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VIA E-MAIL ONLY
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Re: Novartis Comments on "2014 Interim Guidance on Patent Subject Matter Eligibility (Federal Register Vol. 79, No. 241, December 16, 2014)

As the arbiter of what may be patented and what may not, Section 101 is more than just the gatekeeper of the United States patent system—it is the Alpha and the Omega of entire fields of innovation, of companies and industries, and directions of technological progress. For this reason, Novartis thanks the United States Patent and Trademark Office ("the Office") for the opportunity to comment on its revised "*2014 Interim Guidance on Patent Subject Matter Eligibility*" (Interim Guidance), for its responsiveness to our July 31, 2014 comments on the original guidance[1] and those of the many other stakeholders who expressed their views, and for its continued engagement with the public in fashioning sensible approaches to subject matter eligibility that properly reflect the relevant case law, and that fulfill the patent system's mission of broadly incentivizing innovation for the public good.

Novartis is 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. Our businesses include innovative medicines, eye-care (Alcon), high-quality generic medicines and biosimilars (Sandoz), and vaccines, and our medicines and other healthcare products reach more than 1 billion patients around the world each year. As the breadth of our portfolio and the span of our patient-impact demonstrate, innovation is our lifeblood, and it flows in a wide range of directions. Each of those directions requires substantial investment, and in the case of innovative R&D, strong incentives like those provided by the patent system to enable and fund the costly, risky work that it takes to invent, develop, and bring new therapies to patients. Removing these incentives for any type of innovation makes it much more difficult, and in many cases impossible, to continue to invest in that research direction—which is why so much is indeed at stake in defining the bounds of what is, and what is not, patent-eligible.

With that in mind, we commend the Office on its Interim Guidance, which represents a dramatic improvement over the original guidance, and comes much

[1] http://www.uspto.gov/sites/default/files/patents/law/comments/mm-e-novartis20140731.pdf

closer to reflecting and implementing the full scope of eligible subject matter defined by Section 101 and Supreme Court precedent. More specifically, the Interim Guidance's narrowed applicability to only those patent claims "directed to" a judicial exception, its recognition in the case of nature-based product claims that *functional* differences and other properties that differentiate the invention from what exists in nature may satisfy Section 101, and its inclusion of a commonsense "streamlined eligibility" pathway, all give life to important doctrines from Supreme Court case law that the previous guidance omitted, restoring patent-eligibility to a broader range of inventions consistent with the case law, which will help companies like ours continue to innovate in areas that the earlier framework threatened to curtail.

That said, in a few respects, we believe that the Interim Guidance still falls somewhat short of "right" in giving full effect to the binding case law, which we believe can be improved with minimal changes. Heartened by the Office's active solicitation of additional public feedback, and its open intent to reflect and closely trace the relevant case law (see, e.g. Fed. Reg. Vol. 79, No. 241 at 74619), we respectfully submit these comments, which seek to further harmonize the Interim Guidance with Section 101 jurisprudence, resulting in a clearer, stronger framework to further help examiners reach the correct result when examining claims directed to a judicial exception.

I. The Interim Guidance Should be Amended to Clearly Indicate That an "Enlargement of the Range of Utility" of a Natural Product Satisfies Section 101 for a Nature-Based Product

As noted, the Interim Guidance is a dramatic improvement over the original guidance for a variety of reasons, including most prominently its new recognition that a nature-based product is patent-eligible if it exhibits either a structural *or* a *functional* difference from a natural product. This critical correction preserves the patent-eligibility of important inventions related to health, like certain vaccines that may be based on antigens that are structurally similar to what exists in the body, but perform new functions as a vaccine. Still missing from the Guidance, however, at least explicitly, is the recognition that nature-based products may also be patent-eligible if they satisfy other tests set forth in Supreme Court case law, such as a nature-based product that "**enlarges the range of utility**" of a natural product. *See* e.g. *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (finding the claim to a combination of bacteria species ineligible under Section 101 because "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* . . . . Their use in combination *does not improve in any way their natural functioning*.") (emphasis added); *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (Distinguishing the bacterial mix in Funk Bros. from the bacteria at issue). In the pharmaceutical field, for example, isolating or purifying a natural substance in a way that increases its efficacy from the natural form, allows it to be formulated and dosed precisely, reduces side effects, or makes the substance applicable to a wider

class of patients may not always constitute a "different" function or use of the substance, but the resulting product is undoubtedly a product of human ingenuity that satisfies Section 101 on the basis of an "enlarged range of utility."

There is more than one way to give effect to this important test in the framework of the Interim Guidance. In its present form, the Interim Guidance places the eligibility analysis for nature-based products primarily—and, as explained in Section II below, almost exclusively—into "Step 2A," which inquires whether a patent claim is directed to a judicial exception. For nature-based products, the Guidance instructs examiners to apply a "markedly different characteristics" analysis in this step, which, under the Guidance, may be satisfied by a difference in "structure, function and/or other properties." (Fed. Reg. Vol. 79, No. 241 at 74623; 74621). The simplest way to include the "enlarged range of utility" test in the Interim Guidance is to clarify in the text and the flow chart that, under the "markedly different characteristics" analysis, "other properties" may include an enlargement in the range of utility of the naturally occurring counterpart. Particularly since the Guidance already cites *Funk Bros.* more generally for the proposition that a "characteristic changed as compared to nature" should satisfy the test (*see id.* at footnote 27), such a change would be both easy to implement and consistent with the existing framework.

A second way to implement this change would be to revise Step 2A to recognize the "enlarged range of utility" test as a separate analysis from the "markedly different characteristics" analysis, with an equal ability to satisfy Section 101 on a dispositive basis. While we would support any approach that gives full effect to the "enlarged utility" test, we continue to believe, as we discussed in our comments to the original guidance, that the Supreme Court case law establishes and recognizes a multitude of different ways in which Section 101 may be satisfied, only one of which is through the presence of "markedly different characteristics." As we have previously explained, the Court has only ever used this particular framework twice, both times when referring to the particular bacterium at issue in the *Chakrabarty* case, and both times among a string of *other* reasons that the bacterium was patent-eligible, including its status as a "***product of human ingenuity,"*** its "***distinctive name, character and use*** / ***potential for significant utility***" and its contrast to the bacterial mix in Funk Bros. which had resulted in "***no enlargement of the range of their utility."*** *Chakrabarty*, 447 U.S. 303 at 310 (emphases added); *accord Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2216-17 (2013) ("*Myriad*"). We strongly believe that, far from establishing a single standard for analyzing the eligibility of all product claims, the Court's Section 101 jurisprudence sets forth a variety of different ways to satisfy the inquiry, including those listed above and several others. An approach to nature-based products more faithful to the case law would therefore be to recognize these analyses as separate and equal ways to satisfy Section 101, beyond the "markedly different characteristics" framework. To the extent the "markedly different characteristics"

framework remains in Step 2A as currently structured, adding "enlarged range of utility" and, for completeness, "distinctive name, character or use,"[2] as alternative eligibility tests for nature-based products in this Step would harmonize the Guidance with the case law, at least in substance, if not in form.

A third way to achieve the same result—and in our view, the most faithful to the case law—would be to move the entire analysis for nature-based products into Step 2B, instead of giving these types of claims special treatment in Step 2A. If this were done, Step 2B would have to be revised from what (as discussed in Section II of these comments below) is presently a process-claim oriented analysis under the "additional elements" framework, to a more comprehensive analysis that includes the full universe of tests and subtests applicable to nature-based product claims. As discussed in more detail below, this comprehensive analysis could still be framed as an "inventive concept" analysis (though *not* an "additional elements" analysis), or alternatively as an "integration/transformation" test (i.e. "does the claim integrate the judicial exception into something more, thereby transforming the judicial exception into a patent-eligible invention?"), provided that the framework includes the "markedly different characteristics" test (structural and functional), the "enlarged range of utility" test, and all other subtests from the case law applicable to natural product claims. Moving the full nature-based product claim analysis into Step 2B would leave Step 2A as a simple filtering step as it is for all other claim types, simply asking whether the claim is "directed to" a judicial exception, while allowing the existing "streamlined eligibility" pathway to remove claims that are obviously patent-eligible from further analysis under the Guidance.

Ultimately, however, we reiterate our view that, so long as the "enlarged range of utility," "distinctive name, character and use," and other nature-based product tests from the case law are integrated somehow into the Interim Guidance as alternative ways to satisfy Section 101, how the Office frames the analysis is of lesser importance.

II. "Step 2B" of the Interim Guidance Should be Broadened to Give Full Effect to the Relevant Process Case Law, and to Encompass Subtests Useful in the Analysis of Nature-Based Product Claims

A second problem that remains in the Interim Guidance is its narrow approach to the Supreme Court's second step of the *Alice Corp./Mayo* test ("what else is there in the claims before us?"), which in Step 2B appears to require that any claim directed to a judicial exception contain "additional elements" in order to be patent-

[2] The "distinctive name, character, or use" test first appears in *Hartranft v. Wiegmann*, 121 U.S. 609 (1877) (emphasis added). While the Court in *Chakrabarty* referred to "distinctive name, character and use," it did so because the Chakrabarty bacterium actually exhibited all three. In so finding, the Court did not change the test, but merely applied it to the subject matter at hand.

eligible. *See* Flow Chart Step 2B, Fed. Reg. Vol. 79, No. 241 at 74623 ("Does the claim recite additional elements that amount to significantly more than the judicial exception?"). While "additional elements" may be one way to satisfy the second step of the eligibility test for *process claims*, it is not the only way under the relevant case law, and certainly cannot be the sole approach if nature-based product claims are also subject to Step 2B (as the Interim Guidance states they are). In order to give full effect to the Supreme Court's Section 101 case law as applied to all judicial exceptions for all types of claims—products, processes, machines and manufactures—the Office should at least remove the "additional elements" requirement from Step 2B of the Interim Guidance (even for process claims) and frame the question more broadly to include alternative approaches. To the extent the Office either maintains Step 2B as a residual test for nature-based product claims that fail Step 2A, or moves the nature-based product claim analysis entirely into Step 2B as proposed in one of the options above, the Office should further include in this broadened Step 2B framework a variety of tests useful in the analysis of nature-based product claims, including at least the "enlarged range of utility test" and "distinctive name, character or use" tests to the extent not incorporated in Step 2A. We elaborate on each of these points—a general broadening of the Step 2B test, and a further broadening for product claims—in turn below.

A. The "additional elements" test of Step 2B is unduly limiting even for process claims and should be revised to conform to the Supreme Court's broader "Step 2" *Mayo/Alice* framework

Confusingly, while the Interim Guidance includes the "additional elements" requirement in Step 2B of the flow chart, and references this test at least seven times in others areas of the text and Sample Analyses, elsewhere in the Guidance this test is either referred to as a search for "additional *features*" (arguably broader than an "element" in the patent claiming sense) or omitted entirely from the framing of the Step 2B question. This inconsistent framing of the Step 2B test creates uncertainty and confusion for both examiners and applicants, and should be amended to specify a single test that gives full effect to the Section 101 case law. In that regard, we believe that the Office's statement and description of the test in the heading and first sentence of Section B of the Guidance (page 74624) is the most reflective of the proper standard, and should be adopted as the Office's standard for Part 2 of the *Mayo* test:

> B. Flowchart Step 2B (Part 2 *Mayo* test)—Determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception.
>
> A claim directed to a judicial exception must be analyzed to determine whether the elements of the claim, considered both individually and as an ordered combination, are sufficient to ensure that the claim as a whole amounts to significantly more than the exception itself—this has been termed a search for an "inventive concept."

(Fed. Reg. Vol. 79, No. 241 at 74624)[3]

Of the varying approaches taken in the Interim Guidance, the above–quoted test most closely aligns with the Supreme Court's approach to "Step 2" of the Section 101 inquiry in *Alice Corp.*, *Mayo* and the earlier precedents on which these cases are based, all of which recognize that "additional elements" may not be required in order to render a claim directed to a judicial exception patent-eligible. In *Alice Corp.*, for example, the Court, quoting and closely tracing *Mayo*, framed the Step 2 test broadly as a ***"what else is there in the claims before us?"*** analysis, explaining that the test is aimed at "distinguish[ing] between patents that claim the 'building blocks' of human ingenuity and those that integrate the building blocks into ***something more***, thereby 'transforming' them into a patent-eligible invention." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354, 2355 (2014), quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1303 (2012) (internal citations and brackets omitted, emphasis added). The Court then offered at least two ways in which this "what else is there" inquiry can be analyzed: (1) Are there "additional elements" that transform the claim into a patent-eligible invention; *or* (2) does the claim, element-by-element *or considered as a whole* include an "inventive concept" that transforms the claim into a patent-eligible invention?:

> [**"Additional Elements" approach**:] 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
>
> ["**Inventive Concept" ("Significantly More") approach**] 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, quoting *Mayo*, 132 S. Ct. at 1294, 1298 (internal citations omitted); *see also Mayo*, 132 S. Ct. at 1294 (asking "whether the claims ***do significantly more*** than simply describe these natural relations.") (emphasis added)

Giving life to this second approach, the Court in *Mayo* expressly applied it to the process claims at issue there, illustrating how a claim that does not satisfy the "additional elements" test might nevertheless satisfy Part 2 of the Section 101 inquiry. Specifically, the Court, applying the broadly-stated "what else is there" framework that it later adopted in *Alice Corp.*, first considered each of the three steps

[3] This "inventive concept" test is also employed in the section "A Claim Reciting a Plurality of Exceptions" on page 74625 of the Guidance, and is used in the "Sample Analyses" section beginning on page 74625.

of the process to determine whether these additional elements transformed the underlying judicial exception into a patent-eligible invention. After concluding that they did not, the Court did not simply conclude its inquiry, but instead looked at the claim as a whole, inquiring whether "the three steps as an ordered combination adds [something more] to the laws of nature that is not already present when the steps are considered separately." *Id.* at 1298. In conducting this analysis, the Court endorsed and relied upon its earlier decision in *Diehr*, where it recognized that "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." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). Plainly, in such a case, there is no "*additional* element" viewed on its own that transforms the claim into an "inventive concept"—rather, the inventiveness and consequent patent-eligibility flows from something transformative in the way that the inventor arranges existing elements in the claim as a whole.

As currently written, Step 2B, which requires the presence of "additional elements" does not clearly reflect this alternative way of satisfying Section 101, even in the case of process claims. The Internal Guidance should be amended to make clear throughout that the search for an "inventive concept" is not limited to the presence or absence of "additional elements," but may be met if a process claim considered as a whole involves an inventive concept absent additional elements.

B. Step 2B's inclusion of nature-based product claims and other claim types requires a test and subtests that are sufficiently broad to fairly encompass such subject matter

As the above cases illustrate, a strict "additional elements" analysis would be too narrow a test for the Interim Guidance, even if Step 2B were limited to *process* claims. Here, however, the Guidance makes clear that Step 2B is not so limited, but encompasses all judicial exceptions and all claim types, including nature-based product claims that fail the "markedly different characteristics" test of Step 2A. Whether maintained in its current form as a residual test for nature-based product claims, or revised to include the full scope of tests for such claim types (proposed option 3 in Section I of these comments), Step 2B's inclusion of claim types beyond process claims makes it incumbent on the Office to ensure that this part of the test, and any applicable subtests, are sufficiently broad to account for differences between the claim types and to fairly accommodate all of the types.

The importance of broadening Step 2B beyond the "additional elements" test to accommodate nature-based product claims follows both from the logical structure of the Interim Guidance, and from the relevant case law. On the structure, so long as the Guidance continues to instruct examiners to apply Step 2B to residual nature-based product claims that fail Step 2A, it cannot be the case that this Step turns on a standard that so many of them cannot meet. Yet, as the case law demonstrates, this is precisely what results from the current unduly narrow "additional elements" test. In

that regard, it is no coincidence that nearly every case that discusses an "additional elements" approach is a process or abstract idea case. Indeed, the "additional elements" test emerged from this line of cases precisely *because* the types of claims at issue—those to purported applications of principles, algorithms, natural laws, and mathematical formulas—readily lend themselves to this type of approach. More specifically, from the earliest case in the line, *Neilson v. Harford*, 151 Eng. Rep. 1266, 8 M. & W. 806, Web. Pat. Cas. 273 (1844),[4] to *Parker v. Flook*, 437 U.S. 584 (1978), to *Mayo* and *Alice Corp.*, the "additional elements" decisions have all been concerned with the distinction between ineligible claims to a scientific principle *itself* (or law of nature or abstract idea), and eligible claims to *applications* of a principle.[5] Because a logical distinction between a principle and an application of a principle is the presence or absence of additional elements, these cases historically approached the Section 101 inquiry by ignoring or *removing* the principle (or other exception) from the claim and considering whether the elements that remain rise to the level of patent-eligibility. *See also In re BRCA1- and BRCA2-based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 at 764 (Fed. Cir. 2014) (*Myriad III*) (Removing the judicial exception from consideration, and inquiring whether "[t]he non-patent-ineligible elements . . . add 'enough' to make the claims as a whole patent-eligible.").

That analysis simply does not work for nature-based product claims, as we know from the absence of the "additional elements" test from the nature-based product claim case law,[6] and from the fact that such an approach would render ineligible subject matter that the Supreme Court has held is *firmly* patent-eligible. In *Chakrabarty*, for example, the bacteria at-issue was a combination of several natural

[4] For an in-depth analysis of how *Neilson* has shaped subject matter eligibility law in the United States, *see* Lefstin, Jeffrey A., Inventive Application: A History (March 31, 2014). Florida Law Review, Forthcoming; UC Hastings Research Paper No. 94. Available at SSRN: http://ssrn.com/abstract=2398696 or http://dx.doi.org/10.2139/ssrn.2398696.

[5] *Alice Corp.* also considered system and computer readable medium claims, but the patentee conceded that the media claims fell with the method claims, and the Court held the system claims to be "no different from the method claims in substance." (*Alice Corp*. p. 16). Thus, *Alice Corp*. is squarely based on an analysis of the process claims.

[6] See, e.g. the following cases, all omitting a Step 2 *Mayo* analysis and instead focusing on whether the claimed subject matter has been changed in some meaningful way from the naturally-occurring counterpart: *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931) (combination of two natural products, an orange and borate); *Chakrabarty*, 447 U.S. 303 (combination of natural bacteria and natural plasmids); *Ass'n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013) (isolated genomic DNA and cDNA); *Parke-Davis & Co. v H.K. Mulford Co.*, 189 F. 95 (SD N.Y. 1911) (purified adrenalin); *Merck v. Olin Mathieson*, 253 F.3d 156 (4th Circ. 1958) (purified vitamin B-12); *In Re Roslin*, 750 F.3d 1333 (Fed. Cir. 2014) (cloned sheep); *Myriad III* (omitting the Step 2 *Mayo* analysis with respect to claims to a combination of two natural products, i.e. a pair of primers). The sole exception to this may be *Funk Brothers*, which technically involved product claims and an analysis of whether the co-packaging of natural bacteria was sufficient to render the claims patent-eligible, but the Court in that case approached the analysis as an application of a natural *principle* rather than as a nature-based product claim.

products, i.e., a bacteria and natural plasmids from other bacterial sources. Applying the "additional elements" test to this claim would require the removal of all judicial exceptions in the claim, *see, e.g., Myriad III*, 774 F.3d at 764, which in this case would be all of the naturally-occurring bacteria and plasmids. Thus, under an "additional elements" test, *no* elements would remain in this example to render the claim patent-eligible, a result belied by the Court's holding in that case. The same erroneous outcome would be reached for gunpowder and for the Office's own Example 9, claim 5 (a composition comprising pacemaker cells in a biocompatible 3D scaffold) in the Nature-Based Product Examples that accompany the Guidance.

Only by considering the claim as *a whole* in these examples—including the judicial exceptions themselves—could we reach the correct result that the claim is eligible as a combination of elements, even where the elements remain ineligible when considered individually. This latter approach, however, is not the "additional elements" test—which, again, "ask[s] whether the remaining elements, either in isolation or combination with the other *non*-patent-ineligible elements" add enough, *Myriad III*, 774 F.3d at 764 (emphasis added)—but an application of the alternative "inventive concept" test from *Mayo*, *Alice* and *Diehr* described above. At a minimum, then, these examples reiterate the need to broaden Step 2B from an "additional elements" test to an "inventive concept" test to reach the correct result for claim types other than process claims. More than that, however, because no case law applying these types of tests to nature-based product claims exists, examiners and applicants would greatly benefit from further guidance in the form of concrete subtests applicable to nature-based claims.

Unless explicitly added to Step 2A of the Interim Guidance (proposed Option 1 or 2 of these comments), these product-specific subtests in Step 2B should include at least the "enlargement in the range of utility" test described in *Funk Bros.*, *Chakrabarty* and *Myriad*, and the "distinctive name, character, or use" test of *Hartranft* and *Chakrabarty*, accompanied by examples illustrating how to apply these subtests to nature-based products. The addition of these subtests and examples would be especially welcome and valuable since the existing subtests that appear in the Step 2B Guidance are all, like the principal "additional elements" test, derived solely from process claim cases (e.g., addition of non-conventional elements, improvement to another technological field, etc.), and consider only whether a judicial exception has been *applied*, rather than *changed*.[7]

[7] Some of the existing Step 2B subtests also create unnecessary estoppel issues for an applicant seeking to establish patent-eligibility for product claims. For example, an applicant should not be forced to argue that a product claim is confined to a particular useful application of a nature-based product. Rather, a product claim rightfully encompasses all applications of the claimed subject matter, save for those relinquished to overcome prior art.

Of course, were the Office to decide to move the entire nature-based product claim framework from Step 2A to Step 2B (proposed option 3 of Section I above), the need for a sufficiently broad phrasing of Step 2B, and for a comprehensive set of nature-based product claim subtests would be especially great. As previously indicated, this could be accomplished by either (1) maintaining an "inventive concept" analysis as an umbrella test for all claim types (e.g. "whether any element, or combination of elements (including a combination of judicial exceptions), in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception.") and supplementing this test with subtests applicable to each of the claim types; or (2) by adopting the alternative "integration/transformation" approach announced in *Alice Corp.*, i.e. "Does the claim integrate the judicial exception into something more, thereby transforming the judicial exception into a patent-eligible invention?" *See Alice Corp.*, 134 S. Ct. at 2354.[8] In contrast to the existing Step 2B, provided that the proper subtests were included for both process claims (e.g. addition of steps/features that are non-conventional, improvement to a technological field, etc.) and product claims (e.g., markedly different characteristics; expanded range of utility; distinctive name, character or use; etc.), adopting either one of these umbrella tests as the Step 2B framework would allow *all* process and product claims to be subject to a single common framework. In the case of nature-based product claims, this would include those that recite only natural products (e.g., purified enzymes, gunpowder), as well as those that recite elements or features beyond natural products (e.g., a hip implant coated with a natural growth factor).

Ultimately, what again matters is that the Guidance reflect the full scope of the Section 101 case law. In the case of *Mayo* Step 2 (Step 2B), this means that, at minimum, the test should be revised even for process claims to reflect the "inventive concept" framework instead of the "additional elements" one, and to the extent product claims remain subject to Step 2B (either residually or exclusively), that the Step be further revised to include subtests and examples from the product-based case law that apply to these fundamentally different claim types.

III. The Interim Guidance Should be Supplemented With Positive Examples of Nature-Based Product Claims That Satisfy Section 101 Through Functional Differences

As a third area for improvement, examiners and applicants would greatly benefit from the inclusion of nature-based product claim examples that are found to satisfy the "markedly different characteristics" test on account of functional differences, even where they do not exhibit structural differences. As previously noted, the Interim Guidance's addition of functional differences as an alternative way

[8] Revised in this fashion, Step 2B would conform to *Mayo/Alice* Step 2's aim of "distinguish[ing] between patents that claim the 'building blocks' of human ingenuity and those that integrate the building blocks into something more, thereby 'transforming' them into a patent-eligible invention."

to satisfy the "markedly different characteristics" analysis is one of the key improvements to the original Guidance that converted it from a framework that we could not endorse, to one that (ideally with the further improvements proposed in these Comments) we can generally support. As a practical document designed to aid examiners and applicants in the prosecution of real patent applications, however, a test alone is far less valuable than a test accompanied by practical examples of how that test will be applied. For this reason, and to ensure that the absence of such examples does not create a negative bias against subject matter that meets only the "functional differences" test, we request that the Office add at least one example to the Nature-Based Product Examples where a claim reciting only an isolated composition of matter meets the "markedly different characteristics" analysis through functional differences. Such an example could be based, e.g. on the facts in *Merck v. Olin Mathieson, 253 F.3d 156* (4th Circ. 1958) (purified vitamin B-12), or on another purified or isolated substance.

IV. The "Streamlined Eligibility" Pathway Should be Explained in Greater Detail to Provide Applicants and Examiners With Meaningful Guidance as to How this Pathway Will be Applied

Last, and in a similar vein to the previous point, examiners and applicants would in our view greatly benefit from a further explanation as to how the "streamlined eligibility" pathway will apply in practice to various claim types. Like the "functional differences" test, this alternative pathway is a welcome addition to the Guidance which, if meaningfully used and applied, will give fuller effect to the Section 101 case law, and greatly reduce unnecessary burdens on applicants and examiners. That said, while it appears that some of the Examples employ this pathway in reaching their result (e.g., Example 1, claim 2 [fountain-style firework containing gunpowder], Example 3, claims 7-8 [methods of treating particular diseases using purified amazonic acid]), the Guidance does not indicate expressly when it is being used, or precisely how it is being applied. An additional description and some further examples of how and when to apply this pathway will further strengthen the Guidance, to the benefit of applicants and the Office alike.

* * *

We again commend the Office on its much-improved Interim Guidance, and thank it for this opportunity to suggest additional improvements that will move the Guidance even closer to the case law, resulting in a stronger set of principles and examples for all. We look forward to the Office's response, and to a continuing dialogue on this all-important issue.

Respectfully submitted,
/s/ Corey Salsberg

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