The Hon. Michelle K. Lee
Acting Under Secretary of Commerce
Deputy Director, U.S. Patent and Trademark Office

Via email

cc. Peggy Focarino
June E. Cohan
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Re: Supplemental comments on the USPTO *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*

October 14, 2014

Dear Acting Director Lee:

We greatly appreciate the USPTO's outreach to the patent user community in its efforts to revise and improve its March 4, 2014 examination guidance for the determination of subject matter eligibility of claims relating to products and processes derived from natural sources or materials (the "March Guidance"). After the USPTO's extended public comment period ended on July 31, USPTO staff participated in a number of public events and laid out a range of concepts that appear to be under ongoing consideration for revising the March Guidance. In particular, USPTO staff indicated that upcoming revisions of the Guidance may incorporate the following general changes:

- A 101 analysis may be limited to claims "directed to" (rather than merely "reciting" or "incorporating") a judicial exclusion, thereby narrowing the range of claims that would be funneled into this process to only those that really need to undergo 101 analysis.
- The USPTO may consider evidence of "function," or "functional differences" – rather than always requiring structural modifications, as is currently the case - in distinguishing patent-eligible inventions from patent-ineligible natural phenomena/products of nature.
- Revisions may be built around a "unified 101 analytical framework," with particular reference to the Supreme Court's *CLS Bank* decision, that would apply to both process claims on the one hand, and claims to compositions, machines, and manufactured articles on the other hand.

In each instance, USPTO staff expressed interest in feedback and additional thoughts on these concepts from practitioners and other members of the interested public. Accordingly, we hope that you will find our following comments, questions,

and recommendations helpful as you work towards revising and finalizing the Guidance.

Opportunity for public comment:
We strongly recommend that the USPTO should publish its proposed revisions and provide an opportunity for public feedback before the Revised Guidance is finalized and implemented by examiners. Such an opportunity for comment and suggestions for additional refinement would be helpful in further improving the Guidance and ensuring that it reflects the current state of the law as accurately as possible. Additional opportunities for input by the interested public would at any rate be more likely to increase acceptance of such a Revised Guidance by the patent user community. While we understand that examiners and applicants feel a sense of urgency, we believe that the benefits of a reasonable public opportunity to comment on the USPTO's proposed revisions outweigh the benefits of implementing them sooner.

New grounds and/or previous grounds no longer applicable:
Once the Revised Guidance is promulgated, claims that were first rejected under the March Guidance should not get a second action final rejection under the Revised Guidance. Applicants receiving a second 101 rejection under the Revised Guidance, after having received an earlier 101 rejection under the March Guidance, should have an opportunity to respond to new grounds of rejection that are raised by the revisions. Also, we expect that there will be pending applications in which previous grounds of rejection will no longer be applicable under the Revised Guidance – for example because one or more of the "12 factors" earlier applied to the claims were deleted in the Revised Guidance, or because under the Revised Guidance the claim would not be deemed "directed to" a judicial exclusion. In such instances the previous 101 rejection under the March Guidance should be withdrawn.

Substantive issues that would benefit from public comment before revisions to the guidance are finalized and implemented:
With respect to the substance of the upcoming revisions – as best as we can discern it from public statements - we would like to reiterate that we greatly appreciate the Office's high level of public engagement and transparency on the matter. USPTO staff has publicly described the general contours of several substantive revisions to the March Guidance that currently appear to be under consideration inside the Office. Some we find encouraging, some intriguing, some concerning. Some concepts may still be in flux, others may benefit from clarification or refinement so that they can be better understood and accepted by the patent user community when they are finally released. We offer the following observations, recommendations and questions not only in the hope that the USPTO will find them helpful in finalizing the Revised Guidance, but also to illustrate the kinds of issues that could benefit from public comment and dialogue with the USPTO before the Revised Guidance is finalized.

<u>Use of additional caselaw</u> – In framing the March Guidance, the USPTO seems to have focused only on selected Supreme Court cases and has not drawn on all available precedent. Despite being extensively briefed, the Supreme Court has not

overruled or distinguished *Parke-Davis*, *Merck v Olin Mathieson*, *In re Kratz*, *In re Bergstrom* and other cases. To the extent these and other cases are not clearly inconsistent with recent Supreme Court decisions, they remain good law until the courts say otherwise, and it should not fall to the PTO to administratively abrogate them by giving them the "silent treatment." For example, even accepting that the Supreme Court has found patentable subject matter when there were "markedly different characteristics," this standard is not inconsistent with Judge Hand's "different in kind" concept in *Parke-Davis*. Likewise, the Fourth Circuit's focus on the strikingly advantageous properties of the claimed enriched vitamin B12 preparations in *Merck v. Olin Mathieson* is consistent with (and serves as an illustrative contrast to) *Myriad's* concern that the patentee in that case did "not create anything" that was sufficiently distinctive and newly useful. Lower court precedent should be deemed abrogated only to the extent it is *clearly inconsistent* with Supreme Court precedent. Moreover, the USPTO should take this opportunity to consider the Supreme Court's Tariff Act cases, *Hartranft* and *Anheuser-Busch*, which were relied on in its later subject matter eligibility decisions, for further elucidation of factors that qualify a manufactured article as a "manufacture" within the meaning of Section 101 of the Patent Act.

Closer reading of Supreme Court and other case law – Additional insight can be gleaned by a closer reading of those Supreme Court cases on which the USPTO has focused. We find that Supreme Court cases dealing with patentable subject matter are generally framed in broad conceptual brushes, but they are decided on the specific facts presented. We urge the USPTO to closely scrutinize the particular claims at issue in each precedential case, and where necessary analyze the record to appreciate the scope of the claimed subject matter considered by the Supreme Court. We believe that such an analysis will help the USPTO to more accurately put the Court's decisions in context and properly apply the concepts they set forth.

For example, at the September 17 BCP Forum, in response to comments about rejections for diagnostic claims and methods of treatment, USPTO staff suggested that the Office may view the claims in *Mayo* as "treatment claims." But in the text of the *Mayo* decision, the Court explicitly noted that the claims lacked a treatment step. *Mayo* at 1296.

Similarly, as support for the Guidance's discussion of gun powder and for rejections of multipart vaccine formulations, USPTO staff cited *Funk Bros*. But a look at the actual claims at issue in *Funk Bros*., paired with a faithful reading of the decision, reveals that the principle set forth in that case is not that combinations of naturally-occurring products are generally ineligible (or even that they are presumed ineligible absent some additional showing). The principle set forth in *Funk Bros*. (as reiterated and relied on in the *AMP* decision) was that a product of nature cannot be claimed simply by using claim limitations that define the claimed product by nothing other than its natural properties.[1] A flaw in the claim of *Funk Bros.* was the inability of being able to point to a meaningful advance such as modifications that make the

[1] Accord the "metal cases," which featured claims such as: "substantially pure tungsten having ductility and high tensile strength;" or "a form of vanadium which is ductile and homogeneous."

claimed bacterial aggregation "function in new ways" or "enlarge its range of utilities." These two examples illustrate opportunities where the USPTO could extract additional guidance through closer scrutiny of the claims at issue in each case, and by reading the language of the decision through the lens of the claims rather than – more dangerously - according to "what the Court really meant to say."

Use of "function" to demonstrate patent-eligibility – We are greatly intrigued by this concept and would much appreciate further clarification of what the USPTO means and how it expects such evidence is to be used in the analysis. To draw on the USPTO's amazonic acid example: would the applicant have to show that purifying amazonic acid gave it a biological activity that it doesn't have in nature? That may be difficult or impossible, because the applicant may have no clue what amazonic acid naturally does in the leaf. Moreover, sometimes the industrial usefulness of a claimed molecule is based on the very "function" it has in nature – like the new antibiotic composition, or the new substantially pure lignocellulase enzyme. Or does the USPTO mean by considering "function" that purifying amazonic acid allows skilled persons to formulate it into tablets, to administer it at a precise dose with a predictable pharmacokinetic and pharmacodynamic profile, and for the first time to treat human disease while avoiding side-effects, and that in this sense purifying it conferred a new "function" as disease-treating agent? We believe that this conclusion is supported in the case law (see above). Case law also supports the concept that even if a function is known for a natural substance, patent eligibility may be further buttressed by evidence that any "function" is enhanced by purification or enrichment, such as an IC_{50} that is greatly increased over raw preparations out of a bacterial fermentate, or the absence of impurities (specified or not) that would otherwise make cruder preparations unsuitable for human administration. Moreover, is evidence of "function" going to be a threshold matter or does the USPTO expect it to be applied mainly in rebuttal?

At any rate, we recommend that any "functional" distinctions of the claimed invention over the naturally-occurring thing not be used merely as evidence of structural differences, but rather as evidence that can be sufficient without more to support patentable distinctions over the natural product. The Revised Guidance should emphasize that even absent chemical modifications, purification or enrichment *can* give rise to preparations that are every bit as "distinctive" in "name, character, or use," having characteristics "markedly different" from the natural state, or demonstrating an "enlargement in the range of … utility." We recommend that the USPTO seek inspiration in the case law when developing additional examples to illustrate this point. Good fodder for such examples can be found in *Parke-Davis'* remarkable distinctions between purified adrenaline salt vs. the older medicinal powders of shriveled adrenal glands, or in the great advantages of enriched preparations of pure vitamin B12 which the *Merck* court contrasted to the disgusting earlier raw beef liver extracts that had, up to that time, been the only treatment for pernicious anemia. As in those cases, eligibility is not negated simply because the new, real-world usefulness of the claimed preparation depends in part on inherent, natural chemical properties of the natural compound. Such a

rule would exclude far too much because, as the courts have noted, everything operates according to natural laws.

On the use of claim interpretation – We urge the USPTO to ensure that examiners more clearly set forth their claim interpretation and define precisely what they regard as the judicial exclusion and how it is captured by the claim. The Revised Guidance should remind examiners that limitations such as "… and a *pharmaceutically acceptable* carrier"; "a *diagnostic* composition"; "a *treatment-effective* amount…"; "a *washing* liquor, comprising …"; "*diagnosing* a patient as having…" meaningfully limit the claim, have patentable significance, and cannot be discounted. We have seen instances where examiners, after cursory reference to a broadest reasonable claim interpretation, have improperly generalized claims and claim limitations in order to extract a law or product of nature out of an eligible product or process. In so doing, examiners read important limitations out of a claim and, once this is done, unsurprisingly argue that the resulting claim encompasses something that occurs naturally. For example: a natural antibiotic molecule that is secreted into moist soil by a fungus may be dissolved in environmental water, but this is a far cry from a purified antibiotic that is formulated in sterile, pyrogen-free injectable saline. Examiners should not treat both as just "antibiotic in water," but should instead give weight to the "pharmaceutically acceptable" limitation. Similarly, if a claimed diagnostic method requires a laboratory process having individual steps and instrumentalities that were known, but is limited to specific adaptations of those steps to apply a newly discovered law of nature, then the claim should not be deemed to merely recite a law of nature *per se* followed by instruction to "apply it." This is the case for both the laboratory reagents or instruments specified to be used in the process as well as the "informatic" and other analytical steps, e.g. the recitation of novel data manipulation steps which are used, in the context of the claim as a whole, to produce a diagnostic or prognostic score. In each case, the examiner should articulate her or his claim construction, taking care to give claim limitations their proper weight.

"Directed to" – The USPTO suggests that limiting its 101 analysis only to claims that are "directed to" (rather than "reciting" or "incorporating") a natural phenomenon will narrow the funnel for claims that are analyzed for patent eligible subject matter. However, as communicated the concept still seems to be very much in flux, and is poorly understood at least by the patent user community. As an initial matter, we are concerned about the risk that examiners will reach foregone conclusions that a claim is "directed to" a judicial exclusion simply by what they define that judicial exclusion to be. For example, in a claimed method comprising "administering a treatment-effective amount of substantially pure amazonic acid to a patient having breast cancer," the examiner may define the judicial exclusion as "the scientific fact that substantially pure amazonic acid happens to have anti-breast cancer activity." If so defined, the claim might easily be deemed "directed to" the judicial exclusion. If instead the judicial exclusion were defined simply as "amazonic acid," the outcome would likely be different. Accordingly, examiners should be required, as a first step, to define precisely what they regard as the applicable judicial exclusion and where it is recited in the claim. In doing so, the judicial exclusion must be defined narrowly.

The USPTO should also explore whether it can define circumstances under which it would be facially clear that a claim is not directed to a judicial exclusion. By analogy, ex-US jurisdictions have developed standard claim formats (such as Swiss-style and other use-limited composition claims) which ensure that patents for therapeutic drug-treatment methods do not encroach on a physician's ability to practice her or his art, and which therefore do not need to undergo a cumbersome examination for compliance with statutory exclusions of medical treatment methods. For present purposes, the recitation in the claim preamble of, for example, "a vaccine composition, comprising…" should be deemed on its face to be directed to just that: a vaccine composition. Not any conceivable composition. This is not to be confused with the recitation of so-called "magic words" or mere intended uses, because a vaccine composition is both structurally and functionally different from other conceivable compositions comprising the same molecule (as any person of skill in the art will appreciate), and thus represents both a meaningful limitation on claim scope and a specific practical application. The inquiry whether such a claim is directed to a judicial exclusion would thus be conducted against the backdrop of a presumption of eligibility (unlike under the current Guidance, which effectively triggers a presumption of ineligibility if a judicial exclusion is found to be present in the claim)

On the use of "preemption" - We also recommend that the USPTO not focus on "preemption" in defining when a claim is "directed to" a judicial exclusion. We believe that an inquiry that asks, as a condition of patentability, whether a claim forecloses others from accessing a judicial exclusion is not a reliable tool to determine patent-eligibility during examination. Such an inquiry would require examiners to think up alternative ways of practicing the invention, to speculate about whether skilled persons now or in the future would be able to access the natural thing, and to make judgment calls about how convenient or unencumbered such access must be. The only limit on such an exercise would be the examiner's own imagination. And in rebuttal, applicants would be put on record by having to draw non-infringing roadmaps that benefit only their competitors and no one else.

The case law identifies preemption only as (i) the policy underpinning of the Supreme Court's eligibility jurisprudence and (ii) at most as a confirmation whether an already arrived-at conclusion on eligibility conforms to that policy.[2] Accordingly, the need to make preemption or non-preemption findings should arise only in a

[2] *Mayo*, 132 S. Ct. at 1302 ("The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent."); *Alice Corp. v. CLS Bank Int'l*, slip op. at 13 ("This conclusion accords with the preemption concern that undergirds our §101 jurisprudence.").

subsidiary setting when special circumstances make it necessary to corroborate a decision that a claim is or is not "directed to" a judicial exclusion.[3]

A "unified analysis" - The USPTO should continue to be conscious of the different approaches the Supreme Court has taken when it explored the patent-eligibility of processes on the one hand, and compositions and articles on the other. *Alice* provides guidance as to how to analyze process claims based on abstract ideas. But, *Alice* set forth only "a" (not "the") framework for an eligibility analysis that was particularly suited for the kind of claimed subject matter at issue. Its mode of analysis does not necessarily apply in the same way to compositions or manufactures, which have their own line of case law. None of the cases dealing with compositions and manufactures - *Myriad, J.E.M. Ag-Supply, Chakarabrty, Funk Bros.* - has applied an "inventive concept/significantly more" analysis. The *Alice* opinion doesn't even mention these cases, with the exception of *Myriad,* which is only cited for generic older quotes therein. And, conversely, *Myriad* makes no mention of the "process" cases - *Benson*, *Flook*, *Diehr*, and *Bilski* - that feature so prominently in *Alice*. This distinction is both conspicuous and significant.

While it is true that some of the claims involved in *Alice* were formally drawn to computer-readable media and systems, the decision is by any reasonable reading a decision about process claims. The petitioner had conceded that its media claims stand and fall with the method claims. Moreover, unlike other technologies, the computer-implemented arts have long developed unique claiming practices under which process claims are commonly recast in the form of media or device claims that employ substantially the same language and are arguably coextensive in scope. Alice's system claims could thus be disposed of on the same grounds as its process claims: they were, in the Supreme Court's view, "no different in substance," i.e. they claimed the same ineligible process in a different guise.

The Supreme Court may have applied an "inventive concept" / "add enough" analysis when it discerned abstract ideas, laws of nature and natural phenomena in disembodied methods and processes. But when it encountered physical compositions and articles, it engaged in a less intrinsic, and more comparative analysis that queried whether the claimed thing has a "distinctive name, character or use" compared to the natural thing, has "markedly different characteristics," or enlarges its "range of utility." The Court's varied approaches in different cases underscore that inventions derived from nature may be patent-eligible for a variety of different reasons, depending on the claims and facts of a given case, and that there is no one-size-fits-all approach for satisfying section 101. In each of its cases, the Court's mode of analysis was informed by, and suited to, the particular claimed

[3] For example, if an applicant were to claim "a plastic, glass, or ceramic container containing an isolated nucleic acid of SEQ:ID 1 and a suitable solvent," the examiner may argue that it is impossible to make or use an isolated nucleic acid without a container and a solvent, so that such a claim, even though formally directed to a container, is for any conceivable purpose coextensive with a claim to the isolated nucleic acid itself and may be deemed "directed to" it. The burden would then be on the applicant to argue that the claim contains limitations that do not foreclose others from accessing the natural phenomenon.

subject matter at issue. For example, it is nonsensical to analyze a claim reciting an abstract idea by querying whether the claimed invention has "markedly different characteristics," has "enlargement of the range of … utility," or a "distinctive name, character, or use" relative to the underlying abstract idea or any other idea. Instead, such a claim is much more amenable to asking whether the inventor has done "more than simply stating [an] abstract idea while adding the words 'apply it.'" In the same vein, a claim to a modified bacterium is clearly more amenable to a "markedly different characteristics" or "enlargement of the range of … utility" analysis than it is to the question whether the claimed bacterium is an inventive "application" of a naturally-occurring one.

Even assuming that *Alice* (and the cases cited in *Alice*) can properly be understood to apply to compositions of matter, the Office must be aware that the Supreme Court has taken great pains to emphasize how its prior precedent on subject matter eligibility has always been fully consistent with its more recently-decided cases. Accordingly, if the Court indeed intends for *Mayo* and *Alice* to apply to compositions and manufactures, then the "inventive concept"[4] requirement that was "made explicit" in these two cases (*Alice*, at n. 3) must have been satisfied by the "markedly different characteristics" and "potential for significant utility" that were displayed by Chakrabarty's bacterium. Certainly, nothing in *Alice* suggests that highly relevant concepts such as "distinctive name, character or use," "markedly different characteristics," or "enlargement of the range of … utility," cannot or should not be a primary focus for composition and manufacture claims undergoing examination for patentable subject matter. Accordingly, the Revised Guidance should ensure that these important considerations are not, in practice, displaced or relegated to secondary status by examiners who may be encouraged to shoehorn composition or manufacture claims into a more intrinsic, and subjective, "inventive concept" analysis when doing so would not be appropriate for the particular claim at hand. A single analytical framework for all claim types, if the USPTO feels compelled to adopt one, would have to be sufficiently flexible to account for the Supreme Court's varied guidance on the different ways for finding claims eligible under its body of precedent.

[4] The Revised Guidance should also reiterate that the "inventive concept" approach, even when applied, does not mean that a claim must satisfy a "quasi-obviousness" analysis as a threshold inquiry under Section 101. Such an analysis would not only improperly render Section 103 redundant, but would make the "eligibility" inquiry a "moving target" that constantly changes with the evolution of science and technology, rather than a standard based on what exists in nature, as the judicial exception was intended to be. Such a reading of the "inventive concept" approach would plainly risk "eviscerating patent law," against the Supreme Court's repeated warnings.

We thank you in advance for your consideration of our comments, recommendations and questions. We believe that the matters raised above would benefit from further public dialogue with the USPTO before the Revised Guidance is finalized, and we look forward to working further with you on this difficult but critically important subject.

Respectfully submitted,

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