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**VIA E-MAIL ONLY**
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*Re: Novartis Comments on "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products"*

Novartis thanks the United States Patent and Trademark Office ("the Office") for the opportunity to comment on its March 4, 2014 "*Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*" (Guidance). We are a global healthcare company whose mission is to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life for patients across the world. Like others in our industry, our ability to continue to realize our mission and to deliver on our promise to patients is dependent on our ability to continue to invest in innovation, which in turn depends on the existence and reasonable certainty of strong incentives like those provided by robust patent systems.

Without a doubt, one critical attribute of a strong patent system is an examining corps that understands the applicable patent laws, and that is skilled in properly applying those laws to the cases that come before it. With that in mind, we appreciate and as a general matter support the Office's efforts to train and guide its examiners in the wake of important new court decisions that impact patent law, particularly when those decisions come from the Supreme Court, as in the recent *Myriad* and *Mayo* decisions at the heart of the present Guidance.[1] Precisely *because* of the critical importance of such decisions, however—which, by their nature, reflect careful and complex balances of law and policy—we believe that the Office has a legal, public and moral obligation to apply them faithfully and with the utmost care, taking them no further than the nation's highest Court (or other authoritative body, as the case may be) intended.

Unfortunately, with respect to the present Guidance, we share the view of the many other stakeholders who have submitted comments that the Office has failed in this regard, misinterpreting the explicitly narrow holdings of these cases, applying them to a far broader range of subject matter than was ever intended, and

[1] The full citations are: *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107 (2013) ("*Myriad*"), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S. Ct. 1289 (2012) ("*Mayo*").

overstepping the bounds of the role with which the Office has been entrusted. However well-intentioned, the result of this Guidance is the creation of new substantive law that neither Congress nor the Courts have endorsed, that creates undue burdens on patent applicants operating in the biopharmaceutical field, and which has already left a trail of confusion and uncertainty that, if not corrected, will take years for the Courts to sort out. On all counts, the loser is innovation and its expansive array of beneficiaries, including patients who, like us, depend on the strong incentives that patents provide to ensure a robust future of medicine.

Other stakeholders have already commented extensively on the critical role that therapies and treatment methods that in some way are derived from or relate to nature (e.g. antibiotics, vaccines, nucleic acids, proteins, peptides, and other naturally-derived substances) play, and in the future will increasingly play, in modern medicine; the importance of preserving incentives to invent and develop such therapies and methods; and the negative impact that the present Guidance could have on those efforts. *See e.g.* Comments of Cubist Pharmaceuticals, Inc. May 7, 2014; Comments of Pharmaceutical Research and Manufacturers of America, July 31, 2014. We agree with those sentiments, and strongly echo the important policy-based concerns that they raise. Already, we have been faced with additional prosecution burdens under the Guidance, and in some cases with rejections of patent claims covering subject matter like vaccines, a result which the Supreme Court plainly never intended. All of this said, Congress and the Courts are in the best—and, as a legal matter, in the *only*—position to establish, shape, and balance the substantive standards and underlying policies that govern and define patent-eligible subject matter.[2] We therefore focus our comments in two main areas, which we hope will help to illuminate what we view as the Guidance's principal flaws, and, if not withdrawn in its present form (as we strongly suggest), help to illustrate the types of revisions that will be needed to correct them: (1) Where the Guidance goes wrong in its interpretation of the Supreme Court's Section 101 jurisprudence, particularly given the further guidance we now have from the Supreme Court in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (*Alice Corp.*); and (2) Suggestions for how the

[2] As others have pointed out, while the Office "may establish regulations" that govern the conduct of Office proceedings, these must be "not inconsistent with the law," 35 U.S.C. §2(b), and do not amount to substantive rulemaking powers. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir.1996) ("the broadest of the PTO's rulemaking powers-- 35 U.S.C. § 6(a)--authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the PTO'; it does not grant the Commissioner the authority to issue substantive rules."); *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980) (Congress "define[s] the limits of patentability" and "it is 'the province and duty of the *judicial department* to say what the law is.") (quoting *Marbury v. Madison*, 5 U.S. 137, 177 (1803)) (emphasis added).

Office can revise and refocus its Guidance to align it with controlling law and the careful policy balance that underlies it.

## I. The Guidance Conflicts with Section 101 and the Supreme Court's Section 101 Jurisprudence by Expanding the Scope of Judicial Exceptions and Failing to Recognize the Multiple Ways that a Claim May Qualify as Patent-Eligible

As other stakeholders have already commented, the Guidance's broad application to *any* patent claim "reciting or involving" laws of nature, natural phenomena, or natural products, and the "significantly different" test at the Guidance's heart, are creations of the Office that are neither set forth in, supported by, nor consistent with Section 101 of the Patent Act, or the Supreme Court cases that interpret its scope. The Guidance is structured as a formal three-step inquiry: (1) Is the claim directed to one of the four statutory categories (i.e. a process, machine, manufacture, or composition of matter); (2) Does the claim recite or involve judicial exceptions (in relevant part, laws of nature/natural principles, natural phenomena, and natural products); and (3) Does the claim as a whole recite something ***significantly different*** than the judicial exception(s)? *See* Guidance at 2. While the first step in the process comports with Section 101, the second two emphatically do not. We address the problems with these two steps in turn.

### A. The judicial exceptions do not apply to claims that "recite or involve" laws of nature, natural phenomena, or natural products, but only to those *drawn or directed to* such subjects.

The Guidance goes fundamentally wrong in its expansive application to any claim "reciting or involving laws of nature, natural phenomena and natural products." The Supreme Court's limited judicial exceptions to patent-eligible subject matter have never been so broad. As a starting point, it bears re-emphasizing, as the Supreme Court has often done, that from the time of Thomas Jefferson and the first Patent Act (1793) "Congress plainly contemplated that the patent laws would be given wide scope," and expressly "intended statutory subject matter to 'include **anything under the sun that is made by man.**' *Diamond v. Chakrabarty*, 447 U.S. 303, 308-9 (1980) (quoting S Rep. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952)) (emphasis added). With that in mind, the Court has carved out *very* few exceptions—namely, laws of nature, natural phenomena, and abstract ideas—and has cautioned that "courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed,'" an admonition that of course applies even more strongly to the Office. *Chakrabarty*, 447 U.S. at 309 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)).

Consistent with the Constitutionally-mandated narrowness of this approach, the Supreme Court has been careful to apply its judicial exceptions only to claims that are **directed** or **drawn** to an exception—*not*, as the Guidance does, to any claim that merely "recites," "involves," or is "derived from" an exception. In *Alice Corp.*, for example, the Court's most recent case concerning its judicial exceptions, the Court made clear that "[t]he question presented is whether these claims are patent eligible under 35 U.S.C. §101, or are instead **drawn to** a patent-ineligible abstract idea." *Alice Corp.*, 134 S. Ct. at 2352 (emphasis added). Citing *Mayo*, the Court clarified that a proper framework for considering judicial exceptions is aimed at "distinguishing patents that **claim** laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Id.* at 305. Critically, the Court held that the first step in that framework—which coincides directly with the Office's second step—is to "determine whether the claims at issue are **directed to** one of those patent-ineligible concepts." *Id.* (emphasis added). Dispelling any doubt about the scope of the exceptions' application, the Court, *directly contrary to the Guidance*, expressly held that "an invention is ***not* rendered ineligible for patent simply because it *involves* an abstract concept**" or other exception. *Id.* at 2354 (emphasis added).

The Court's earlier Section 101 cases, and particularly those on which the Office relied in formulating its Guidance, similarly contradict the Guidance's broad scope. In *Mayo*, for example, the Court discussed its "long held" rule that while "laws of nature, natural phenomena, and abstract ideas" *themselves* are not patentable (citing a long line of cases going back to the 1840s), a claim is *not* subject to the exception "simply because it *contains* a law of nature or a mathematical algorithm," applies one of the exceptions, or is created with the aid of an exception. *Mayo*, 132 S. Ct. at 1293 (emphasis added) (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981); *Parker v. Flook*, 437 U.S. 584, 590 (1978)). In *Myriad*, the Court was even more explicit, devoting an entire section to the "important" "note [of] what is *not* implicated by this decision." *Myriad*, 133 S. Ct at 2119. One such area is "scientific alteration of the genetic code," which the Court emphasized "presents a ***different inquiry"*** than claims directed to natural products themselves (as the isolated DNA claims in the case were held to be), and for which the Court "express[ed] no opinion about the application of §101 to such endeavors" at all. *Id.* (emphasis added). As the Court in all of these cases noted, this critical distinction between claims directed to exceptions themselves and those that merely involve, apply or recite them, is based on the serious concern that "too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 132 S. Ct. at 1293.

Question 2 of the Office's Guidance disregards these explicit admonitions, subjecting not just claims drawn or directed to judicial exceptions, but also any claim that merely "recites," "involves," or is "derived from" any of them, to an onerous patent-eligibility analysis that neither Congress nor the Supreme Court intended. As one example, a claim to "DNA in which the order of the naturally occurring nucleotides has been altered"—the very example that the Supreme Court in *Myriad* held would involve "**a *different inquiry***" from a claim to isolated DNA, and likely ***no*** Section 101 inquiry at all—would, under the Office's Guidance, be subjected to precisely the same inquiry, particularly given the Guidance's explicit application to "nucleic acids" and all "chemicals derived from natural sources." Guidance at 3. As the Supreme Court has expressly admonished against this result, and, as noted, has more recently held that a claim is ***not*** ineligible "simply because it *involves*" one of the exceptions, *Alice Corp.*, 134 S. Ct. at 2354, the Guidance clearly conflicts with the law of the land. While we believe, particularly given the Court's subsequent decision in *Alice Corp.*, that the Guidance should be withdrawn in its entirety, at a minimum we respectfully urge the Office to limit its threshold Question 2 to only those claims that are **drawn or directed to** one of the judicial exceptions.

### B. The Office's "significantly different" test is neither set forth in, nor consistent with Supreme Court case law

The Guidance's third question, asking "whether the claim as a whole recites something ***significantly different*** than the judicial exception" is equally troubling in its disregard of the explicit limitations of the relevant Supreme Court cases, and its misinterpretation of their holdings. At the outset, as other stakeholders have noted and as the Office admitted at the May 9, 2014 Office Forum, this test appears *nowhere* in any of the cases. Instead, the Office has assembled it from passages harvested from separate decisions—an act of independent lawmaking, which as previously discussed, the Office does not have authority to undertake. In any event, it's clear from these decisions, both separately and in the collective, that the Supreme Court never endorsed such a test for patent eligibility, and did not intend so rigid and restrictive an approach.

The Office states that the test is grounded in *Myriad*, informed by some of its earlier precedents (specifically, *Chakrabarty* and *Mayo*), and makes much of *Myriad*'s observation that *Chakrabarty* was "central" to the *Myriad* analysis. We agree that *Chakrabarty* was central to the Court's analysis in *Myriad*, but contrary to the Office's "significantly different" test, neither *Myriad* nor *Chakrabarty* considered the "markedly different characteristics" of the modified *Chakrabarty* bacterium to be "central" to the Section 101 inquiry. For starters, in *Myriad*, as others have commented, far from establishing *any* universal test, the Court was explicit that it was "**merely hold[ing]** that genes and the information they encode are not patent eligible

under §101 simply because they have been isolated from the surrounding genetic material." *Myriad*, 133 S. Ct. at 2120 (emphasis added).[3] Even for the narrow isolated DNA claims at issue, though, to which, again, the Court expressly limited its holding, the Court never announced or applied a "significant difference" test for patent eligibility, or anything similar. The *only* mention of "markedly different characteristics"—a notably *different* standard than the Office's "significant difference" test, as we discuss more below—was a single reference to the specific modified bacterium in *Chakrabarty*, which that earlier decision had considered to be only one relevant factor among many in finding the bacterium patent-eligible. Notably, after this reference, the Court in *Myriad* never applied a "markedly different characteristics" framework to the isolated DNA claims, which would have been par for the course for any formal legal test. The most it did in this regard was to consider whether the separation of the genes from the genome "created a unique molecule." While differences between the claimed molecule and the naturally occurring one may be one factor relevant to this inquiry, the "uniqueness" was not by any means the focus of the Court's inquiry. Instead, the Court focused almost exclusively throughout its decision on the "creation" aspect, *i.e. what the patentee did* with the material it had found in nature, concluding that "Myriad did not create anything," that isolating a gene is "not an act of invention," and, ultimately, that the claims "fell squarely within the law of nature exception" because "discovery [of the BRCA genes], by itself, does not render the BRCA genes 'new . . . composition[s] of matter,' §101, that are patent eligible." *Myriad*, 133 S. Ct. at 2117; s*ee also id.* at 2120 (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.") (emphasis added).

In *Chakrabarty*, the Court likewise mentioned the "markedly different characteristics" of the bacterium only once, and again, only in the context of several other important reasons why the bacterium was patent-eligible, including explicitly both the **nature of the work that the inventor did**, and the **utility or function of the claimed invention**. In fact, read in its proper context, "markedly different characteristics" were only a small part of the rationale for why the *Chakrabarty* bacterium was patent-eligible, the *main* reasons being its inventiveness and utility as compared to the mere mixing of natural bacteria in the earlier *Funk Bros.* case:

> [R]espondent's micro-organism plainly qualifies as patentable subject matter . . . . .[as it is] a ***product of human ingenuity*** having a distinctive name,

[3] For additional reasons why *Myriad's* holding is limited to isolated DNA, and should not extend to other "isolated" natural products (proteins, peptides, vaccines, etc.), see the May 9, 2014 Office Forum presentation of Dr. Leslie Fischer (Novartis).

***character and use***. The point is underscored dramatically by comparison of the invention here with 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."*** [*Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948)].

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. at 310 (emphases added) (internal citations and quotations omitted); *accord Myriad*, 133 S. Ct. at 2216-17 (*Chakrabarty* "held that the modified bacterium was patentable" because the claim was to **"a *product of human ingenuity*** having a distinctive ***name, character and use*** . . . . The *Chakrabarty* bacterium was new 'with markedly different characteristics from any found in nature,' due to the additional plasmids ***and resultant 'capacity for degrading oil.'***") (emphasis added) (internal quotations omitted).

*Mayo* also established no "significantly different" test, or any similar comparative framework. Rather, in addressing the patent-eligibility of process claims directed to a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, the Court inquired "whether the claims ***do significantly more*** than simply describe these natural relations." *Mayo*, 132 S. Ct. at 1294 (emphasis added). Unlike the Office's "significantly ***different***" test—which again does not appear anywhere in the decision—*Mayo*'s "do significantly *more*" framework does not simply look for the presence or absence of additional steps or structural elements, but, consistent with *Myriad* and *Chakrabarty*, again considers *what the inventors actually did* (*i.e.* whether the claim as a whole includes an "inventive concept"), which may include inventive uses or adding functional features. *See id.* at 1294, 1299 (describing the search for an "inventive concept"); *id.* at 1300 (Claims may be patent-eligible if they "confine[] the claims to a particular, useful application of the principle."). Importantly, this inquiry is undertaken both element-by-element, and by considering the claim as a synergistic whole, *i.e.* whether the

elements "as an ordered combination" add something to a law of nature "that is not already present when the steps are considered separately." *Id.* at 1298.[4]

Collectively, then, what these cases *actually* hold is that where a claim appears to be directed to a judicial exception, there are multiple ways to nevertheless satisfy Section 101, including a demonstration of an **inventive contribution or concept,** of the claimed subject matter's **utility,** or of a **functional difference** over the exception. It is here, in failing to recognize the central significance of these critical other factors, and instead effectively limiting the Section 101 inquiry to the presence or absence of **structural** differences, that the Guidance truly goes awry. Vaccines provide a case in point. For many vaccines, it is preferable or even necessary for the vaccine and its protein antigen to be structurally *the same* as the antigen that exists on the surface of the target pathogen in order to trigger the desired immune response to make the vaccine effective. Yet, from a functional perspective, these substances are the antitheses of each other—one causing illness, the other preventing it. Few would argue that vaccines, which serve such a fundamentally different function from antigens in nature—and as a result have likely saved more lives than any other innovation in history—[5] are but "nature's handiwork" lacking an inventive concept or the mark of human ingenuity; yet under the current Guidance, they can be, and with alarming frequency have already been, rejected under Section 101 for failing to demonstrate a structural difference from a natural product.

Other commentators have suggested that this error originates, at least in part, from the conspicuous difference between the "significantly different" language of the Office's test and the "markedly different characteristics" statement in *Chakrabarty*, pointing out that the Office's omission of the broad term "characteristics" unduly

[4] Applying this framework, the Court found the particular method claims at issue to be ineligible, because "any additional steps consist[ed] of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add[ed] nothing significant beyond the sum of their parts taken separately." *Mayo*, 132 S. Ct. at 1298; see also id. at 1300 ("Simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."); *accord Alice Corp.*, 134 S. Ct. at 2355.

[5] The Center for Disease Control and Prevention (CDC), for example, estimates that vaccines given to infants and young children over the past two decades alone will prevent 322 million illnesses, 21 million hospitalizations and 732,000 deaths over the course of their lifetimes. CDC, "Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013," (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm). As just two examples of longer-term impact, had smallpox not been eradicated through vaccines in 1980, it would still kill an estimated 2 million people annually. And before its effective eradication, polio paralyzed up to 1000 children *per day*. UK National Health Service, "How vaccination saves lives," (available at http://www.nhs.uk/Conditions/vaccinations/Pages/vaccination-saves-lives.aspx).

narrows the test's scope. For the reasons discussed, we again believe that even this analysis puts too much emphasis on the Court's fleeting reference to "markedly different characteristics" in *Myriad* and *Chakrabarty*—a conclusion confirmed by the Court's recent decision in *Alice Corp.* (discussed below)—and that, as the cases confirm, the presence of "markedly different characteristics" are at most just one of several ways to satisfy the Section 101 inquiry. However one frames the problem, though, we agree unequivocally that the Office's failure to acknowledge and give effect to the amount of human intervention and ***functional*** differences embodied in a patent claim *vis a vis* the judicial exception is one of the Guidance's most fatal flaws, rendering it incompatible with the will of Congress and the law of the land. The Guidance should be withdrawn accordingly, at least to ensure that these other factors are given their due recognition as alternative ways in which the inquiry can be satisfied.

### C. *Alice Corp.* confirms that the approach in the Guidance is wrong, and compels the Office to withdraw it accordingly

Lest any doubt remain as to the proper framework for approaching Section 101, the Court's most recent case on the subject, *Alice Corp.* makes clear that it is *not* the one in the Guidance. As discussed in Section IA above, in *Alice Corp.*, the Court suggested that claims directed to natural laws, natural phenomena, and abstract ideas should be addressed under the two-step framework of *Mayo*.[6] Notably, in its discussion, the Court again made not a *single* reference to "markedly different characteristics" or "significant differences" as the standard under which claims should be analyzed. Given that *Alice Corp.* post-dates the Guidance and all of the cases on which it relies, this is reason enough for the Office to withdraw the Guidance, at least until it has given ample consideration to the impact.

Giving *Alice Corp.* the consideration that we believe the Office must, it is quite clear that the Court has endorsed a broad inquiry into the ways that a claim that appears to be directed to a judicial exception may nevertheless satisfy Section 101. More specifically, the Court has now confirmed (as it had stated in *Mayo*) that the second-step of the proper framework (equivalent to Question 3 of the Guidance) is a broad inquiry into **"[w]hat else is there in the claims before us?:"**

> In *Mayo*[], we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the

[6] While the Court did not include "products of nature" explicitly in its framework, we assume for this discussion (subject to the Court's further clarification at some later point) that this exception is encompassed under the umbrella of "laws of nature" or "natural phenomena."

> claims at issue are directed to one of those patent-ineligible concepts . . . . If so, we then ask, **"[w]hat else is there in the claims before us?"** To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. We have described step two of this analysis as a **search for an "'inventive concept'"**—i.e., an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."

*Alice Corp.*, 134 S. Ct. at 2355 (emphasis added) (citations omitted).

*Alice Corp.* is thus fully consistent with the correct reading of *Myriad*, *Mayo* and *Chakrabarty* that we set forth above, recognizing that an inventive contribution to what originally may have been a judicial exception, ***including functional elements or uses***, satisfies the Section 101 inquiry. As Donald Chisum has since observed, though, the case actually appears to go even further, creating yet another way to satisfy the statute, through what he refers to as a "technological solution" test. As Professor Chisum explains (here, with respect to abstract ideas):

> [*Alice Corp.*] supports the following proposition: a novel and unobvious solution to a technical problem is not an 'abstract idea,' and a claim drawn to such a solution, even if broad, is not subject to the *Mayo* framework . . . . [I]n its discussion of the 1981 *Diehr* decision in connection with the second *Mayo* step. . . [t]he Court noted that "the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer." In contrast, the claims in *Alice* did not "improve the functioning of the computer itself" or "effect an improvement in any other technology or technical field." The Court had discussed and distinguished the *Diehr* case before, in both *Bilski* and *Mayo*, but never on the basis that *Diehr* entailed a technological improvement. Thus, the *Alice* discussion of *Diehr* in terms of a solution to a technical problem is important new ground . . . . Hence there are strong grounds for the proposition that ***a patent claim reaches a safe harbor from Section 101 abstract idea scrutiny, including the Mayo second question for an "inventive concept," if the claimant establishes that the claim is directed to a solution of a technological problem***.

Donald Chisum, "The Supreme Court's Alice Decision on Patent Eligibility of Computer-Implemented Inventions: Finding an Oasis In the Desert," (Patently-O, June 23, 2014; available at http://patentlyo.com/patent/2014/06/eligibility-implemented-inventions.html ) (emphasis added).

We agree with Professor Chisum that *Alice Corp.* supports a "technological solution" test for patent eligibility as an additional way to analyze and satisfy the Section 101 inquiry. Given *Alice Corp.'s* express application to laws of nature and natural phenomena, and assuming (again, for purposes of the present discussion) that the framework set forth also applies to products of nature, this "important new ground" that Professor Chisum identifies should also apply to each of these other judicial exceptions. In other words, under a "technological solution test," any claim directed to a technological solution to a problem should be automatically exempt from further Section 101 scrutiny (the "safe harbor" to which Professor Chisum refers), a result wholly consistent with *Alice Corp.'s* admonition (discussed in Section IA above) that only claims ***directed*** or ***drawn to*** an exception itself are subject to the inquiry. This test is also consistent with the inventive concept and ***functional differences/utility*** concepts historically set forth in the Supreme Court's Section 101 case law, including, as noted, the second part of the *Alice Corp*. framework. Thus, even where a claim appears to be directed to an exception, including a natural product, a showing that the claim as a whole provides a technological solution to a problem (*i.e.* demonstrates in terms of features (either structural or functional) a new technical effect resulting from such features) should be sufficient to render the claim patent-eligible.

To illustrate the proper application of *Alice Corp*. to "natural product" claims, we apply an inventive technological solution test to claims 1-7 of the sample claims presented at the 2014 BIO International Convention and posted on the Office website (http://www.uspto.gov/patents/announce/bio_sample_claims_2014-06-25.pdf):

> ***Claim 1:*** *Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO:1 and contains at least one sequence modification relative to SEQ ID NO: 1.* The claim is patent-eligible. The problem to be solved is how to provide a particular DNA sequence modification of wild-type Antibiotic L DNA that is suitable for inclusion in an *in vitro* expression system. The claimed subject matter solves this problem in an inventive way, since it would not be obvious to a person skilled in the art to particularly use this particular nucleotide sequence modification to express Antibiotic L, *e.g.*, in yeast cultures.
>
> ***Claim 2:*** *Polypeptide comprising an amino acid sequence that has at least 90% identity to SEQ ID NO: 2 and contains at least one sequence modification relative to SEQ ID NO: 2.* The claim is patent-eligible. The problem to be solved is how to provide a particular amino acid sequence modification of wild-type Antibiotic L that enables easier purification of Antibiotic L from yeast cultures. The claimed subject matter solves this problem in an inventive way, since it would not be obvious to a person skilled in the art to particularly use

this particular amino acid sequence modification to enhance purification of Antibiotic L from yeast cultures.

***Claim 3:*** *A nucleic acid comprising SEQ ID NO: 1 and a fluorescent label attached to the nucleic acid.* The claim is patent-eligible. The problem to be solved is how to screen for SEQ ID NO:1 and closely related nucleotides. The claimed subject matter solves the problem in an inventive way, since it would not be obvious to a person skilled in the art to particularly fluorescently label SEQ ID NO:1, of all possible screening methods.

***Claim 4:*** *A chimeric or humanized antibody to Antibiotic L.* The claim is patent-eligible. The problem to be solved is the provision of a novel antibody that can be used to isolate Antibiotic L from cultures or screen cultures for Antibiotic L. The claimed subject matter solves this problem in an inventive way, since it would not be obvious to a person skilled in the art to use this particular novel antibody to isolate Antibiotic L from cultures.

***Claim 5:*** *Purified Antibiotic L.* The claim is patent-eligible. The problem to be solved is how to obtain Antibiotic L in pure form (*e.g.*, for use as novel antibiotic to treat infections with bacteria X). The claimed subject matter solves this problem in an inventive way, since it would not be obvious to a person skilled in the art how to obtain Antibiotic L in a purified form suitable for treatment, simply because Antibiotic L occurs in a non-purified form in nature.

***Claim 6:*** *Antibiotic L, which is expressed by recombinant yeast.* The claim is patent-eligible. The problem to be solved is the provision of a method of providing novel Antibiotic L to treat infections with bacteria X in an industrial scale. The claimed subject matter solves this problem in an inventive way, since it would not be obvious to a person skilled in the art how to obtain Antibiotic L by means of yeast expression, simply because Antibiotic L occurs in nature.

***Claim 7:*** *A human or fully human antibody to Antibiotic L.* The claim is patent-eligible. The problem to be solved is the provision of a novel antibody that can be used to isolate Antibiotic L from cultures or screen cultures for Antibiotic L. The claimed subject matter solves this problem, since it would not be obvious to a person skilled in the art how to obtain a fully human antibody simply from an antibody to Antibiotic L that occurs naturally in *coyotes*, a different species.

As can be seen from the above analysis, the application of a "technological solution test" to "natural products" confirms the patent-eligibility of subject matter that, according to the current Guidance, may otherwise incorrectly be considered ineligible. Because the present Guidance fails to incorporate these fundamental principles, we respectfully request, in addition to the other suggestions set forth below, that the Office withdraw the Guidance pending further consideration of *Alice Corp.*

## II. The Office Should Withdraw the Guidance, but at Minimum Must Comprehensively Revise it to Reflect the Proper Scope of Supreme Court Precedent

As discussed above, in light of both the Supreme Court's interim decision in *Alice Corp.* and the Guidance's fundamental failure to state and apply the correct legal framework under the Court's earlier precedents, we respectfully join the other commentators who have called upon the Office to withdraw the current Guidance in its entirety. In formulating any new Guidance, we further request that the Office continue its dialogue with the public through public roundtables, public notice, and opportunities to comment on future draft Guidance. We believe that this is the only proper and practical action at this time, given the comprehensive revisions that would be required to bring the current Guidance in line with Section 101 case law.

Should the Office nevertheless decide to maintain the current Guidance, we respectfully request that the Office, at minimum, revise it to clarify the following fundamental points, both in the Overall Process (Part I and Flow Chart) and wherever applicable thereafter throughout:

(1) Question 2 should be revised to read
*"Is the claim **directed or drawn to** one or more judicial exception(s)?"*

(2) Question 3 should be revised to read
*"Does the claim as a whole nevertheless qualify as eligible subject matter by virtue of any of the following:*

*i. the claim includes an inventive concept or inventive contribution*
*ii. the claim as a whole demonstrates a new utility from that of the judicial exception*
*iii. the claim is directed to a solution of a technological problem, or*
*iv. the claim, element-by-element or as a whole, includes a structural or functional difference over the judicial exception."*

To further assist with these necessary revisions, we next provide some specific examples of changes that could be made to help conform the Guidance to controlling

law. To be clear at the outset, the following are meant to illustrate the types of revisions that we believe would be necessary throughout the Guidance if it were to be made consistent with law (though, again, withdrawal is preferable). We do not mean to suggest that merely implementing the examples below would solve the problem.

**A. Proposed revisions to Part II: How to Analyze "Significantly Different"**

In addition to revising this overall topic to be consistent with Supreme Court law (*e.g.* changing to "How to Analyze Eligible Subject Matter Under Question 3"), the Office should revise the example in this section concerning nucleic acid, as it is presently unclear and inconsistent with case law. Specifically, to illustrate its broader contention that "not every factor will be relevant to every claim and, as such, need not be considered in a subject matter eligibility analysis," the Guidance presently states that "for a claim drawn solely to a nucleic acid, factors b)-f) and h)-l) would not be relevant" and eligibility "would therefore turn on an analysis of [only] factors a) and g)." (Guidance at 4). Given the Supreme Court's apparent holdings in *Mayo* and now *Alice Corp.* that the framework set forth in those cases applies to all judicial exceptions—which, as noted, is consistent in any event with the proper reading of *Myriad* and *Chakrabarty* in terms of the multiple ways that Section 101 can be satisfied—it is incorrect to suggest that any of the factors identified in the Guidance are necessarily irrelevant to the inquiry. In the stated nucleic acid example, factor f) for instance could be highly relevant under a proper reading of the case law, if, for example, the claim were to an isolated DNA that was isolated using a novel technique, that provides a technical solution to a problem, or that demonstrates one of the well-known secondary considerations of non-obviousness (e.g. long felt need in the art or unexpected results). Though the Guidance states that its twelve-factor test is similar to the *Wands*-factor based analysis for enablement under Section 112, in the case of the latter, ***all*** factors are considered when the test applies. To make the Guidance more consistent with the case law, and with the analogy to the *Wands*-factor test, we suggest that the Office remove the statements and examples suggesting that Examiners should selectively apply the factors. While, as discussed above, the factors themselves also need to be comprehensively corrected to reflect Supreme Court case law, enabling the applicant to access and the Examiner to consider any and all of them is critical to a proper reflection of the law.

**B. Examples**

**1. Example A should be revised to consider the proper scope of eligibility factors, including specifically the existence of functional differences**

Example A, claim 1, is directed to "a stable, energy generating plasmid, which provides a hydrocarbon degradative pathway," while Claim 2 is directed to a

*Pseudomonas* bacterium with at least 2 stable, energy generating plasmids providing a separate hydrocarbon degradative pathway." In the Guidance, Claim 1 is analyzed only on the basis of factor a), *i.e.,* whether there is a *structural* difference between the claimed plasmid and naturally occurring plasmids. As discussed above, however, the law, under both *Chakrabarty/Myriad* and *Mayo/Alice Corp.* is quite clear that ***functional*** differences (as well as multiple other factors) may well be sufficient to satisfy Section 101. In the example, Claim 1 provides for two very important functional limitations which may provide the grounds for eligibility. The first is the "stable" limitation. If the invention of Claim 1 were the first "stable" plasmid invented, or even a more stable plasmid than previously provided, then this distinguishing functional feature could at least provide, *e.g.,* a solution to a long felt need in the art, or a surprising result. For the same reasons, this limitation could, in such case, satisfy the claim under the "technological solution" test discussed above, and, depending on the facts, could supply a critical "inventive concept" under *Mayo*, *e.g.*, if other known plasmids are all unstable or less stable.

The second functional limitation of Claim 1 is that the plasmid degrades a hydrocarbon. As discussed above, in *Chakrabarty*, the precedent upon which Example A relies, the Court expressly held the modified bacteria to be patent-eligible not only due to the presence of additional plasmids, but also due to the bacteria's resultant "capacity for degrading oil"—an unequivocally ***functional*** limitation. The Guidance is therefore plainly wrong, both in limiting its analysis of this Example to factor a)—which in itself is erroneous in its limitation to structural limitations—and in failing to consider factors b)-f).

The Guidance's analysis of Claim 2 of Example A is similarly flawed. According to the Guidance, claim 2 satisfies the "significantly different" test and is thus patent-eligible because it claims something structurally different from the naturally-occurring bacteria (*i.e.* the bacteria contains more than one plasmid). While we fully agree that the claim is patent-eligible, we do not share the Office's view that a structural difference is the only reason, if it is even a reason here at all. Arguably, at least, the *Pseudomonas* bacterium in this claim can be seen as *not* being structurally distinct from a naturally occurring *Pseudomonas*, depending on how one construes a bacteria's "structure." For example, the transfected plasmids do not alter the cell wall, the organelles, or the shape of the bacteria. Indeed, placed under a microscope, a wild type *Pseudomonas* and a plasmid transfected *Pseudomonas* would be indistinguishable. But, as in *Chakrabarty,* it is the ***functional*** difference between the wild-type bacteria and the claimed subject matter that should be dispositive, eliminating the need to determine whether a sufficient structural difference is present to satisfy Section 101. Due to the introduced plasmids, for example, the bacteria functions differently, a fact that the Example seems to acknowledge, but without giving effect to factors other than a). *See* Guidance at 6 ("and *functionally different*

(it is able to degrade at least two different hydrocarbons") (emphasis added). Given the proper reading of Supreme Court law, and the Office's acknowledgment of the functional difference in the claim, factors b)-f) should again plainly be included in the analysis. [7, 8]

**2. Examples B, F and G should be revised to remove superfluous claim limitations that, at best, unduly complicate the eligibility analysis, and at worst again conflict with Supreme Court law.**

As a final illustration—and again, only to demonstrate the types of revisions that, absent withdrawal, would be required throughout to bring the Guidance into line with Section 101 case law—at least Examples B, F and G are flawed due, among other things, to their inclusion of multiple claim limitations that are superfluous to a proper eligibility analysis. Superfluous limitations risk promoting an erroneous bias against eligibility of claims containing fewer limitations. For example, Claim 3 of Example B, which is a method-of-treatment claim, includes limitations such as the time period for taking the daily dose, and the actual daily dose range. The inclusion of these limitations could erroneously suggest that method-of-treatment claims require dosages, dosing regimens, or similar limitations in order to satisfy Section 101—a result clearly contrary to *Mayo*, which explicitly observed that "a typical patent on a new drug or a new way of using an existing drug" is generally patent-eligible. *Mayo*, 132 S. Ct. at 1302. As Claim 3 is patent-eligible without the superfluous dosage and timing limitations, we suggest the following (again illustrative) revisions, aimed at simplifying the Example and demonstrating what, in our view, is a more complete and proper eligibility analysis under *Mayo* and the Supreme Court's other controlling precedents:

> Claim 3.
> A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer [~~for a period of time from 10 days to 20 days~~, ~~wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid~~.]

Analysis of factors weighing toward eligibility:

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[7] For example, the claim recites elements (additional plasmids) that impose meaningful limits on claim scope, as in factor b). The bacteria include elements (additional plasmids) that transform the bacteria and include a practical application as in factor e). Finally, addition of plasmids to bacteria must be more than conventional or routine in the field, otherwise the claim would be rejected under factor f).

[8] For further discussion of the central importance of functional limitations in Supreme Court case law, see the May 9, 2014 Office Forum presentation of Dr. Leslie Fischer (Novartis).

Factor a) is not relevant, because the claim is a process claim, not a product claim.[9]

Factor b) is satisfied. The step of administering ~~a particular dosage of~~ amazonic acid ~~(0.75 to 1.25 teaspoons per day) for a particular length of time (10-20 days)~~ to a particular patient (patient with colon cancer), meaningfully limits the scope of the claim to a particular application of amazonic acid. Because the amazonic acid is used for treatment of a specific cancer, i.e., colon cancer, this ~~specific dosage and treatment period limitations~~ narrows the scope of the claim~~,~~ such that others are not substantially foreclosed from using amazonic acid in other ways, e.g., ~~to treat colon~~ other cancers ~~at other dosages or for other lengths of time,~~ to treat other cancers, etc.[10]

Factor c) is satisfied. The administering step is significantly related to the judicial exception, because it is a step in which amazonic acid is manipulated in a particular and significant way. The preamble of the claim indicates that the goal of the claimed method is "treatment," meaning that the step of administering is central to the claimed method.

Factor d) is satisfied. The administering step requires administration of ~~a particular dosage of~~ amazonic acid to a patient with colon cancer ~~for a particular length of time,~~ and thus is more than a general instruction to use amazonic acid but is specifically directed to treating a patient with colon cancer. [11]

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[9] Novartis Comment: To the extent that *Alice Corp.* mandates that the same standard or set of standards applies to all judicial exceptions, including natural products, the Office's distinction between products and processes in factors a) and g) is fundamentally incorrect. If this is the correct reading of *Alice Corp.*, factor a) and g) could be rewritten to ask whether the claimed subject matter satisfies a technological solution test, includes an inventive concept or new utility, or a functional difference, regardless of whether the claim is a product or process.

[10] Novartis Comment: While, given the Court's subsequent decision in *Alice Corp.*, we do not believe *Mayo*'s preemption test to be necessarily dispositive of the eligibility analysis (since, e.g., a utility, functional difference, and technological solution test would all support patent eligibility), to the extent the standard applies in a given case, it simply mandates that a patent claim cannot preempt all uses of a natural law. Here the claimed method of treatment is only directed to use of the compound in treating colon cancer, leaving treatment of other cancers or diseases free to others. As such, it cannot possibly preempt all uses of a natural law.

[11] Novartis' Comment: As noted, in *Mayo,* the Court observed that "a typical patent on a new drug or a new way of using an existing drug" should be patent-eligible, because such claims "confine their reach to particular applications" of natural laws. *See Mayo*, 132 S. Ct. at 1302. The additional limitations in the Example (dosage and regimen) and in the Office's reasoning are therefore neither necessary nor helpful in explaining the proper application of *Mayo*, and run the risk of creating a misperception that such limiting elements are required.]

Factor e) is ~~not~~ satisfied. ~~There is no machine or transformation recited in the claim.~~ Treating a patient results in a transformation of that patient by introduction of the relevant compound into the patient and modification of the patient's biochemical profile.

Factor f) is satisfied. Prior usage of Amazonian cherry tree leaves was for treatment of breast cancer patients. It was not well-known, routine or conventional to use amazonic acid (either isolated or in leaf form) to treat colon cancer, or in fact to treat any other cancer ~~at the recited dosage or for the recited length of treatment time~~.

Analysis of factors weighing against eligibility:

Factor g) is not applicable because the claim is not a product claim.

Factor h) is not satisfied, because the administering step is for a ~~not recited at a high level of generality, but instead recites a specific dosage of amazonic acid to be administered for a specific time to~~ a specific type of cancer patient.

Factor i) is not satisfied. Amazonic acid can be applied in other ways, e.g., to treat ~~colon cancer at other dosages or for other lengths of time, to treat~~ other types of cancer or other diseases~~, or in other compositions.~~

Factor j) is not satisfied. It was not well-known to use Amazonian cherry tree leaves or amazonic acid to treat colon cancer~~, or in fact to treat any cancer at the recited dosage or for the recited length of treatment time~~.

Factor k) is not satisfied. The administering step is not merely appended to the judicial exception, but instead is significantly related to the amazonic acid. The preamble of the claim indicates that the goal of the claimed method is "treatment," meaning that the step of administering is central to the claimed method.

Factor l) is not satisfied. Administering ~~a particular dosage of~~ amazonic acid for a specific cancer ~~particular length of time~~ is more than a mere field of use, because it limits the claim scope to a particular application of amazonic acid to a specific cancer, i.e., colon cancer.

As noted, Examples F and G contain similarly superfluous limitations that do not appear to be relevant to patent-eligibility, and thus raise similar concerns. For example, Example F's claim to "a method for determining whether a human patient has degenerative disease X" includes limitations to a particular antibody (XYZ) and a particular technology (flow cytometry) which, in our view, are not necessary to

render the claim patent-eligible. Example G likewise includes such additional limitations (e.g. Claim 3, which includes the additional steps of "filtering" and "positioning," and within the "positioning" step the USPTO includes multiple features relating to distance (30-60 cm) and time (30-60 mins)), to the point that it is unclear what steps and/or features in the Office's view render the claim patent-eligible. While *Mayo* explained that a process reciting a law of nature must have "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself," *Mayo*, 132 S. Ct. at 1297, it did not suggest that multiple features are necessary in order to provide that assurance. Each of these Examples, and again any and all other Examples suffering from similar infirmities, should be revised consistently with our suggestions for Example B above, to avoid creating an erroneous belief among Examiners and members of the public that including multiple limitations beyond an alleged judicial exception is particularly significant, or, more importantly, that claims including only one additional feature will not qualify as patent-eligible.

**CONCLUSION**

We again thank the Office for the opportunity to comment on its Guidance in this all-important area of patent law. Subject matter eligibility cuts to the very heart of the patent system, and lawmaking in this area has a profound impact on the scope and direction of innovation. Such an undertaking should be left to Congress and the Courts, whom the public has entrusted with this role, and in all events cannot be taken lightly. With the benefit of *Alice Corp.*, which now clarifies the Supreme Court's earlier holdings on the narrow scope of the judicial exceptions and the broad approach to assessing whether claims are patent-eligible, we believe it only proper for the Office to withdraw its inconsistent Guidance, and to issue new Guidance only after careful reflection and due consideration of the points raised above and in other stakeholder's comments. Should the Office maintain its present approach, we at least request that it duly and carefully consider ours and others' suggested revisions. We look forward to the Office's reaction and response.

Respectfully submitted,
/s/ Corey Salsberg

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