-95 (judicial exception claimed: process providing only a new and better method for calculation is not patentable); *Gottshalk v. Benson*, 409 U.S. 63, 71 (1972) (judicial exception claimed: claim to computer algorithm is an attempt to patent an idea). Importantly, the Supreme Court does not treat the analysis of patent eligibility as a balancing of factors.³ The correct line drawing test is a question of **whether a claim does or does not claim more than a judicial exception itself.** A balancing test would involve weighing different factors to see which factors outweigh others. A balancing test is not typical helpful in categorizing a claim. A line drawing test is.

³ While the Supreme Court mentions balancing in discussing patent eligibility, it is in the context of the policy behind the line drawing test, not as the basis of the test. For example, “patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention.” *Mayo*, 566 U.S., at ___ (slip op., at 23) (internal quotes and brackets omitted).

While the effort by the Patent Office to incorporate all of the rationales and justifications the Supreme Court has deployed in cases on patent eligibility is appreciated (especially in view of the doctrinal difficulty of doing so), nothing in the relevant Supreme Court cases points toward or is consistent with a “balancing” of the different rationales as “factors.”

To determine whether or not something is significantly different from a claimed judicial exception, the Guidance offer a set of “factors.” These factors are to be considered as follows:

On balance, if the totality of the relevant factors weigh toward eligibility, the claim qualifies as eligible subject matter. If the totality of the relevant factors weighs against eligibility, the claim should be rejected. 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.

Guidance, page 4.

The analysis of Question 3 in the Guidance is set up to weigh or balance these factors in order to determine if a judicial exception itself is claimed or if more than the judicial exception is claimed. The Question 3 factors then make it a balancing test of whether the claim has something extra that makes it “markedly different” from the judicial exception. According to the materials released by the Patent Office, this is true (that the Question 3 factors are considered) regardless of whether the claim includes a patent eligible, new, and nonobvious process, composition, product, or machine. While it appears that the Question 3 factors would come down on the side of patent eligibility when the claim includes a patent eligible, new, and nonobvious process, composition, product, or machine, it leaves the contrary possibility open. If the claim includes a patent eligible process, composition, product, or machine that is not new or not nonobvious, then the risk becomes much greater that the claim as a whole will be found not patent eligible by an examiner under the Guidance. Such an “old” process, composition, product, or machine risks being viewed as conventional, routine, insignificant pre- or post-solution activity, or a “mere” field of use limitation.

Use of factors that are to be weighed also creates an improper presumption that the claimed subject matter is not patent eligible. Especially in the case of the negative factors, if any one of these factors is found to be met, then the examiner might support a rejection. This is contrary to Supreme Court precedent. The Supreme Court looks to see if one of the limited judicial exceptions applies and then decides whether what is claimed is more than just the judicial exception. In this context, the presence of certain relationships and facts can indicate that the claimed invention includes more than the judicial exception alone. For example, if the claim uses a man-made composition of matter, then it should not matter whether any natural product or law of nature is recited by the claim. Use of a man-made product should always be enough. Although the examples in the Guidance appear to mostly get to this correct result, the logic of the Guidance opens the door for misapplication of the Guidance by examiners to find an incorrect result.

For these reasons the correct approach for analyzing Question 3 is to assess whether any one or more of relevant factors (a) through (f) is present in the claim. If one or more of these factors is present, the claim should be assessed as patent eligible. Only if none of relevant factors (a) through (f) are present in the claim should the claim be assessed as not patent eligible.⁴

Based on the Supreme Court precedent and the analysis above, attached as an appendix is an edited version of the Guidance that includes changes based on the correct standard for assessing patent eligibility.

The views expressed in the comment reflect the views of the undersigned as an individual and as a concerned member of the patent bar. They do not necessarily represent, and should not be attributed to, anyone else, including especially clients that the undersigned represents.

Very truly yours,

A handwritten signature in black ink, appearing to be 'R. Hodges'.

Robert A. Hodges, Ph.D., J.D.

RAH/

⁴ Note that factors than those mentioned in Supreme Court decisions and used in the Guidance may also indicate that the claimed subject matter is more than the judicial exception itself, and is thus patent eligible.

Appendix Revised Guidance For Determining Patent Eligibility

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

After determining what applicant invented and establishing the broadest reasonable interpretation of the claim in accordance with MPEP § 2103, walk through the three questions in the flowchart below to determine whether the claim is drawn to patent-eligible subject matter. If not, then the claim is prima facie ineligible, and the claim should be rejected using revised form paragraph 7.05.13 (shown below in Part IV).

1. 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?⁵

If no, the claim is not eligible for patent protection and should be rejected under 35 U.S.C. 101, for at least this reason. See MPEP § 706.03 for a description of the appropriate form paragraphs to use in rejecting the claim.

If yes, proceed to Question 2.

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

If no, the claim is patent-eligible, and the analysis is complete.

If yes, or if it is unclear whether the claim recites or involves a judicial exception, proceed to Question 3.

Judicial exceptions include abstract ideas, laws of nature/natural principles, natural phenomena, and natural products.⁶ In particular, claimed subject matter that must be analyzed under Question 3 to determine whether it is a natural product includes, but is not limited to: chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature.

⁵ A summary of the four statutory subject matter categories, as they have been interpreted by the courts, is provided in MPEP § 2106(I). As a reminder, claims to humans per se are not directed to a statutory subject matter category, pursuant to Section 33(a) of the America Invents Act.

⁶ As described in MPEP § 2106, in addition to the terms laws of nature, physical phenomena, and abstract ideas, judicial exceptions have been described using various other terms, including natural phenomena, products of nature, natural products, naturally occurring things, scientific principles, systems that depend on human intelligence alone, disembodied concepts, mental processes and disembodied mathematical algorithms and formulas, for example. The exceptions reflect the judicial view that these fundamental tools of scientific and technological work are not patentable.

If there is any doubt as to whether the claim recites a judicial exception (e.g., the claim recites something similar to a natural product), the claim requires further analysis under Question 3. For example, if the claimed product is a protein or a mineral, then the analysis must proceed to Question 3, in order to determine whether the protein or mineral is claimed in a manner that is altered in form or function from the significantly different than naturally occurring proteins or minerals such that protein or mineral has a distinctive name, character, or use.⁷ This is the case regardless of whether particular words (e.g., “isolated”, “recombinant”, or “synthetic”) are recited in the claim.

3. Question 3: Does the claim as a whole consist of only an unaltered natural product or a combination of unaltered natural products that do not have a new use or function?

If the answer is yes, the claim is not patent-eligible and should be rejected under 35 U.S.C. 101. See revised form paragraph 7.05.13 (reproduced below in Part IV), which should be used in rejecting the claim.

If the answer is no (i.e., the claim includes more than just the product of nature, the product of nature has a new use or function, or the claim is a method that recites or involves a law of nature, natural phenomena, or abstract idea), proceed to Question 4.

4. Question 4: Does the claim recite or involve a product of nature that has a distinctive name, character, or use compared to the naturally occurring product of nature?

If yes, the claim is patent-eligible, and the analysis is complete.

If no, proceed with Question 5.

5. Question 5: Does the claim as a whole recite consist of only old, conventional, and well know elements beyond the law or nature, natural phenomenon, or product of nature something significantly different than the judicial exception(s)?

If the claim recites an abstract idea (whether alone or in combination with other judicial exceptions), it should be analyzed for subject matter eligibility using only the existing guidance in MPEP § 2106(II).

Otherwise, answer this Question using the factor-based analysis of “significantly different” that is discussed below in Part II.

If the answer is no (i.e., the factor-based analysis indicates that the claim as a whole includes more than just old, conventional, and well know elements beyond the law of nature, natural phenomenon, or product of nature is not significantly different than the judicial exception(s)), the claim is patent-eligible, and the analysis is complete.

⁷ *Chakrabarty*, 447 U.S., at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)); *accord American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11-12 (1931) (a manufacture is something given “new forms, qualities, properties, or combinations” or that “possesses a new or distinctive form, quality, or property”).

If the answer is yes (i.e., the factor-based analysis indicates that the claim as a whole consists of only old, conventional, and well know elements beyond the law of nature, natural phenomenon, or product of nature ~~is significantly different than the judicial exception(s)~~ the claim is not patent-eligible and should be rejected under 35 U.S.C. 101. See revised form paragraph 7.05.13 (reproduced below in Part IV), which should be used in rejecting the claim.

~~If the answer is yes (i.e., the factor-based analysis indicates that the claim as a whole is significantly different than the judicial exception(s)), the claim is patent-eligible, and the analysis is complete.~~

II. How To Analyze Whether A Claim Claims More Than Just A Judicial Exception Itself⁸“Significantly Different”

If the claim recites or involves a judicial exception, such as a law of nature/natural principle or natural phenomenon (e.g., the law of gravity, $F=ma$, sunlight, barometric pressure, etc.), and/or something that appears to be a natural product (e.g., a citrus fruit, uranium metal, nucleic acid, protein, etc.), then the claim only qualifies as eligible subject matter if the claim as a whole ~~claims more~~ recites something **significantly different** than the judicial exception itself. A claim to more than a judicial exception itself ~~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).

The following factors should be used to analyze the claim to assist in answering Question ~~53~~ for claims reciting or involving judicial exceptions other than abstract ideas.⁸ If the claim includes one or more of the factors ~~On balance, if the totality of the relevant factors weigh toward eligibility, the claim qualifies as eligible subject matter. If the claim lacks all of the factor~~ totality of the relevant factors weighs against eligibility, the claim should be rejected. 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. This factor-based analysis, which requires consideration and subsequent weighing of multiple factors, is similar to the *Wands* factor-based analysis used to evaluate whether undue experimentation is required to make and use a particular claimed invention. See, e.g., MPEP 2164.01(a) for an explanation of the *Wands* analysis.~~

Many of these factors originate from past eligibility factors. However, not every factor will be relevant to every claim and, as such, need not be considered in every analysis. For example, for a claim drawn solely to a nucleic acid, factors b) through f) ~~and h) through l)~~ would not be relevant, because the claim does not contain any elements in addition to the

⁸ Claims reciting an abstract idea should continue to be analyzed for subject matter eligibility using only the existing guidance in MPEP § 2106(II), even if the claims also recite or involve another judicial exception.

nucleic acid. Eligibility of such a claim would therefore turn on an analysis of factors a) ~~and g~~). These factors are not intended to be exclusive or exhaustive as the developing case law may generate additional factors over time.

Factors that indicate weigh toward eligibility ~~(significantly different)~~:

- a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring, and markedly different in structure from naturally occurring products, and/or having a new use or function compared to the naturally occurring product.
- b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
- c) 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).
- d) 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).
- e) 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) or integrates the judicial exception(s) into a particular practical application. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors).
- f) 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.

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

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

Factors a) ~~and g)~~ concern the question of whether something that initially appears to be a natural product is in fact non-naturally occurring, is markedly different in structure from naturally occurring products, and/or has a new use or function compared to the naturally occurring product (that is, the product has a distinctive name, character, or use compared to the naturally occurring product of nature) and markedly different from what exists in nature, i.e., from naturally occurring products. This question can be resolved by first identifying the differences between the recited product and naturally occurring products, and then evaluating whether the identified differences together indicate arise to the level of a **marked** difference in structure, function, and/or use. Generally, a structural difference must either be significant in itself or, if not, the difference must give the product a different use of function. Even a product of nature that is not itself structurally altered could still have been processed or combined with other elements such that the product has acquired a new use or function. Such was the case in the microorganism and plasmids of *Chakrabarty*. Not all differences rise to the level of marked differences, e.g., merely isolating a nucleic acid changes its structure (by breaking bonds) but that change does not create a marked difference in structure between the isolated nucleic acid and its naturally occurring counterpart and does not result in a new use or function beyond the its naturally occurring informational content. *Myriad*, 133 S. Ct. at 2116-2118 (even though an isolated gene is a non-naturally occurring fragment of chromosomal DNA, it is not markedly different from the chromosomal DNA because its nucleotide sequence has not been changed). Instead, ~~thea marked~~ difference must be a significant structural difference and/or one that results in a new use or function, i.e., more than an incidental or trivial difference.

The fact that a ~~marked~~ difference came about as a result of routine activity or via human manipulation of natural processes does not prevent the ~~marked~~ difference from indicating weighing in favor of patent eligibility. For example, cDNA having a nucleotide sequence that is ~~markedly~~ different from naturally occurring DNA is eligible subject matter, even though the process of making cDNA is routine in the biotechnology art. *See id.* at 2119. Similarly, a hybrid plant that is ~~markedly~~ different from naturally occurring plants is eligible subject matter, even though it was created via routine manipulation of natural processes such as pollination and fertilization. *See, e.g., J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145 (2001).

IV. Form Paragraph

Revised form paragraph 7.05.13 should be used when rejecting claims (machine, composition, manufacture, or process claims) that recite or involve a law of nature/natural principle, natural phenomenon, or natural product for lack of subject matter eligibility under 35 U.S.C. 101. This form paragraph must be preceded by form paragraphs 7.04 and 7.05.

¶ 7.05.13 Rejection, 35 U.S.C. 101, Non-Statutory (Law of Nature or Natural Phenomenon) [REVISED]

the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claim(s) [1] do not recite something more and/or significantly different than a judicial exception. The rationale for this determination is explained below: [2]

Examiner Note:

1. This form paragraph should be used when rejecting claim(s) that have a law of nature/natural principle or a natural phenomenon, e.g., a natural product, as a claim limitation.
2. In bracket 2, identify the judicial exception(s) that is/are recited or involved in the claim, and explain why the features (e.g., element(s) or step(s) in addition to the judicial exception(s)) in the claim do not result in the claim as a whole reciting something more and/or significantly different than the judicial exception itself. In particular, explain why the claim features do not make the claim more than a claim to the judicial exception itself~~add significantly more to the judicial exception and/or demonstrate that the judicial exception is in fact markedly different from what exists in nature~~. For instance, element(s) or step(s) in addition to the judicial exception can be shown to be extra-solution activity or mere field of use that impose no meaningful limit on the performance of a claimed method, or can be shown to be no more than well-understood, purely conventional, and routinely taken by others in order to apply the judicial exception. The explanation needs to be sufficient to establish a prima facie case of patent ineligibility under 35 U.S.C. 101.