

The March 2, 2014 USPTO memorandum “*Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*” (“Guidance”) correctly recognizes claims to certain products and processes as patent eligible, but unfortunately leaves other important areas that deserve and need patent protection in limbo.

Even before the Guidance, the state of personalized medicine prosecution in the USPTO had created extreme frustration for patent holders, patent applicants, patent practitioners, and, from informal discussions, the Examining Corps. The Guidance fails to recognize expressly the patent eligibility of pure personalized medicine methods. With this oversight, the USPTO Guidance potentially allows examiners to take Supreme Court and Federal Circuit precedents to unnecessary and incorrect conclusions. The Guidance points to alleged legal standards, such as “markedly different” and “significantly more,” that are not sufficiently articulated or applied as true legal standards, and does not fully consider the actual holdings and teachings of legal precedent. Subsequent USPTO discussions of the Guidance, as in the BCP<sup>1</sup> “Evaluating Subject Matter Eligibility Under 35USC § 101” PowerPoint of April 16, 2014, exacerbate the problem.

Example “F” in the Guidance<sup>2</sup> is the only example that considers a claim that touches on personalized medicine, but the claim is not to a pure personalized medicine method. In essence, Example F instead addresses the patent eligibility of an “antibody XYZ”, which the Guidance

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<sup>1</sup> Biotechnology/Chemical/Pharmaceutical Customer Partnership

<sup>2</sup> Entitled “Process Claim Involving A Natural Principle And Reciting Natural Products” and reciting a single claim A method for determining whether a human patient has degenerative disease X, comprising: obtaining a blood sample from a human patient; determining whether misfolded protein ABC is present in the blood sample, wherein said determining is performed by contacting the blood sample with antibody XYZ and detecting whether binding occurs between misfolded protein ABC and antibody XYZ using flow cytometry, wherein antibody XYZ binds to an epitope that is present on misfolded protein ABC but not on normal protein ABC; and diagnosing the patient as having degenerative disease X if misfolded protein ABC was determined to be present in the blood sample.”

states “does not exist in nature, and is not purely conventional or routine in the art (it was newly created by the inventors).” Put another way, Example “F” in the Guidance provides a corollary that, where a patent applicant has a novel and patent eligible antibody, the applicant also has a patent eligible diagnostic method using that antibody. Taken to a foreseeable, *de facto* result, the Guidance could lead examiners to categorically reject all pure personalized medicine methods, *i.e.*, diagnostic or prognostic methods that do not employ one or more of 1) a novel and patent eligible laboratory tool (such as an antibody) or 2) analytical steps<sup>3</sup> that are not “routine or conventional”—which would be clear legal error.

The following is an example of a pure personalized medicine method (“proffered claim”):

A method of determining the diagnosis/ prognosis of a human patient for disease X, comprising the steps of:

- obtaining an isolated biological sample from the patient;
- artificially and detectably labeling<sup>4</sup> the isolated biological sample for measuring the level of analyte(s) Y;
- measuring the level of the analyte(s) Y using the artificially and detectably labeled biological sample; and
- comparing the level of the analyte(s) Y to one or more suitable controls and assigning the patient a diagnosis/prognosis for disease X on the basis of the comparison.

For the purpose of this example, it can be assumed that the comparing/ assigning step employs a previously unknown “natural law” based on the level of analyte(s) Y, which is typically the case for personalized medicine methods. Also, the steps for labeling and measuring the analyte should be assumed to be either well known in the art or adequately described in the underlying specification.

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<sup>3</sup> That is, application-agnostic, basic analytical steps that could be applied to a wide array of biological samples, irrespective of the particular analyte.

<sup>4</sup> We submit that this labeling should be construed liberally to encompass detecting a labeled analyte or an unlabeled analyte bound to labeled reagents, such as nucleic acid probes or antibodies.

The Guidance should have addressed such a method and should have concluded it was patent eligible based on Supreme Court and Federal Circuit precedent. Without improved guidance, examiners will continue to proffer inconsistent and improper rejections based primarily on contorted readings of *Prometheus*<sup>5</sup>, and to a lesser extent, *Diehr*<sup>6</sup>, *Flook*<sup>7</sup>, *Benson*<sup>8</sup>, *Bilski*<sup>9</sup>, and *Chakrabarty*<sup>10</sup>.

In *Prometheus*, the Supreme Court invalidated a claim to a method of optimizing therapeutic efficacy for treating an immune-mediated gastrointestinal disorder with steps of: 1) administering a drug, 2) determining the level of a metabolite of the drug, and 3) a “wherein” clause providing the levels of the metabolite for which an increase or decrease in the drug is indicated—the clause did not require any active step integrating it into the method. The Court supported its conclusion, in part, by reasoning that “the ‘wherein’ clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient,”<sup>11</sup> while the administering step “simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs.”<sup>12</sup>

Notably, the Court stated:

At the time the discoveries embodied in the patents were made, **scientists already understood** that the levels in a patient’s blood of certain metabolites, including, in particular, 6–thioguanine and its nucleotides (6–TG) and 6–methyl–mercaptopurine (6–MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective.

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<sup>5</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012).

<sup>6</sup> *Diamond v. Diehr*, 450 U.S. 175 (1981).

<sup>7</sup> *Parker v. Flook*, 437 U.S. 584 (1978).

<sup>8</sup> *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>9</sup> *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>10</sup> *Diamond v. Chakrabarty* 447 U.S. 303 (1980).

<sup>11</sup> *Prometheus* at 1297.

<sup>12</sup> *Ibid.*

*Prometheus* at 1295, emphasis added. See also *Prometheus* at 1298 (“[S]cientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. Thus, this [determining] step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.” (Citations omitted.)).

In short, the *Prometheus* Court determined that the alleged natural law was already known, and that the administering step merely identified the relevant audience, while the “wherein” clause—which provided the allegedly novel aspect of the claim—only provided an abstract instruction to “apply it” (*i.e.*, no active steps accompanied the “apply it” instruction or otherwise integrated it into the method as a whole). In short, the claim at issue in *Prometheus* laid the alleged natural law particular metabolite levels indicating, but not requiring, a need to change treatment--naked, unapplied and unintegrated into any active step of the method. *Prometheus* is readily reconciled with earlier Supreme Court precedents and distinguished from pure personalized medicine methods.

The *Prometheus* Court cited *Benson*, the earliest of *Benson*, *Flook*, and *Diehr*. *Benson* addressed whether claims<sup>13</sup> directed to “data processing method[s]” for converting binary coded

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<sup>13</sup> Claim 13 of the application at issue provided:

“A data processing method for converting binary coded decimal number representations into binary number representations comprising the steps of

(1) testing each binary digit position ‘1,’ beginning with the least significant binary digit position, of the most significant decimal digit representation for a binary ‘0’ or a binary ‘1’;

(2) if a binary ‘0’ is detected, repeating step (1) for the next least significant binary digit position of said most significant decimal digit representation;

(3) if a binary ‘1’ is detected, adding a binary ‘1’ at the (i + 1)th and (i + 3)th least significant binary digit positions of the next lesser significant decimal digit representation, and repeating step (1) for the next least significant binary digit position of said most significant decimal digit representation;

(4) upon exhausting the binary digit positions of said most significant decimal digit representation, repeating steps (1) through (3) for the next lesser significant decimal digit representation as modified by the previous execution of steps (1) through (3); and

(5) repeating steps (1) through (4) until the second least significant decimal digit representation has been so processed.”

*Benson* at 74, internal quotes omitted.

decimal (BCD) numbers into pure binary numbers were patent eligible processes. The *Benson* court noted that “[t]he claims were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use” and that the

claim [was] so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion [and that] [t]he end use may (1) vary from the operation of a train to verification of drivers’ licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus.

*Benson* at 64, 68. As a result, the *Benson* Court concluded that the claims at issue were not patent eligible, reasoning that

in practical effect [patenting an idea] would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.

*Id.* at 71-72.

In *Flook*, the Supreme Court considered method claims directed to updating an alarm limit on a process variable (*i.e.*, a number),<sup>14</sup> where the methods were divorced from any particular device or concrete physical steps. The process was only vaguely limited to a field of

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<sup>14</sup> Claim 1 of the application provided:

“A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of

$$Bo+K$$

wherein Bo is the current alarm base and K is a predetermined alarm offset which comprises:

- (1) Determining the present value of said process variable, said present value being defined as PVL;
- (2) Determining a new alarm base B1, using the following equation:

$$B[1]=Bo(1.0<v1>minF)+PVL(F)$$

where F is a predetermined number greater than zero and less than 1.0;

- (3) Determining an updated alarm limit which is defined as B1+GK; and thereafter
- (4) Adjusting said alarm limit to said updated alarm limit value.”

*Flook* at 596-597, internal quotes omitted.

use by stating, in the claim preamble, that the process variable was “involved in a process comprising the catalytic chemical conversion of hydrocarbons.” *Flook* at 596. The *Flook* Court stated that “[v]ery simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101.” *Id.* at 595, fn18. To support this conclusion, the Court first noted, at 586, that

[t]he patent application does not purport to explain how to select the appropriate margin of safety, the weighting factor, or any of the other variables. Nor does it purport to contain any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system. All that it provides is a formula for computing an updated alarm limit.

The Court likened the claim at issue to “a claim that the formula 2pir can be usefully applied in determining the circumference of a wheel.” *Id.* at 595. Notably, the dissenting opinion by Justice Stewart, joined by the then Chief Justice Burger and future Chief Justice Rehnquist, cast the legal question as “whether a claimed process loses its status of subject-matter patentability simply because *one step* in the process would not be patentable subject matter if considered in isolation.” *Id.* at 599, emphasis in original. In reaching the opposite conclusion to that of the majority, the dissent also noted that “thousands of processes and combinations have been patented that contained one or more steps or elements that themselves would have been unpatentable subject matter.” *Id.* at 599-600. Therefore *Flook* built on *Benson* by establishing that a bare algorithm (*Benson*) does not become patentable merely by vaguely limiting it to a particular field, *e.g.*, in the claim preamble.

*Diehr* provided a middle ground between the majority and dissent of *Flook*. At issue were claims to methods of manufacturing precision molded products or methods of operating a rubber-molding press for such precision molded compounds, where the processes used the

Arrhenius equation.<sup>15</sup> In line with its precedents, the *Diehr* Court observed that “Arrhenius’ 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 by § 101.” *Diehr* at 188.

Expanding on this reasoning, the *Diehr* Court noted that the claims at issue were not directed to a mathematical formula, but, rather,

a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, *they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.* These include installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time. Obviously, one does not need a “computer” to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of “overcuring” or “undercuring,” the process as a whole does not thereby become unpatentable subject matter.

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<sup>15</sup> “1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

providing said computer with a data base for said press including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press, initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure, constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding, constantly providing the computer with the temperature (Z), repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is

$$\ln v <v1>equ CZ+x$$

where v is the total required cure time,

repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and opening the press automatically when a said comparison indicates equivalence.”

*Diehr* at 181, internal quotes omitted.

*Diehr* at 187, emphasis added. In so doing, the *Diehr* Court reiterated the importance of the “as a whole” inquiry when analyzing claims under 35 U.S.C. §101:

***It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.***

This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all 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 of 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 reaching its conclusion that the claims at issue were patent eligible, the *Diehr* Court cited, with apparent approval, the Examiner’s conclusion that steps other than those performed by a computer following stored instructions were “conventional and necessary to the process” (*Diehr* at 181), an opinion shared by the dissent in *Diehr*. See *Diehr* at 208 (“There is no suggestion that there is anything novel in the instrumentation of the mold, in actuating a timer when the press is closed, or in automatically opening the press when the computed time expires....These elements of the rubber-curing process apparently ***have been well known for years.***” Emphasis added.). In sum, *Benson*, *Flook*, and *Diehr* stand for the proposition that an algorithm, equation, or natural law in isolation (*Benson*) or restricted to a particular field by empty verbiage (*Flook*) is not patent eligible, while the same algorithm, equation, or natural law integrated with active steps—even only routine and conventional steps—(*Diehr*) is patent eligible.



Notably, *Prometheus* cites *Diehr*<sup>16</sup> for the idea that “insignificant postsolution activity” does not make unpatentable principles into patentable processes. The referenced passage of *Diehr*, where the process was found to be patent eligible, was contrasting with *Flook*, where the process was not patent eligible. This contrast, which is the basis for this oft-cited principle of patent law, is best articulated in footnote 14, on page 1060 of *Diehr*, which provides, in pertinent part:

A mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiesce to limiting the reach of the patent for the formula to a particular technological use. A mathematical formula in the abstract is nonstatutory subject matter regardless of whether the patent is intended to cover all uses of the formula or only limited uses. **Similarly, a mathematical formula does not become patentable subject matter merely by including in the claim for the formula token postsolution activity such as the type claimed in *Flook*.** We were careful to note in *Flook* that the patent application did not purport to explain how the variables used in the formula were to be selected, nor did the application contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit. *Ibid.* All the application provided was a “formula for computing an updated alarm limit.

Therefore, the *Diehr* Court made a clear distinction between **a)** using a (known) formula, equation, or algorithm in a process, even in a process otherwise containing only conventional and necessary steps as in *Diehr*, and **b)** using a formula, equation, or algorithm, as in *Flook*, essentially limited only by an intended use in the claim preamble.

*Bilski* followed a fact pattern most similar to that of *Flook*. In considering a claim instructing how to hedge risk,<sup>17</sup> the Court reasoned that the Petitioners were trying to “patent

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<sup>16</sup>*Diehr* at 191-192 (by way of *Bilski* at 3230); see *Prometheus* at 1298.

<sup>17</sup> Consisting of the steps:

“(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;

both the concept of hedging risk and the application of that concept to energy markets.” *Bilski* at 3229. The Court stated that

[t]he 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.

*Id.* at 3231. Again, as with *Flook*, *Bilski* provided abstract claims that lacked concrete steps and only attempted to limit certain claims to a particular field of use with vague verbiage, essentially suggesting to apply the hedging method in energy markets.

Taken together, *Benson*, *Flook*, *Diehr*, and *Bilski* provide the context for interpreting *Prometheus*—such as what is meant by asking if a claim does “significantly more” than describe a natural law, formula, equation, or algorithm. *Benson* provided a bare mathematical algorithm, unrestricted to any particular field, while *Flook* and *Bilski* limited an algorithm to a particular field with only empty verbiage, *e.g.*, in the claim preamble. *Diehr*, in contrast, recited a known equation together with definitive steps (albeit well-understood, routine, conventional activity already engaged in by the relevant skilled artisan), and therefore provided a process that was patent eligible.

The proffered claim is plainly far more analagous to those in *Diehr* than to those in *Benson*, *Flook*, and *Bilski*. Again, *Benson*, *Flook*, and *Bilski* all claimed an abstract idea, algorithm, or mathematical equation (analogous to a natural law in the proffered claim), at most limited to a particular field by empty verbiage without any active steps, such as the recitation

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(b) identifying market participants for said commodity having a counter-risk position to said consumers; and  
(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.”

*Bilski* at 3223-3224, internal quotes omitted.

“involved in a process comprising the catalytic chemical conversion of hydrocarbons” in the claim preamble in *Flook*. *Prometheus* stands in line with *Benson*, *Flook*, and *Bilski*, since, in *Prometheus*, *e.g.*, identifying a relevant audience did not make an otherwise unapplied natural law patent eligible, just like limiting an algorithm, mathematical equation, or abstract idea to a particular field with empty verbiage did not make them patent eligible. In contrast, like *Diehr*, the proffered claim recites definitive steps that are adequately described in the specification or well known to the skilled artisan (in contrast to, *e.g.*, *Flook*), such as isolating a sample, artificially and detectably labelling it, and using it to measure analyte levels. The position that these steps, in isolation, could, *arguendo*, be considered pre-solution activity that was well-understood, routine, and conventional at the time the invention was made is in no way prejudicial to the subject matter eligibility of the proffered claim as a whole, because the same was true of the process in *Diehr*—*i.e.*, the steps outside of the mathematical equation were conventional. In fact, the proffered claim provides an even stronger case for patent eligibility than did those in *Diehr*, since, unlike in *Diehr*, where the equation (analogous to the alleged natural law) was well-known, the “natural principle” (the association of the analyte levels to a diagnosis/prognosis) was not known.

The proffered claim also provides that the biological sample is artificially and detectably labeled, which gives an alternative basis to establish patent eligibility. The Supreme Court’s *Myriad*<sup>18</sup> decision, together with the preceding Federal Circuit decision, provides that methods that properly employ products of man are patent eligible. Specifically, *Myriad* reaffirmed the patent eligibility of products of man, such as cDNA, noting that “cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived[, and,] [a]s a

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<sup>18</sup>*Association for Molecular Pathology, et al., v. Myriad Genetics, Inc., et al.*, 133 S. Ct. 2107 (2013).

result, cDNA is not a ‘product of nature’ and is patent eligible under §101... .” 133 S. Ct. 2119. *Myriad* at the Federal Circuit,<sup>19</sup> in turn, held that a process claim that employed a transformed cell “which is made by man, in contrast to a natural material,” was patent eligible. Notably, the Supreme Court decision in *Myriad* did not address any method claims and, instead, addressed only claims to compositions of matter, leaving the Federal Circuit’s holding on this method claim intact.

The Guidance overly inflates the importance of the “markedly different” legal standard referenced in the Guidance. The USPTO should be liberal when evaluating the hand of man in a claim to a composition of matter (or a method using the composition) under this standard. *Myriad* only references “markedly different” characteristics in a discussion of *Chakrabarty*. *Myriad* does not itself explicitly address or apply this as a legal standard. To the extent “markedly different” may have been implicitly used as a standard by the *Myriad* Court, it was as a very low barrier, where the Court used cautious, qualifying language: “cDNA is not a ‘product of nature’ and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA *may* be indistinguishable from natural DNA.” 133 S. Ct. 2119, emphasis added. Put another way, it is common knowledge to undergraduate biology students that cDNA is not, in a practical sense of the term, markedly different from isolated DNA encoding the same molecule.

*Chakrabarty*, the actual source of the “markedly different” term, addressed the patent eligibility of a claim to a *Pseudomonas* bacteria containing plasmids providing hydrocarbon degradative pathways, and also referenced “markedly different” only once. That sole reference

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<sup>19</sup> *Association for Molecular Pathology (AMP) and ACLU v. USPTO and Myriad Genetics*, 689 F.3d 1303, 1334 (Fed. Cir. 2012).

was not part of the case’s holding, in the affirmative, that “respondent's micro-organism constitutes a ‘manufacture’ or ‘composition of matter’ within the meaning of the statute.” 447 U.S. 307. Instead, the “markedly different” reference in *Chakrabarty* was a nod to the inventors, when contrasting the bacterium claimed by Chakrabarty to claims to mixtures of naturally-occurring *Rhizobium* bacteria that were invalidated in a pre-1952 case, *Funk*<sup>20</sup>. Specifically, the *Chakrabarty* Court quoted from *Funk*, noting that in *Funk*:

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

447 U.S. 310. The *Chakrabarty* Court merely stated “[h]ere, 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.” *Id.* So while the *Chakrabarty* Court used the term “markedly different”, it was contrasting the *Chakrabarty* invention to one where there was **no** difference relative nature. Markedly different may have been a fact distinguishing *Chakrabarty* and *Funk*, but it was not a necessary distinction. In fact, the *Chakrabarty* invention was based on combining using bacteria with known elements (different plasmids) with known properties (metabolizing different hydrocarbon components of crude oil), for known purposes (biological control of oil spills; previously done with mixtures of bacteria). *See* 447 U.S. 305, fn1, fn2. In short, to the extent “markedly different” is an applicable standard, it should be a liberal one that errs toward patent eligibility, not an onerous one.

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<sup>20</sup> *Funk Brothers Seed Co. v. Kalo Inoculant Co.* 333 U.S. 127 (1948).

In short, the Guidance has left too much open to varied examination practices, particularly for pure personalized medicine methods. We believe existing Supreme Court and Federal Circuit precedents provided enough guidance for the USPTO to provide an example, such as the proffered claim, and an analysis where that claim is determined to be patent eligible. We hope some form of this submission can be incorporated into future training tools to help provide better consistency, clarity, and guidance for examiners and patent applicants alike in the field of personalized medicine methods.

Respectfully submitted,

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