THE BOSTON PATENT LAW ASSOCIATION

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Via E-Mail: *2014_interim_guidance@uspto.gov*
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Re: Comments on 2014 Interim Guidance on Patent Subject Matter Eligibility ("Interim Guidance") in response to request for comments at 79 Fed. Reg. 74618 (Dec. 16, 2014)

Dear Sir:

The Boston Patent Law Association ("BPLA") thanks the United States Patent and Trademark Office ("USPTO") for the opportunity to comment on the USPTO's 2014 Interim Guidance on Patent Subject Matter Eligibility ("Interim Guidance"). The BPLA is an association of intellectual property professionals, providing educational programs and a forum for the exchange of ideas and information concerning patent, trademark, and copyright laws in the Boston area. These comments were prepared with the assistance of the Patent Office Practice Committee of the BPLA. The BPLA submits these comments solely as its consensus view. They are not necessarily the views of any individual member, any firm, or any client.

We appreciate the USPTO's efforts to further clarify patent examination related to claims directed to the three judicial exceptions to patent-eligible subject matter—laws of nature, natural phenomena, and abstract ideas. We commend the USPTO for taking a significant step forward with the Interim Guidance and the related Nature-Based Product Examples and Abstract Idea Examples (collectively, the "Examples"). We appreciate that the Interim Guidance addresses many of the issues that the BPLA raised in its July 28, 2014 comments to the March 4, 2014, Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products ("March 2014 Guidance").

We offer these comments on the Interim Guidance to assist the USPTO in its efforts to further hone the Guidance as a useful tool for examiners and practitioners. As the USPTO further refines its subject matter eligibility guidance, the Guidance should:

1. Focus the subject matter eligibility analysis on preemption, which is the underlying reason for the judicially-created exceptions;
2. Further clarify the criteria for a "streamlined eligibility analysis" that bypasses the full eligibility analysis;
3. Delineate the differences between the "markedly different" and "significantly more" analyses for nature-based claims;
4. Clarify the "inventive concept," particularly for computer-based claims;
5. Better define the "abstract idea" concept; and
6. Include further examples depicting additional types of claims and expanding on the claim sets in the current Examples.

I. SUBJECT MATTER ELIGIBILITY SHOULD BE ANALYZED THROUGH THE LENS OF PREEMPTION

As an initial matter, we recommend that the USPTO reconsider its Interim Guidance, and particularly the associated examples, through the lens of preemption, which is at the root of the judicially-created exceptions to the broad categories of patent-eligible subject matter under 35 U.S.C. § 101. The three judicial exceptions are not based on the statutory text or the extensive legislative history of the Patent Act of 1790, Patent Act of 1952, or subsequent reform acts. Rather, the judicial exceptions are grounded in the common law, reaching back to English common law, and represent a policy concern "against upholding patents that claim processes that too broadly preempt the use of" the excepted subject matter.[1]

The Supreme Court has "insist[ed] that a process that focuses upon the use of a [judicial exception] also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [judicial exception] itself."[2] Recognizing that the Court has not explicitly defined the terms "inventive concept" or "significantly more," the USPTO should interpret these constructs under the Court's overarching criterion: an element or a combination of elements reaches the level of "inventive concept" if its addition turns a preemptive claim into a non-preemptive claim. The Court has consistently applied this foundational principle by considering whether the claim in question preempts a law of nature, natural phenomenon, or abstract idea. In *Mayo*, for example, the Court concluded that "[t]he presence here of the basic underlying

[1] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___, 132 S.Ct. 1289, 1294 (2012); *see also Alice Corp. Pty. v. CLS Bank Int'l*, ___ U.S. ___, 134 S. Ct. 2347, 2354 (2014) ("We have described the concern that drives this exclusionary principle as one of pre-emption.").

[2] *Mayo*, 132 S.Ct. at 1294.

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."[3]

Conversely, when holding a claimed invention directed to eligible subject matter, the Court has done so because the claimed invention does not preempt the purported exception. In *Diamond v. Diehr*, for example, the Court upheld the claims as eligible because "[a]lthough [the patentees'] process employs a well-known mathematical equation, they do not seek to pre-empt the use of that equation, except in conjunction with all of the other steps in their claimed process."[4] Similarly, in *Research Corp. Techs., Inc. v. Microsoft Corp.*, the Federal Circuit upheld a claim as eligible because "the patentees here 'do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of 'halftoning in computer applications.'"[5]

Thus, the Guidance should convey, in all stages of the analysis, that preemption is the overarching criterion for determining subject matter ineligibility. The Court's cases repeatedly emphasize that preemption is both a necessary and sufficient condition for deeming a claim ineligible.

The Interim Guidance mentions preemption for the streamlined eligibility analysis but fails to emphasize the role of preemption in other sections of the analysis. As detailed below, ignoring the overarching principle and rigidly applying the Interim Guidance test risks driving examiners to miss the big picture, apply disparate clues as general rules, and end up rejecting eligible claims that do not preempt a judicial exception.

A more accurate analysis should look for lack of preemption at each stage of the analysis while considering the claim at different levels of detail, *i.e.*, starting from the coarse grained level for the streamlined analysis and ending at the fine grained level for the "significantly more" analysis. Therefore, we propose the following preemption-focused analysis, which modifies the Guidance's framework by adding the preemption-focused streamlined eligibility analysis step after the Interim Guidance's Step 1:

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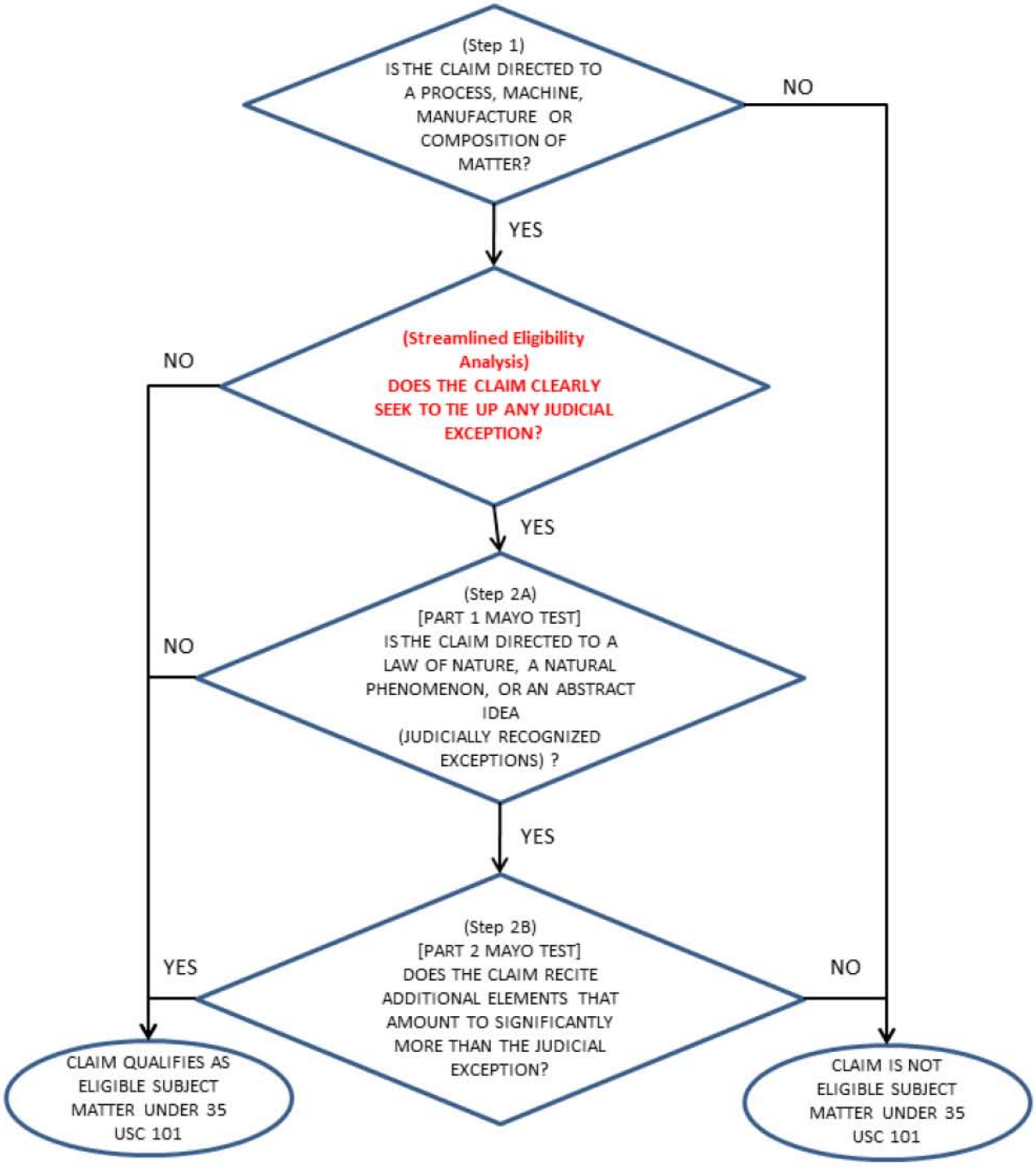
[3] *Id.* at 1302; *see also Alice*, 134 S.Ct. at 2358 (noting that the "pre-emption concern . . . undergirds our § 101 jurisprudence").

[4] 450 U.S. 175, 176 (1981).

[5] 627 F.3d 859, 869 (Fed. Cir. 2010).



The proposed streamlined eligibility analysis step is performed after determining in Step 1 whether the claim is to a process, machine, manufacture or composition of matter. The next question is to ask whether the claim clearly seeks to tie up any judicial exception. If no, then the claim qualifies as eligible subject matter under 35 U.S.C. 101. If yes, then the analysis would

proceed to the two-part analysis outlined in Step 2 of the Interim Guidance. The proposed flowchart including the streamlined eligibility analysis makes explicit what seems to be implied in the Interim Guidance, which states that "a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it."[6]

II. THE GUIDANCE SHOULD FURTHER CLARIFY THE CRITERIA FOR BYPASSING THE *MAYO* ANALYSIS AND ENTERING THE "STREAMLINED ELIGIBILITY ANALYSIS"

Streamlined eligibility analysis is available for claims that "clearly do not seek to tie up any judicial exceptions." The rationale behind this analysis is that such claims would not preempt others from using the alleged law of nature, natural phenomenon, or abstract idea. This analysis overlaps with the "as a whole" analysis discussed below in that it directs the examiner to determine if a claim is eligible for streamlined analysis based on an examination of the claim as a whole. The Interim Guidance states that "if there is doubt as to whether the applicant is effectively seeking coverage for a judicial exception itself, the full analysis [and not the streamlined analysis] should be conducted."[7] The USPTO provides this direction without defining the term "tie up" or specific criteria for determining whether an invention ties up a judicial exception. The lack of clear criteria for determining if a claim is eligible for streamlined eligibility analysis can make any such determination subjective and difficult.

The streamlined eligibility analysis examples in the Interim Guidance (Section I.B.3) are not helpful in any practical way because the examples are not close calls.[8] Two of the examples are a plastic chair with wood trim and an electrical contact made of gold. Wood and gold are generally products of nature; although the Interim Guidance does not indicate whether the particular wood or gold in the examples are "markedly different" from the natural product, the mere recitation of wood and gold should not subject them to the full subject matter eligibility analysis. While we understand that the Interim Guidance included these examples to provide a contrast with the March 2014 Guidance, we do not find them helpful in deciding whether to apply the streamlined eligibility analysis to less extreme real-life claims. The Nature-Based Product Examples and Abstract Idea Examples provide little additional guidance. For example, neither the Nature-Based Product Examples nor the Abstract Idea Examples mention the phrase "streamlined eligibility analysis." This lack of lucidity makes claim drafting challenging for patent practitioners and makes conducting the streamlined eligibility analysis difficult for examiners.

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[6] 79 Fed. Reg. at 74625.

[7] *Id.*

[8] *Id.*

On the other hand, the Nature-Based Product Examples include some instances in which streamlined eligibility analysis can be applied. As Example 3 notes, Claims 7 and 8 do not require "a full eligibility analysis . . . because the claims clearly do not seek to tie up all practical uses of the nature-based products."[9] The specific analysis of those claims, however, does not explicitly indicate that they are subject to a "streamlined eligibility analysis." The analysis of those claims could also be improved to indicate how the claims differ from the claims that the Supreme Court held to be directed to ineligible subject matter in *Mayo*. In addition to Claims 7 and 8 of Example 3, we suggest that at least the following Nature-Based Product Examples should be subject to the streamlined eligibility analysis: Claim 2 of Example 1, Claims 3 and 4 of Example 7, and Claim 5 of Example 9.

III. THE GUIDANCE SHOULD HIGHLIGHT THAT CLAIMS ARE ALWAYS CONSIDERED "AS A WHOLE"

In-line with the BPLA's prior comments to the March 2014 Guidance, the Interim Guidance improves the formulation at Step 2A of the process to ask whether the claim is "directed to" a judicial exception, as opposed to asking whether the claim "recites or involves" a judicial exception.[10] In the Interim Guidance's framework, the streamlined analysis and the analyses under Steps 2A and 2B depend on analyzing the claim "as a whole." Having a correct understanding of how the "as a whole" analysis applies to subject matter eligibility is important since this application affects the overall analysis of a claim. Thus, it is important for both patent examiners and patent practitioners to understand how this standard is to be applied with regard to subject matter eligibility.

As *Mayo* requires, the Interim Guidance instructs examiners to "determine whether the claim as a whole is directed to a judicial exception."[11] This formulation is an improvement over the March 2014 Guidance, which first asked whether the claim "recites" or "involves" such an exception. Despite this good start, however, the Interim Guidance seems to regress by collapsing "directed to" and "recites": "A claim is directed to a judicial exception when [a judicial exception] is recited (i.e., set forth or described) in the claim."[12] The implication of considering whether a claim "recites" a judicial exception seems to curtail a consideration of the claim "as a whole" because the analysis focuses on identifying any part of the claim that "set[s] forth or describe[s]" an abstract idea, law of nature, or natural phenomenon.

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[9] Nature-Based Product Examples at 3.

[10] 79 Fed. Reg. at 74619, n.2 (noting that the overall subject matter analysis has been revised based on "claims directed to judicial exceptions . . . rather than claims merely 'involving' an exception").

[11] 79 Fed. Reg. at 74622.

[12] *Id.*

The MPEP defines "as a whole" by citing *Diehr*. "In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process maybe patentable even though all the constituents of the combination were well known and in common use before the combination was made."[13] While this definition is helpful, the application of this definition in the context of the Interim Guidance's subject matter eligibility analysis needs to be clearer. For example, only a subset of the Examples specifically state that a claim is being analyzed "as a whole":

- In the Nature-Based Product Examples:
  - Example 1, Claim 2 – eligible claim directed to fireworks;
  - Example 3, Claims 7 and 8 – eligible claims directed to administration of amazonic acid as a treatment;
  - Example 9, Claim 4 – ineligible claim directed to a population of man-made cells in a container; and
  - Example 9, Claim 5 – eligible claim directed to a population of man-made cells in a biocompatible scaffold.
- In the Abstract Idea Examples:
  - Example 2 – eligible claims directed to web page outsource provider;
  - Example 3 – eligible claims directed to halftoning in digital imaging;
  - Example 4 – eligible claims directed to Global Positioning Systems (GPS); and
  - Example 8 – ineligible claims directed to use of copyrighted materials as currency for advertising.

Further iterations of the Guidance and related examples should include additional discussion that applies the "as a whole" analysis to more borderline situations. Applying the "as a whole" analysis to borderline situations will better define both claim drafting and claim examination. In other words, how much has to be added to a particular claim, either in number of elements, or types of elements, to turn an ineligible into an eligible claim, when the claim is analyzed "as a whole"? This question is important with regard to nature-based method claims, because the Interim Guidance and the Examples do not focus on nature-based method claims. As discussed below, particularly enlightening and helpful to patent examiners and patent practitioners would be examples of claims directed to a range of diagnostic, treatment, prognostic, or similar methods.

IV. THE DISTINCTION BETWEEN THE "MARKEDLY DIFFERENT" AND "SIGNIFICANTLY MORE" ANALYSES IS NOT DELINEATED

Generally, the USPTO has not clearly delineated the difference between the "markedly different" analysis and the "significantly more" analysis for nature-based claims. Only one

[13] 450 U.S.at 188-89; MPEP § 2103.

example in the Nature-Based Product Examples, Claim 5 of Example 9, includes an analysis in which the claim is deemed to be directed to a natural phenomenon (Step 2A: YES), but would qualify as eligible subject matter because it recites additional elements that amount to significantly more than the judicial exception (Step 2B: YES). We suggest that the USPTO present examples of additional sets of claims, wherein the claims fall into a continuum that spans both sides of patent eligibility and, in particular, shows the conditions in which a claim crosses the borderline from ineligibility to eligibility. We understand from the Interim Guidance that the USPTO plans to issue "[a]dditional explanatory example sets relating to claims that do and do not amount to significantly more than a judicial exception."[14] The BPLA welcomes such additional examples.

A. Further Examples Related to Purified Natural Products Will Promote Consistent Examination

Given the history of nature-based product claims and the narrow rule set forth in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*[15]—native DNA is not patent eligible and non-native cDNA is patent eligible, the USPTO should tread lightly when subjecting nature-based product claims to a subject matter eligibility analysis. In *Myriad*, the claimed patent ineligible DNA performs the function of encoding genetic information in its natural state. The claimed patent-eligible cDNA, on the other hand, performs a similar function but has a markedly different structure because it includes only the coding regions (exons). *Myriad* does not address purified natural products, including proteins, and there are long-standing reliance interests that would be affected if *Myriad* had changed the law to render unpatentable purified natural products with previously unproven functionality (*e.g.*, anti-cancer effects).

For instance, Example 3 of the Nature-Based Product Examples focuses on a purified natural product, amazonic acid, that the USPTO notes is structurally and functionally identical to the amazonic acid found in the leaves of the Amazonian cherry tree.[16] The Interim Guidance does not explain why the purified amazonic acid is not structurally and functionally different from the natural product in the leaves, which could cause confusion. First, structurally the natural product has presumably gone through a process that separates it from the other components of the Amazonian cherry tree leaves. Separation processes typically change the structure of the natural products obtained. In fact, Example 3 states that "[m]any have tried and failed to isolate the cancer-fighting chemical from the leaves,"[17] indicating the inventors here may have accomplished something different and inventive to obtain purified amazonic acid. Second, the Interim Guidance fails to note why the purified amazonic acid does not have different functional properties than the amazonic acid in the leaves. Natural products frequently

[14] 79 Fed. Reg. at 74619.

[15] ___ U.S. ___, 133 S.Ct. 2107 (2013).

[16] Nature-Based Product Examples at 3.

[17] *Id.*

have different functional properties when they are purified (*e.g.*, when they are >90% pure) because, *inter alia*, the natural product is not bioavailable in sufficient quantity to be used as a treatment in its natural state.

The Interim Guidance's analysis of Claim 1 in Example 3 specifically notes that the "limited background information" does not indicate that "purified amazonic acid has any characteristics (structural, functional, or otherwise) that are different from naturally occurring amazonic acid." We appreciate the USPTO's attempt to analogize purified natural products to the DNA at issue in *Myriad*, but purified natural products typically do have functional characteristics that are different from the corresponding naturally occurring compounds.

Therefore, in the natural product context, we recommend noting that similar claims would be patent eligible if the purified natural product had a function different from its natural function, which is true of many natural products and has historically provided the basis of industries, including the life sciences industry, which has conferred countless benefits on humanity.[18]

B. Further Examples Related to Pharmaceutical Compositions Comprising a Natural Product Would Promote Consistent Examination

In addition, the amazonic acid example (Example 3 of the Nature-Based Product Examples) could include a claim directed to purified amazonic acid in a pharmaceutically acceptable form, *e.g.*, including excipient(s) and/or adjuvant(s). Natural products are frequently provided in a pharmaceutical composition that can transform the purified natural product into a different composition with markedly different structural and functional characteristics. Claim 5 of the same example is helpful, but it includes multiple features of the pharmaceutical composition that, according to the background, appear to solve a problem particular to amazonic acid. Thus, the example as written could cause confusion regarding the eligibility of a claim directed to a purified natural product in a pharmaceutically acceptable composition. A claim that ties purified amazonic acid to a pharmaceutical composition can be markedly different from the natural product itself. That claim also would not preempt all uses of the natural product. Therefore, we recommend adding such an example.

V. THE GUIDANCE AND EXAMPLES SHOULD CLARIFY WAYS TO IDENTIFY THE INVENTIVE CONCEPT BY USING PREEMPTION AS ITS GUIDING PRINCIPLE

When discussing the search for the ever-elusive "inventive concept" required under Step 2B (*Mayo* test part 1), the Interim Guidance and the Examples provide either no guidelines or

[18] *See, e.g.*, *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103-104 (S.D.N.Y. 1911) (Hand, J.) (upholding patentability of purified adrenaline); *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 163-64 (4th Cir. 1958) (upholding patentability of purified vitamin B12).

incomplete guidelines. The Interim Guidance could remedy this shortcoming by recognizing the foundational preemption principle as the basis of the search.

In analyzing *Mayo*, for example, the Interim Guidance states that "any additional steps [in the claims at issue] consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."[19] Also, in analyzing *Alice*, the Interim Guidance states that "all of these computer functions [recited in the claims at issue] are 'well understood, routine, conventional activit[ies]' previously known to the industry. . . . Considered as an ordered combination, the computer components of the method add nothing that is not already present when the steps are considered separately."[20] Moreover, the Interim Guidance's analysis of *Alice* states that "[e]ach [additional] step does no more than require a generic computer to perform generic computer functions." In each case, the Interim Guidance follows these statements with the conclusion that the additional elements do not qualify as an "inventive concept," without explaining the connecting logic—they do not qualify because the additional elements do not cure the preemptive effect of the claims at issue in those cases. Missing this logic may create some falsely dispositive rules, *e.g.*, the rule that to qualify as inventive concepts, additional claim elements cannot be "routine," "well understood," or "generic computer functions," or that they should add something "significant beyond the sum of their parts taken separately." A potential rule, instead, is that the additional elements, whether or not they satisfy the above falsely dispositive rules, qualify as an inventive concept if they transform a preemptive claim into a non-preemptive claim.

Similarly, the analysis of *DDR Holdings, LLC v. Hotels.com, LP*[21] in the Interim Guidance does not include any logic for finding the "inventive concept." In *DDR*, the Federal Circuit found that the claims qualified as eligible subject matter.[22] To show a practical application of the Interim Guidance's framework, the Abstract Idea Examples applied the framework to *DDR*. In particular, Example 2 shows that the claims at issue would be eligible because the answer to Step 2A is NO.[23] The Abstract Idea Examples further observed that the Federal Circuit "went on to point out certain features of the claim that amount to an inventive concept."[24] To elaborate that inventive concept, however, the Abstract Idea Examples merely quoted the corresponding passage of the opinion. The quoted passage, however, simply lists a set of claim limitations without explaining which limitation, or combination of limitations, qualifies as an "inventive concept" or why. In fact, the Example misses a key section of *DDR*

[19] 79 Fed. Reg. at 74627.

[20] *Id.* at 74628.

[21] 773 F.3d 1245 (Fed. Cir. 2014).

[22] *Id.* at 1257-59.

[23] Abstract Idea Examples at 6.

[24] *Id.*

explaining that the claims recite additional limitations that qualify as an "inventive concept" because they prevent the claims from being preemptive:

> It is also clear that the claims at issue *do not attempt to preempt every application* of the [purported abstract ideas]. Rather, they recite a specific way to [implement a process]. As a result, the . . . claims [at issue] include "*additional features*" that ensure the claims are "more than a drafting effort designed to monopolize the [abstract idea]." . . . In short, the claimed solution amounts to an *inventive concept* for resolving this particular Internet-centric problem, rendering the claims patent-eligible.[25]

By missing this important criterion, the Interim Guidance fails to provide a complete explanation of its Step 2B.

VI. THE GUIDANCE AND EXAMPLES SHOULD CLARIFY WHAT IS AND IS NOT AN "ABSTRACT IDEA" UNDER THE CASE LAW

While recognizing that the courts have not provided a clear definition of "abstract idea," we recommend further developing the explanation in the Interim Guidance based on the examples in the case law. The Interim Guidance focuses on specific case law examples of abstract ideas, but it does not explain what an "abstract idea" is. We suggest further developing the Guidance's discussion of the four categories of abstract ideas recognized in the case law: "fundamental [and longstanding] economic practices, certain methods of organizing human activities, an idea of 'itself,' and mathematical relationships/formulas."[26]

For example, the USPTO has stated, based on *Bilski v. Kappos*, that fundamental economic practices are abstract ideas. In *Bilski*, however, the Supreme Court stated that the claims were directed to "a fundamental economic practice *long prevalent in our system of commerce*."[27] In *Alice*, the Court left off the latter clause in one place, but only after a lengthy discussion of *Bilski* noting that the "abstract idea" in that case, as in *Alice*, is a "building block of the modern economy,"[28] implying that the practices existed long before the patents.

We welcome the USPTO's including Examples 1 and 2 in the Abstract Idea Examples to demonstrate claims that are not directed to an abstract idea and, thus, qualify as eligible subject matter under Step 2A. The explanation of the claims, however, is not particularly useful as a practical matter because these claims are directed to inventions that differ from claims that the courts have found recite abstract ideas. Therefore, we recommend tying the analysis to the

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[25] *DDR Holdings*, at 1259 (emphases added).

[26] 79 Fed. Reg. at 74622.

[27] *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (emphasis added).

[28] *Alice*, 134 S.Ct. at 2356.

identified "abstract idea" categories by pointing out that those claims, viewed as a whole, are not ***directed to*** any of the following: a fundamental, longstanding economic practice; a method of organizing human activities; an idea of 'itself;' or a mathematical relationship or formula.

VII. MORE EXAMPLES FOR ADDITIONAL TYPES OF CLAIMS WILL PROMOTE CONSISTENT EXAMINATION

As the title implies, the Nature-Based Product Examples focus on the judicial exception for claims directed to natural phenomena. Only three claims of the nature-based product examples are directed to method claims, none of which inform the analysis applicable to claims under *Mayo*. As discussed above, we welcome the USPTO's implicit indication that claims directed to a method of treatment should be subject to a streamlined eligibility analysis, but we recommend that the USPTO include additional examples directed to the following types of claims.

- ***Diagnostic Claims***. The March 2014 Guidance included a number of claims directed to methods of detecting the presence of a nature-based product. We are pleased that the USPTO has superseded the analysis set forth in that Guidance, but we would appreciate further detailed analysis of claims like those set forth in Examples F and H. In redrafting those examples, we recommend that the USPTO further include a broader set of claims that illustrate the requirements of both Step 2A and Step 2B. In particular, the USPTO should include claims that are not, as a whole, directed to a judicial exception, recognizing that the relevant judicial exception in a diagnostic claim may be a natural product, a natural law, or an abstract idea.[29] Therefore, alternative analyses are warranted, wherein the same claim is analyzed based on each exception that applies to it.

- ***Personalized Medicine Claims***. Medicine is entering a new age in which therapies will be targeted to patient populations based on the underlying genetic basis of their disease. In parallel, many new therapies are being developed to genetically manipulate patients' cells, either *in vivo* or *ex vivo*. Therefore, it is important for the USPTO to provide guidance regarding the patentability of claims where a genetic trait, *e.g.*, a blood-borne marker or a gene associated with particular cancer cells, determines the patient's susceptibility to treatment.

- ***Pure Business Method Claims***. Regarding business method claims, practitioners have been asking for a clear answer to the question whether such a claim can be subject matter eligible even if it is a "pure" business method claim, for example, a business method claim that does not use any machine, such as a computer. A pure business method claim may recite a novel and specific way of doing some business.

[29] *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 762 (Fed. Cir. 2014).

It may, for example, recite a novel and a nonobvious method of combining disparate types of insurance or financial products to derive value for its users. Such a pure business method claim, therefore, may not fit the definition of a "fundamental economic practice long prevalent in our system of commerce," which the Supreme Court has categorized as an abstract idea.[30] The Supreme Court and the Federal Circuit have not given any clear answer. The Interim Guidance and the Abstract Idea Examples also do not shed any light on this issue, as they do not include any examples with such "pure" business method claims. The USPTO may be able to advance this discussion by disclosing some of the examples that it encounters during prosecution, and the manner in which examiners address this subject matter. These examples would clarify patent eligibility of pure business methods, and provide courts with potential guidance for their analysis.

VIII. CONCLUSION

The BPLA appreciates the opportunity to comment on the Interim Guidance. Thank you for considering our comments.

Sincerely,

Boston Patent Law Association

By: _____

Daniel A. Lev
Reza Sadr
David J. Wilson

[30] *Alice*, 134 S.Ct. at 2356.