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Legislative Consultant

Washington, DC

hayden.gregory@americanbar.org

AMERICAN BAR ASSOCIATION

July 30, 2014

Via e-mail: myriad-mayo_2014@uspto.gov

Michelle K. Lee

Deputy Undersecretary of Commerce and Deputy Director
of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Comments of the American Bar Association Section of Intellectual Property Law in Response to the USPTO's Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena & Natural Products

Dear Deputy Director Lee:

The American Bar Association Section of Intellectual Property Law (“IPL Section”) thanks the United States Patent and Trademark Office (“USPTO”) for the opportunity to comment on the USPTO’s Guidance for the examination of patent claims concerning laws of nature, natural phenomena, and natural products, entitled “2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products” (“Guidance”).¹ The views expressed herein are presented on behalf of the Section of Intellectual Property Law. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

The ABA is the leading national voluntary bar organization of the legal profession, having nearly 400,000 members. Its members come from each of the fifty states, the District of Columbia, and the U.S. territories. Membership includes attorneys in private practice, government service, corporate law departments, and public interest organizations, as well as legislators, law professors, law students, and non-lawyer associates in related fields. Particularly

¹ Memorandum from Andrew H. Hirschfeld, Deputy Comm’r for Patent Examination Policy, 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products (Mar. 4, 2014), available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

relevant to this case, the IPL Section is the world's largest organization of intellectual property professionals, with approximately 25,000 members.

The IPL Section appreciates the USPTO's efforts to further improve the examination of claims concerning laws of nature, natural phenomena, and natural products in view of the Supreme Court's recent patentable subject matter decisions. The Section appreciates the USPTO's invitation for public comment regarding the Guidance. Further, the Section appreciates the associated "Training Slides," dated March 19, 2014. The IPL Section suggests that there are issues that should be addressed to enhance the effectiveness of the 2014 Guidelines. The USPTO has requested the public's comments on the impact of the Supreme Court decisions on the analysis of subject matter eligibility during patent examination.² The USPTO further requested alternative approaches for implementation of the decisions to those taken by the USPTO and additional examples "for use by the Office to create a more complete picture of the impact of Supreme Court precedent on subject matter eligibility." We offer the comments below in response to the USPTO's request, in an attempt to assist the USPTO in these efforts.

I. THE USPTO'S GUIDANCE REFLECTS AN OVERLY BROAD APPLICATION OF THE SUPREME COURT CASES REGARDING PATENTABLE SUBJECT MATTER

In *Alice Corp. v. CLS Bank*, No. 13-298, slip op. (S. Ct. June 19, 2014), the Court cautioned against applying the exceptions under Section 101 too broadly, because at some level, all inventions "embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.* at 6. The Court noted that the concern underlying these judicially created exceptions is "pre-emption," i.e., patents that cover laws of nature, natural phenomena, or abstract ideas may preempt fields of innovation, thereby impeding rather than furthering the Constitutional mandate to "promote the Progress of Science and useful Arts." *Id.* (quoting U.S. Const., art. 1 § 8, cl. 8). Over application of Section 101 will likewise impede the Constitutional mandate to "promote the Progress of Science and useful Arts," by leading companies away from certain areas of technology relating to, for example, natural products, and/or leading companies to keep such work as trade secrets and not sharing such technology with the public.

Further, Section 101 needs to be applied in the overall context of the statute because it plainly is not the only section to govern patentability. Title 35 provides separate and distinct sections for determining the types of inventions that are (a) patent eligible (Section 101); (b) novel—a condition for patentability (Section 102); (c) non-obvious subject matter—another condition for patentability (Section 103); and (d) required conditions for obtaining a valid patent (Section 112). Each of these requirements is laid out separately and distinctly in the patent law. No section cross-references another section by stating that conditions for the cross-referenced section must also be met in order to meet the conditions of that particular section. Instead, the

² See, "Notice of Forum on the Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products," Federal Register, 79(74):21736-21738 (April 17, 2014).

requirements are described as individual, non-dependent requirements, all of which must be met to obtain a valid patent.

The Guidance issued by the USPTO provides a much broader application of analysis for subject matter eligibility than what is dictated by recent Supreme Court cases. Under the Guidance, any claim “reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products” must be examined using the guidance. This approach goes far beyond what is required by the case law, sweeping too many types of claims into the detailed Section 101 analysis, particularly those that merely “involve” natural products. Second, the USPTO’s Guidance is overly broad because it conflates the analysis of Section 101 with other separate requirements for patentability under the statute. Finally, as described below, the Guidance should also apply *Myriad* and *Mayo* in the proper context and thus consistent with the International treaty obligations of the United States, particularly the Agreement on Trade–Related Aspects of Intellectual Property Rights (“TRIPs”) which also define inventions eligible for patent protection and exclusion thereof.³

A. Broad Application of the Guidance Prohibiting Classes of Inventions Is Not In Accordance with the Statute or Supreme Court Cases

For manufactures or compositions of matter, the proper rule fashioned by the Court is a straightforward test of patent-eligibility: any such invention must demonstrate the "hand of man," something that is “a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980) (“*Chakrabarty*”), citing *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887). Broad applications of categorical prohibitions for classes of inventions runs contrary to both prior precedent and the plain language of the statute (as recognized by the Court in *Chakrabarty* that “in choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope”). The Court also discerned Congress’s intent from legislative history, extending from the first Patent Act (Act of Feb. 21, 1793, § 1, 1 Stat. 319) through the 1952 Act, which contained the famous quotation that patent eligibility should extend to “‘include anything under the sun that is made by man,’ S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).” Indeed, the categories the Court has recognized are limited, to “[t]he laws of nature, physical phenomena, and abstract ideas,” rather diffuse categories that are intended to work at the margins for inventions claimed so broadly as to encompass, for example, a composition of matter as it is found in nature, unchanged in any way by man. But the Court clearly intended these to be the exception rather than the rule. And, the Court stated, should anyone believe these limitations were not sufficient to promote progress in the useful arts, their remedy was with Congress, which has the power to make these decisions:

We have emphasized in the recent past that “[our] individual appraisal of the wisdom or unwisdom of a particular [legislative] course . . . is to be put aside in

³ Agreement on Trade–Related Aspects of Intellectual Property Rights (“TRIPs”), see generally Uruguay Round Agreements Act, Pub.L. No. 103–465, 108 Stat. 4809 (1994) (codified as amended at scattered sections of the United States Code).

the process of interpreting a statute.” *TVA v. Hill*, 437 U.S., at 194. Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Cf. 42 U. S. C. § 2181 (a), exempting from patent protection inventions “useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.” Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent’s invention.⁴

Chakrabarty, 447 U.S. at 318.

In addition to these jurisprudential considerations, the effectiveness of using the substantive sections of the Patent Act can be appreciated by reviewing how the Court *has* done so. For example, in the *Wood-Paper Patent Cases*, 90 U.S. 566 (1874), claims for the product of a method for making paper from wood pulp, which product comprised substantially purified cellulose, were invalidated because the claims inherently encompassed compounds in the prior art that could not be made patentable merely by isolating them. Specifically in this regard, the Court said:

It [the isolated cellulose] may have been in existence and in common use *before* the new means of obtaining it was invented, and possibly *before* it was known that it could be extracted from the subject to which the new process is applied. . . . If, then, the Watt & Burgess patent for a product is sustainable it must be because the product claimed, namely, “a pulp suitable for the manufacture of paper, made from wood or other vegetable substances,” was unknown prior to their alleged invention. But we think it is shown satisfactorily that it had been produced and used in the manufacture of paper long before 1853, the year in which the original patent of Watt & Burgess was dated.

Id. (emphasis added).

The Court’s concern was the traditional concern that a patentee not be permitted to withdraw from the public domain subject matter that had been previously freely available for

⁴ These considerations are not a thing of the past; indeed, the Court has recently enunciated similar sentiments in its appreciation of its role, in *Nat’l. Fed. Indep. Bus. v. Sebelius*, 132 S.Ct. 2566 (2012):

Our permissive reading of these powers is explained in part by a general reticence to invalidate the acts of the Nation’s elected leaders. “Proper respect for a co-ordinate branch of the government” requires that we strike down an Act of Congress only if “the lack of constitutional authority to pass [the] act in question is clearly demonstrated.” *United States v. Harris*, 106 U. S. 629, 635 (1883). Members of this Court are vested with the authority to interpret the law; we possess neither the expertise nor the prerogative to make policy judgments. Those decisions are entrusted to our Nation’s elected leaders, who can be thrown out of office if the people disagree with them. It is not our job to protect the people from the consequences of their political choices.

public use. The Court did not choose (and it was not necessary) to define categories of subject matter that are *per se* patent-ineligible.⁵

The same infirmities arose in the patents at issue in *Cochrane v. Badische Anilin Soda Fabrik*, 111 U.S. 293 (1884). The patents at issue in that case involved methods for preparing a dye, alizarine, and the product of such methods (termed “artificial alizarine” by the patentees). The Court said it was plain, from the patent specification itself, that what the disclosed process produced was “alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine.” *Id.* at 308. The Court found that claims to “artificial alizarine” were not patentable, not because the claimed product was isolated or a “product of nature,” but because what was claimed was something that was already known:

According to the description in [the patents in suit], and the evidence, the article produced by the process described was the alizarine of madder, having the chemical formula $C_{14}H_8O_4$. It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction to being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially, for the first time, from anthracine, if it was set forth as alizarine, a well-known substance. *Wood Paper Patent*, 90 U.S. at 593. There was therefore no foundation for reissue No. 4,321, for the product, because, on the description given, no patent for the product could have been taken out originally.

Id.

It is clear that the Court once again expressed its traditional concern that a patentee not be permitted to use a process for making a known article to remove that article from the public domain.⁶ Nowhere in the opinion does the Court indicate that the product claims are insufficient because they encompass patent-ineligible subject matter categorically. The Court clearly took the more prudent route of applying substantive patent law regarding the lack of novelty of the synthetic alizarine rather than creating a categorical exclusion of the naturally occurring dye.

Even the *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) case, properly appreciated, illustrates that the Court’s concerns in this regard were not to render certain types of inventions categorically patent ineligible. In the *Funk Brothers* case, the Court held unpatentable an article of manufacture comprising a mixture of two types of nitrogen-fixing

⁵ Indeed, the Court expressly declined to decide whether purification could convert a compound present in an impure state into a patent-eligible purified compound as the product of a process:

It is insisted, however, that the paper pulp which had been produced before the invention of Watt & Burgess was not pure cellulose, that it was only approximately pure, and from this it is argued that the pure article obtained from wood by their process is a different and new product, or manufacture. Whether a *slight* difference in the degree of purity of an article produced by several processes justifies denominating the products different manufactures, so that different patents may be obtained for each, may well be doubted, and *it is not necessary to decide*. *Id.* at 594 (emphasis added).

⁶ Indeed, the Court cited the *Wood Paper Patent Cases* for this proposition.

bacteria, in a context where the bacteria were known in the art, and also known to fall into six well-defined groups that could not be cultivated together.⁷ The Court said that it had "long been well known" to produce cultures of these bacteria in the laboratory and provide farmers with such cultures for inoculating leguminous plant seeds, and also that the properties of the different bacterial species, their capacity to infect different plants, and their growth inhibition were known in the art. Under these circumstances, the Court held that claims to the co-cultures were unpatentable:

For patents cannot issue for the discovery of the phenomena of nature. *See Le Roy v. Tatham*, 55 U.S. 156, 175 (1852). The *qualities* of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown *phenomenon of nature* has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

Funk Brothers, 333 U.S. at 130 (citations omitted; emphasis in original).

The meaning and consequences of the *Funk Brothers* decision, and a clearer understanding of the relevance of this decision to this court's consideration of the case at bar, can be gleaned from Justice Frankfurter's concurring opinion. Justice Frankfurter sheds useful light on the decision: first, that such co-cultured mixtures had been prepared before in the art, meeting with "indifferent success," and second, that the claims were not limited to the specific combinations of strains to be mixed, but encompassed all mixtures:

Insofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention and as such patentable, I agree, provided not only that a new and useful property results from their combination, but also that the particular strains are identifiable and adequately identified. I do not find that Bond's combination of strains satisfies these requirements. The strains by which Bond secured compatibility are not identified and are identifiable only by their compatibility . . . [The patentee] appears to claim that since he was the originator of the idea that there might be mutually compatible strains and had practically demonstrated that some such strains exist, everyone else is forbidden to use a combination of strains whether they are or are not identical with the combinations that Bond selected and packaged together. It was this claim that, as I understand it, the District Court found not to be patentable, but which, if valid, had been infringed . . . The consequences of such a conclusion call for its rejection. Its

⁷ Because they exhibited growth inhibition when grown in mixed culture; Claim 4 illustrates the claims of the patent-in-suit, U.S. Patent No. 2,200,532:

4. An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific. *Funk Brothers Seed Co.*, 333 U.S. at 128 n.1

acceptance would require, for instance in the field of alloys, that if one discovered a particular mixture of metals, which when alloyed had some particular desirable properties, he could patent not merely this particular mixture but the idea of alloying metals for this purpose, and thus exclude everyone else from contriving some other combination of metals which, when alloyed, had the same desirable properties. In patenting an alloy, I assume that both the qualities of the product and its specific composition would need to be specified. The strains that Bond put together in the product which he patented can be specified only by the properties of the mixture.

Id. at 133-34.

These considerations complement the statements in the majority opinion, with which Justice Frankfurter concurred, and show that the Court's concern was not categorically precluding from patenting a "product of nature" *per se* but rather a patent claim that encompassed *any* combination of bacterial species exhibiting a particular biological property. It was the abstract application of the phenomenon of nature rather than the specific application that troubled the court and led to the invalidity of the patent.

B. *Myriad* Should Be Limited to its Facts And Each Substantive Provision of the Patent Act Should Be Separately Considered

The *Myriad* Court was careful to limit its decision to the nucleic acids before it, and held that there was insufficient evidence that the isolated chromosomal DNA evinced sufficient evidence of "the hand of man" because it was not sufficiently changed from its state in nature. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107 (2013)) ("*Myriad*"). This purported lack of change was based on the Court's assessment that the nature of isolated DNA resided in its sequence, crediting the argument that DNA as an informational molecule was identical in its chromosomal as in its isolated state. For the same reasons the Court held cDNA patent-eligible because it had a different sequence (insofar as introns contained in the chromosomal sequence had been spliced out of the mRNA from which the cDNA was synthesized by man). These considerations are inherently limited to DNA and do not amount to a proclamation by the Court that Section 101 categorically precludes patentability merely because a compound is derived from a natural source.⁸

⁸ Similar considerations with regard to categorical exclusions from patent eligibility under the 1952 Act have been voiced in other fora. *See, as an example, Merck & Co. v Olin Mathieson Chemical Corp.*, 253 F.2d 156, 161-162 (4th Cir. 1958):

The Patent Act of 1952 (35 U.S.C.A. § 101), as its predecessors, authorizes a patent for 'any new and useful... composition of matter...' provided only that the conditions for patentability, which are specified in *succeeding sections*, are met. There is nothing in the language of the Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability. All of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials.

A similar assessment of the proper role of the substantive provisions of the Patent Act (Sections 102, 103, and 112) applies to claims to methods, despite recent unsettling of the law by dicta provided in the Court's opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 123 S. Ct 1289 (2012). In *Mayo*, the Supreme Court provided additional commentary relating to "further arguments in support of Prometheus' position" which did not contribute to the holding of the case. *Mayo*, 132 S. Ct. at 1302-05. However, this commentary and its relation to the patent eligibility analysis in the case has led to much discourse among patent practitioners regarding the conflation of Section 101 with other sections of the patent law, particularly Sections 102, 103, and 112. In view of these unsettling statements by the Court, the process for analysis of patent eligible subject matter under Section 101 needs to be clarified.

The distinction between Section 101 and the substantive provisions of the Patent Act has been noted in court precedent as well.

The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy "the conditions and requirements of this title." § 101. Those requirements include that the invention be novel, *see* § 102, nonobvious, *see* § 103, and fully and particularly described, *see* § 112.

Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010). This "threshold test" argument was submitted by the U.S. Government as *amicus curiae* in *Mayo*, saying that "virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101's demands." *Mayo*, 132 S. Ct. at 1303. Once the minimum requirements for patent eligibility have been met, the other conditions for obtaining a valid patent required by Sections 102, 103 and 112 may be adequately used to determine patentability and validity.

The *Mayo* court responded to the Government's threshold test argument, saying:

We recognize that, in evaluating the significance of additional steps, the § 101 patent eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry

A product of nature which is not a 'new and useful... machine, manufacture, or composition of matter' is not patentable, for it is not within the statutory definition of those things which may be patented. Even though it be a new and useful composition of matter it still may be unpatentable if the subject matter as a whole was obvious within the meaning of Section 103 (35 U.S.C.A. 103), or if other conditions of patentability are not satisfied.

In dealing with such considerations, unpatentable products have been frequently characterized as 'products of nature.' See *Funk Brothers*, 333 U.S. 127 (a composite culture of noninhibitive strains of different, but known, species of bacteria); *In re Marden*, 47 F.2d 957, 18 C.C.P.A., Patents, 1046 (uranium); *In re Marden*, 47 F.2d 958, 18 C.C.P.A., Patents, 1057 (ductile vanadium); *General Electric Co. v. DeForest Radio Co.*, 28 F.2d 641 (3d Cir. 1928) (tungsten). But where the requirements of the Act are met, patents upon products of nature are granted and their validity sustained.

entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

Id. at 1304. This dicta in *Mayo* has disrupted well-settled precedent, which states:

It has been urged that novelty is an appropriate consideration under § 101. Presumably, this argument results from the language in § 101 referring to any “new and useful” process, machine, etc. Section 101, however, is a general statement of the type of subject matter that is eligible for patent protection “subject to the conditions and requirements of this title.” Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty. The question therefore of whether a particular invention is novel is “wholly apart from whether the invention falls into a category of statutory subject matter.” *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979) (emphasis deleted). *See also Nickola v. Peterson*, 580 F.2d 898 (6th Cir. 1978). The legislative history of the 1952 Patent Act is in accord with this reasoning. The Senate Report stated:

Section 101 sets forth the subject matter that can be patented, ‘subject to the conditions and requirements of this title.’ The conditions under which a patent may be obtained follow, and Section 102 covers the conditions relating to novelty.”

S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) (emphasis added). It is later stated in the same Report: “Section 102, in general, may be said to describe the statutory novelty required for patentability, and includes, in effect, an amplification and definition of ‘new’ in section 101.” *Id.* at 6.

Finally, it is stated in the “Revision Notes”: “The corresponding section of [the] existing statute is split into two sections, section 101 relating to the subject matter for which patents may be obtained, and section 102 defining statutory novelty and stating other conditions for patentability.” *Id.* at 17.

In this case, it may later be determined that the respondents’ process is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or nonobviousness under § 103. A rejection on either of these grounds does not affect the determination that respondents’ claims recited subject matter which was eligible for patent protection under § 101.

Diamond v. Diehr, 450 U.S. 175, 190-91 (1981). The Court’s *Mayo* decision did not overrule *Diehr*, and if and when the Court wishes to do so it will be able to enunciate its reasoning more clearly than the dicta contained in the *Mayo* decision. Until then, based on Supreme Court precedent and legislative history, clearly, the different sections of Title 35 are separate and distinct requirements. Contrary to the dicta in *Mayo*, the analysis of patent eligibility for subject matter of a claimed invention under Section 101 should not overlap with the analyses of patentability under Sections 102 and 103, or the requirements for obtaining a valid patent under

Section 112. To conflate any one of these requirements with another would violate the principle of *stare decisis* and frustrate the legislative intent of the Patent Act.

Because Sections 101, 102, 103, and 112 are separate and distinct inquiries which should be resolved independently from one another, any formulation of a patent eligibility test under Section 101 that imports into the patent eligibility analysis the criteria or analysis for determining patentability addressed by Sections 102 and 103, as well as the criteria required for obtaining a valid patent under Section 112, is improper.

II. SUPREME COURT PRECEDENT SHOULD BE READ AND APPLIED THROUGH THE GUIDANCE CONSISTENTLY WITH THE OBLIGATIONS OF THE UNITED STATES UNDER TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS).

The Guidance should also apply *Myriad* and *Mayo* not only in the proper context of the remainder of the patent statute, but also in the context of the International treaty obligations of the United States, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights. The ABA IPL takes no position on whether the application of the Guidance will lead to inventions being denied patent eligibility in violation of TRIPS. But, as written the Guidance and the exclusions for patent eligibility under TRIPS do not appear to be consistent and could lead to such allegations when inventions are denied patent eligibility under the Guidance. Further, the United States should remain a strong advocate of IP rights globally and should ensure that the USPTO Guidance is applied consistently with the letter and principles embodied in TRIPS.

TRIPS provides defines subject matter eligible for patenting in Article 27, which reads as follows:

1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.⁹

Notably, TRIPS is obligatory to member states to provide patent protection in its use of the phrase “shall be available.” Further, TRIPS provides specific exclusions from patentability as follows:

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect

⁹ 33 I.L.M. 81 (1994), 93-94, 1994 WL 327459.

ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.¹⁰

Accordingly, TRIPS provides broad criteria for patent eligibility, namely “any inventions, whether products or processes, in all fields of technology” with specific exclusions as defined by Article 27(3). Historically, laws of nature, abstract ideas, and physical phenomena were accepted as being excluded from Article 27 because laws of nature and physical phenomena were a mere discovery and abstract ideas lacked the specificity of an invention. That is, the product of nature was not an invention made by man under U.S. parlance in *Chakrabarty* or “not having a technical effect” in EPO parlance. A narrow reading of *Myriad* and *Mayo* can be reconciled with this. However, a broad reading cannot. Arguably, the standard dictated by TRIPS is that the claimed invention must merely be “distinguished” in a non-trivial way from the natural product or process so as to give a new technical effort or to reflect the hand of man. Therefore, the USPTO in its Guidance should not put undue weight on the word “significant” when assessing the differences between what occurs in nature and the claim.

The United States and specifically the USPTO should remain a strong advocate for TRIPS. The U.S. would not take lightly a member state carving out certain technology from the patent eligibility requirements of Article 27, and therefore the USPTO should reflect carefully on whether the Guidance as written will result in an invention or a category of inventions being declared ineligible for patent protection inconsistently with the letter and principles of TRIPS. The IPL Section respectfully submits that it remains important that the USPTO continues to lead by example in following the letter and principles embodied in TRIPS and narrowly apply *Myriad* and *Mayo* to do so.

¹⁰ *Id.*

III. THE USPTO’S ARTICULATED STANDARD FOR PATENT ELIGIBILITY OF CLAIMS “RECITING OR INVOLVING” A JUDICIAL EXCEPTION IS FLAWED AND IS NOT SUPPORTED BY SUPREME COURT DECISIONS

A. “Significantly Different” Should Mean Different From What Occurs In Nature

As the Congressional Committee Reports accompanying the 1952 Patent Act inform us, Congress intended statutory subject matter to be broadly interpreted and “include anything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), citing S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) and H.R. Rep. No 1923, 82d Cong., 2d Sess., 6 (1952).

The IPL Section notes that the USPTO’s Guidance undermines this Congressional intent and misinterprets U.S. Supreme Court precedent on patent eligibility by requiring a marked or significant difference from what occurs in nature – even after it has been established that the claimed subject matter does not, in fact, exist in nature. The IPL Section recommends that the USPTO revise its Guidance by instructing examiners to analyze patent eligibility of a composition, combination, application, or manufacture based only on whether it can be distinguished from a judicial exception, and not by requiring Examiners to apply the poorly defined, arbitrarily applied, standard of “marked,” or “significant difference.”¹¹

1. “Significantly different” is not a standard imposed by the Supreme Court

The USPTO’s imposition of a requirement of “significantly different” or “markedly different” is the pivotal feature of its patent eligibility analysis. The USPTO’s Guidance states:

Myriad relied on *Chakrabarty* as “central” to the eligibility inquiry, and reaffirmed the Office’s reliance on *Chakrabarty*’s criterion for eligibility of natural produces (i.e., whether the claimed product is a non-naturally occurring product of human ingenuity that is markedly different from naturally occurring products).

Guidance at 1, citing *Chakrabarty*, 447 U.S. 303 (1980) (emphasis added). However, neither *Myriad* nor *Chakrabarty* impose a standard requiring that non-naturally occurring subject matter must be “significantly different” from what occurs in nature to be patent eligible.

The only question before the *Chakrabarty* Court was whether a living organism is excluded under 35 U.S.C. §101 from patent eligibility.

¹¹ *Alice Corp.* emphasized that a claim must be directed to something “significantly more” than an abstract idea itself in order to be a patent-eligible invention. *Alice Corp.*, slip op. at 6. The Guidance’s requirement of a “significant difference” for claims reciting or involving a natural product is not the same as or consistent with an analysis of “significantly more” in connection with an abstract idea. Even if it is the same, a “significantly more” standard should be satisfied if the subject matter that has a distinctive name, character, or use, or a new form, quality, or property, as discussed in detail herein.

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101 Specifically, we must determine whether respondent’s micro-organism constitutes a “manufacture” or “composition of matter” within the meaning of the statute.

Chakrabarty, 447 U.S. at 307 (emphasis added). The appealed rejection from the patent examiner rested on two grounds: (1) whether the microorganism was a product of nature, and (2) whether as living things, microorganisms are not patentable subject matter. *Id.* at 306. The Patent Office Board of Appeals found that Chakrabarty’s bacteria was not a product of nature but affirmed the second ground of rejection. *Id.* Thus, the issue of whether or not Chakrabarty’s bacteria was sufficiently distinct from a product of nature to render it patent eligible was not before the Court. The only question it addressed was whether or not a living organism could constitute a manufacture or composition of matter, i.e., whether the organism reflected the hand of man.

The *Chakrabarty* Court used the term “markedly different” only once, in distinguishing the holding of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948):

Here, by contrast, the patentee produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.

Chakrabarty, 447 U.S. at 310. This statement, without more, provides no basis for the USPTO’s unshakable conclusion that the *Chakrabarty* Court articulated a threshold “criterion” that must be met to establish patent eligibility. It is equally, if not more, reasonable to conclude that the Court was merely emphasizing a fact relevant to Chakrabarty’s invention.

The USPTO cites to pages 2116-2117 of the *Myriad* decision in support of its statement in the Guidance that “*Myriad* relied on *Chakrabarty* as ‘central’ to the eligibility inquiry.” Guidance at 1. In fact, what the *Myriad* decision says is that “*Myriad* [the party] recognizes that our decision in *Chakrabarty* is central to this inquiry.” This is a different statement altogether and not one that clearly indicates that the Court did actually rely on *Chakrabarty* as central to the inquiry. *Myriad*, 133 S. Ct. at 2116. But even if the *Myriad* Court did consider *Chakrabarty* central to the patent eligibility inquiry, nothing in the *Myriad* decision can be construed as setting a requirement of “significant difference.”

This is evident from the Court’s discussion of the patent eligibility of cDNA, which stated that “cDNA is not a product of nature and is [thus] patent eligible under § 101.” *Id.* at 2119. The *Myriad* Court does not analyze the distinctions between cDNA and naturally occurring DNA to determine whether the differences are “significant” or marked. The Court simply states that cDNA is not a product of nature, i.e., it is “different” from what exists in nature and thus is patentable. Whether a composition, combination, application, or manufacture is “different” from what exists in nature is the only standard for patent eligibility that the USPTO should be instructing its examiners to apply.

2. Subject matter should be patent eligible if it is different from nature in character, use, or possesses a new form, quality, or property

If the USPTO is unwilling to drop the improperly imposed requirement for “significant difference,” the Guidance should make clear that a significant difference is present if the claimed subject matter is different from nature in character, or use (*Hartranft, Chakrabarty, Myriad*) or a new form, quality, or property (*American Fruit, Chakrabarty*), as compared to what exists in nature.

The Supreme Court stated in *Chakrabarty* that

[Chakrabarty’s] claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity “having a distinctive name, character [and] use.” *Hartranft v. Wiegmann*, 121 U.S. 609, 615, 7 S.Ct. 1240, 1243, 30 L.Ed. 1012 (1887).

Chakrabarty, 447 U.S. at 306. *Hartranft* is a tariff case that addressed whether certain imported shells were articles of manufacture. The shells had been treated with acid to remove an outer layer and then polished. The *Hartranft* Court held that the shells “had not been manufactured into a new and different article, having a distinctive name, character, or use,” suggesting that a distinction in any one would be sufficient to render the subject matter an article of manufacture. *Hartranft*, 121 U.S. at 615 (emphasis added). The change in the *Hartranft* quote made by the *Chakrabarty* Court (“or” to “and”) again emphasizes the facts in that case, i.e., that Chakrabarty’s invention possessed all three distinctions. Nor does *Chakrabarty* in any way imply that a functional distinction alone is not sufficient to establish a difference from what exists in nature. This interpretation of the *Chakrabarty* Court’s meaning is supported by its statement:

[T]his Court has read the term “manufacture” in §101 in accordance with its dictionary definition to mean “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.” *American Fruit Growers, Inc. v. Grogdex Co.* 283 U.S. 1 ... (1931).

Chakrabarty, 447 U.S. at 308 (emphasis added).

IV. THE CLAIMS AS A WHOLE, INCLUDING BOTH STRUCTURE AND FUNCTION MUST BE ASSESSED IN DETERMINING DISTINCTIONS FROM JUDICIAL EXCEPTIONS

The analysis in the Guidance’s regarding the standard for patent eligibility is also flawed and unsupported by Supreme Court precedent because of the insistence that any “significant difference” must include a structural component. Thus, despite stating that patent eligibility should be determined based on the claim as a whole, the analysis in the Guidance makes clear that critical distinctions between the claim as a whole and the judicial exception (e.g., functional distinctions) will be ignored absent a tandem structural distinction.

A. The Guidance Should Recognize that Functional Distinctions, Without a Corresponding Structural Difference Can Establish Patent Eligibility

As one example of the USPTO’s failure to give sufficient weight to all elements of a claim, consider Example D (Composition Reciting Multiple Natural Products).

As the Guidance states, the claim in Example D is modeled on the claim at issue in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). The claim at issue in *Funk Brothers* was a combination of unaltered natural bacterial strains defined only by their classification in the genus *Rhizobium* and by their function to be unaffected by other strains. As a result, the combination of bacterial strains in *Funk Brothers* lacked specificity and both structural differences and functional differences from the natural strains. As the Court’s statements in *Funk Brothers* makes clear, a lack of both structural and functional differences from what occurs in nature was central to the holding. Thus, *Funk Brothers* cannot be said to require a structural difference in combined natural products regardless of the presence of a new, non-natural function.

The decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), is consistent with this. The claim in *Chakrabarty* was to a bacterium containing energy-generating plasmids that each provided a separate hydrocarbon degradative pathway. Chakrabarty added naturally occurring plasmids to a naturally occurring bacterium to create a new combination and a bacterium with new properties and uses (degradation of hydrocarbons in an oil spill). Importantly, Chakrabarty did not alter the plasmids or the bacterium (other than by combining them). The plasmids retained their natural structure and ability to express a degradative pathway. The bacterium was also structurally unaltered except for the added plasmids.

Chakrabarty held that Chakrabarty's “micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Chakrabarty*, 447 U.S. at 309-10 (misquoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)) (brackets in original). Significantly, the Court emphasized the new function of the bacterium, stating that Chakrabarty’s “human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty’s invention is believed to have significant value for the treatment of oil spills.” *Id.* at 305.

Thus, the Court in *Chakrabarty* established that products of nature manipulated such that they have a new characteristic—a new structure, new property, new function, or new use—are not products of nature and are thus patent eligible. Both *Funk Brothers* and *Chakrabarty* show that functional features of a claim to a natural product or to a combination of natural products are to be considered in deciding patent eligibility. Such functional features, which are as much a part of the claim as structural features, must be included in patent eligibility analysis.

Despite this, the analysis of Question 3 in Example D¹² betrays a failure to consider the claim as a whole. As discussed above, the claim as a whole lacks any structural or functional differences from the individual bacterial strains. Yet the Example states, regarding factor a, that “[b]ecause the bacteria are structurally identical to naturally occurring bacteria, they are not markedly different” (emphasis added). By failing to consider if any functional differences are present, the Example leaves the false impression that such differences, if present, could not confer patent eligibility.

A claim as a whole includes all of its structural properties and all of its functional properties. Failing to properly consider functional properties of a claim fails to consider the claim as a whole.

It is recommended that the Guidance be reworded to include consideration of functional differences in natural products or combinations of natural products. Notable examples of these changes include:

- a) Claim is a product claim reciting something specifically that initially appears to be a natural product(s), but after analysis is determined to be non-naturally occurring and ~~markedly~~ different in structure and/or function from naturally occurring products. Page 4, lines 20-22.
- g) Claim is a product claim reciting something specifically that appears to be a natural product(s) that is not ~~markedly~~-different in structure or function from naturally occurring products. Page 4, lines 38-39.

This question can be resolved by ~~first~~ identifying the differences in structure and/or function between the recited product(s) and naturally occurring products; ~~and then evaluating whether the identified differences together rise to the level of a **marked** difference in structure. Not all differences rise to the level of marked differences, e.g., merely isolating a nucleic acid changes its structure (by breaking bonds) but that change does not create a marked difference in structure between the isolated nucleic acid and its naturally occurring counterpart.~~ Page 5, lines 9-13 (boldface in original).

Factor a) is not satisfied, because ~~none of the natural~~ products recited in the claim are not ~~markedly~~ different from what occurs in nature. The specification describes that applicant has not changed the bacteria in any way, but instead has simply combined various strains of naturally occurring bacteria together. Because the bacteria are structurally and functionally identical to naturally occurring bacteria, they are not ~~markedly~~ different. Page 11, lines 4-7 (Example D).

However, a further and perhaps clearer analysis of Example D is that the claim fails to describe a specific application of a law of nature or natural phenomenon. The claim embodies an

¹² Example D is modeled on the claim at issue in *Funk Brothers* and recites a combination of unaltered natural bacterial strains.

abstract, purely functional description of the strains (other than being a member of the broad genus *Rhizobium*) being claimed in combination. Such a claim cannot represent a specific application of the law of nature. In this regard, the Guidance should make clear that the specific combination of specific strains is patent eligible and may be patentable if novel and non-obvious due to unexpected activity (function) arising from the combination. That is, if the claim were directed to “An inoculant comprising Strain A (defined by structure or ATCC deposit) and Strain B (defined by structure or ATCC deposit).” The claim to the inoculant is a specific composition made by man analogous to cDNA following *Myriad*, and therefore the inoculant should be evaluated as any other composition to determine if it is novel and non-obvious.

An analysis of Example E under the revised Guidelines should lead to a determination that the claim is patent eligible.

Claim 1 of Example E recites:

1. A pair of primers, the first primer having the sequence of SEQ ID NO:1 and the second primer having the sequence of SEQ ID NO: 2.¹³

In analyzing the claim, the Guidance states that the claim fails patent-eligibility because it is to a judicial exception - a composition of matter. The claim is interpreted to recite two naturally occurring DNA sequences found on a human chromosome. In addition, the claim as a whole, according to the Guidance, does not recite something significantly different than the natural products, e.g., “the claim does not include elements in addition to the judicial exceptions that add significantly more to the judicial exceptions, and also does not include features that demonstrate that the recited products are markedly different from what exist in nature.” Guidance at page 12.

The Guidance goes on to note that under Factor a) of the analysis, the claim fails because the distinct difference between the primers and the naturally occurring DNA is that the primers are isolated from the chromosome and the primers have the same function as their natural counterpart DNA - to hybridize to their complementary nucleotide sequences.

Example E of the Guidance fails to properly analyze the claim in the context of the holdings of *Myriad* and *Chakrabarty*. In *Myriad*, the Court noted that while isolated genomic DNA and isolated DNA fragments were not patent-eligible, a combination of fragments combined by man, i.e., cDNA, was patent-eligible because it is a man-made composition – a combination of naturally occurring products that is not found in nature. The *Myriad* Court noted:

cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a “product of nature” and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.

¹³ Claim 2 of Example E is a method of amplifying a target DNA sequence, and therefore is not germane to this discussion.

Myriad, slip op. at 20.

Indeed, the holding of *Myriad* is narrow – “[w]e merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material.” *Id.* at 22. The Court in *Myriad* did not comment on the function of the cDNA, having determined that it was structurally different from the natural counterpart.

The invention in *Chakrabarty* also was to a man-made combination of natural products that the Supreme Court determined was patent eligible. In contrasting Chakrabarty’s invention to a combination of natural products (plasmids in a bacterium) from the combination of root-nodule bacteria in *Funk Brothers*, the Supreme Court noted that the combination in *Funk* did not produce a new bacteria, no change in the species of bacteria and no enlargement of the range of their utility. Each species had the same effect it always had.

Thus, in analyzing claim 1 of Example E as a whole under the modified factors a) and g), the combined DNA sequences, claimed as primers, would be patent-eligible because the function of the claimed primers is functionally different from the individual isolated DNA as they exist in nature. Significantly, the claim to primers is a specific application of the two naturally occurring sequences. The specific combination does not exist in nature as claimed and would have a different function. It is understood in the art that a pair of primers have sequences that allow them to amplify a target complimentary polynucleotide sequence due to their ability to hybridize to complimentary DNA in close proximity to each other. Thus, the function of the primer pair is expanded from the use of the primers individually. Individually, the primers will only hybridize to complimentary polynucleotides. However, in combination, the primer pair permits the amplification of a target sequence. In contrast, if the claim described the primers solely by their native function rather than sequence, the claim could properly be characterized as an abstract application of the law of nature rather than a specific application and be rejected as patent ineligible.

B. The Supreme Court Acknowledges the Importance of Functional Distinctions

To support its position that a structural distinction is required to establish “marked difference,” the USPTO appears to rely heavily upon a statement made by the *Myriad* Court about the holding in *Funk Bros.* (“The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way.”) *Myriad*, 133 S. Ct. at 2117. Yet in *Funk Bros.*, as it did in *Chakrabarty*, the Supreme Court emphasized the importance of structural and functional distinctions equally:

The aggregation of select strains of the several species into one product is an application of that newly discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species

has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided, and act quite independently of any effort of the patentee.

Funk Brothers, 333 U.S. at 442 (emphasis added).

Moreover, nothing in the *Myriad* decision itself supports the USPTO's articulated test for patent eligibility. The Office argues that although the Supreme Court noted the minor structural distinctions between isolated DNA and the natural product, it still found isolated DNA patent ineligible. However, the Supreme Court expressly noted that the *Myriad* claims are "concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule." *Myriad*, 133 S. Ct. at 2118 (emphasis in original). The Court implies that because the claimed sequence did not change, the information did not change, and as a result, that there is no difference between the genetic material in nature and as an isolated DNA molecule. Thus, while most practitioners can agree that a structural difference can support eligibility under 35 USC § 101, the USPTO's requirement of a structural difference to distinguish a claimed subject matter from nature ignores the very holdings of the Supreme Court that it uses to support its guidelines.

As part of the multi-factor test the USPTO has set forth in the March 2014 *Guidance*, examiners should be instructed to consider whether the claim as a whole, regardless of the presence or absence of a structural distinction, improves upon the function of a natural product or provides a new or different function or utility compared to that found in nature. If a functional distinction is found, the subject matter of the claim should be patent eligible, even if the only structural distinction is that the claimed subject matter differs from nature by being isolated or purified from its natural surroundings. Contrary to the USPTO's interpretation, *Myriad* did not state that isolation of a product of nature from its natural surroundings could never render the product patent eligible in any situation; it states only that isolation alone did not render genes patent eligible.

We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.

Myriad, 133 S. Ct. at 2120 (emphasis added). The Court's emphasis on the informational component of *Myriad*'s claims, combined with this concluding statement in the opinion make it clear that the holding in *Myriad* should not be extrapolated to subject matter that is not "concerned primarily with the information contained in the genetic *sequence*." If isolation/purification of a natural product results in a different composition or manufacture, a composition or manufacture that has new and useful functions, characteristics, or qualities, it should be patent eligible.

V. THE CLAIMS AS A WHOLE, INCLUDING ALL ELEMENTS MUST BE CONSIDERED IN DETERMINING DISTINCTIONS FROM JUDICIAL EXCEPTIONS

Whether differences between claimed subject matter and judicial exceptions must simply be differences, or they must be significant differences, the USPTO must consider the claim as a whole and not simply identify a single element as “involving or relating to” a judicial exception.

The Guidance pays lip service to the idea that a claim must be evaluated as a whole; however, in practice, it does just the opposite. A claim to a firework is not a claim to a natural product. A firework is an article of manufacture that includes as integral elements, natural components. The claim, taken as a whole, cannot possibly be considered as falling within a judicial exception and the USPTO’s insistence on a heightened scrutiny of such a claim clearly implies that the Guidelines encourage an improper and piecemeal analysis of the claims.

A. Combinations of Natural Products Should be Patent Eligible If the Combinations Do Not Exist in Nature or Do Not Naturally Exist in a Form or Ratio that Provides a Functional Distinction

The Guidance encourages Examiners to reject as patent ineligible claims directed to *combinations* of natural products, where the combination does not include an additional step or element that is non-natural. For example, the Guidance indicates that the entire class of inventions relating to combinations of natural products where there is no identifiable structural change, regardless of whether the combination has a distinctive character, use, form, quality, or property should be considered patent ineligible. This attempt at a *per se* rule is in error. If the claim as a whole is different from what exists in nature and represents a specific application of the law of nature then the combination product is non-natural and should be patent eligible. In determining, for example, whether a combination product confers a character, use, form, quality, or property than what exists in nature, whether the combination product is “functionally” distinct from what occurs in nature should be considered. The Guidance erroneously fails to consider whether a combination product *as a whole* is functionally distinct from what occurs in nature so as to ensure that entire classes of inventions are not foreclosed from patenting. By discounting the importance of functional differences when considering the patentability of combinations of natural products, the United States Patent and Trademark Office has misinterpreted *Chakrabarty* and *Funk Brothers*. Both of these cases highlighted *functional* distinctions between the claimed combination product and what existed in nature.

For instance, *Chakrabarty* did not rely solely on structural differences between the claimed bacteria and its natural counterpart. In *Chakrabarty*, the Supreme Court noted that an altered bacterium merely comprised “markedly different **characteristics** from any [bacterium] found in nature, and one having the potential for significant **utility**.” 447 U.S. 303, 310 (1980) (emphasis added). Despite the 2014 Guidance’s recognition that the *Chakrabarty* claimed bacterium was both structurally and functionally different than what occurs in nature (*see* 2014 Guidance at 6) Factors a) and g) focus only on structural distinctions and do not instruct an analysis of functional distinctions. Factors a) and g) should be amended to consider functional distinctions between the claimed product and what is found in nature.

Similarly, in *Funk Brothers*, the Supreme Court highlighted the lack of **functional** distinctions between the claimed combination of bacteria and bacteria as found in nature. The Supreme Court found that the claimed mixture of bacteria had the same structure, function, and utility as bacteria individually as they existed in nature, and thus found the claims patent ineligible. Instructive, however, is that the Court’s patent eligibility determination focused on differences in function, not structure:

Each of the species of root-nodule bacteria contained in the package **infects** the same group of leguminous plants which it always infected. No species acquires a different **use**. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their **utility**. Each species has the same **effect** it always had. The bacteria **perform** in their natural way. **Their use in combination does not improve in any way their natural functioning**. They serve the ends nature originally provided, and act quite independently of any effort of the patentee.

Funk Brothers, 333 U.S. at 131 (emphasis added).

Thus, *Funk Brothers* did not base their analysis of patent eligibility solely on structural distinctions, but rather considered whether the claim as a whole was functionally distinct from what occurs in nature.

Accordingly, functional distinctions should not be ignored when considering whether a combination of natural products is patent eligible. Functional distinctions alone should be sufficient to distinguish a claimed invention from a mere aggregation of natural products for patent eligibility purposes. Failure to do so may in effect foreclose from patenting the class of inventions related to combinations of natural products.

B. Methods of Treatment Employing a Natural Product or Combination of Natural Products Are Patent Eligible Without the Unreasonable Limitations Imposed by the Guidelines

Supreme Court precedent does not require or even suggest that methods of treatment employing a natural product must be limited in scope to avoid foreclosure of other uses in order to be patent eligible. The IPL Section recommends that the USPTO revise its Guidance to reflect that a method of treatment employing a natural product is a patent eligible application of the natural product.

Specifically, in discussing Example B - Claim 3 of the Guidance, which recites a new method of treating a disease (colon cancer) with a natural product known to be useful to treat a different disease (breast cancer), the USPTO instructs examiners that the claim is patent eligible because the recitation of particular dosage amounts and a specific treatment regimen, “meaningfully limits the scope of the claim to a particular application” of the natural product. The Guidance states:

Because the specific dosage and treatment period limitations narrow the scope of the claim, others are not substantially foreclosed from using [the natural product]

in other ways, e.g., to treat colon cancer at other dosages or for other lengths of time, to treat other cancers, etc.

The USPTO does not provide any support in Supreme Court precedent for such a requirement (i.e., “meaningfully limiting” the scope of the claimed use of a natural product or avoiding “substantial foreclosure” of other uses of the natural product). Nor would it find such support.

As Justice Thomas made clear, the *Myriad* Court did not even consider method claims employing natural products or claims to applications of knowledge obtained from natural products.

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had *Myriad* created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. . . .

Similarly, this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.

Myriad, 133 S. Ct. at 2120 (emphasis in original).

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289, 1302 (2012), the Supreme Court implied that a new way of using an existing drug constituted a particular application of natural laws.

Unlike, say a typical patent on a new drug or a new way of using an existing drug, the [Prometheus] patent claims do not confine their reach to particular applications of those laws.

Id. The Court did not suggest that a separate rule applied if the existing drug was a natural product. Nor did the Court say that a new way of using an existing drug or natural product must be limited in scope to avoid substantial foreclosure of the use of the drug or natural product.

It is untenable that the USPTO Guidance should instruct examiners to look for limitations in scope that avoid foreclosure of other uses in order to find a method of treatment employing a natural product patent eligible when there is simply no basis in the Statute or the case law to support such a requirement. Thus, The IPL Section of the American Bar Association urges the USPTO to eliminate Example B, Claim 3 and its attendant analysis from the Guidance.

C. Diagnostic Claims Should be Considered as a Whole, Including Combinations of Steps and Components

A diagnostic claim should be patent eligible under Section 101 where the diagnostic claim as a whole, other than a mental process, is limited to a specific application of a law of nature, a natural phenomenon, or an abstract idea, or alternatively where the diagnostic claim requires or involves a transformation of matter.

The present claim in the Guidance is as follows:

A method for diagnosing a patient as having degenerative disease X, comprising:

contacting a sample of blood obtained from the patient with an antibody that specifically recognizes an epitope of misfolded protein P, said epitope comprising at least amino acids 1-3 of SEQ ID NO:1; detecting whether binding of the antibody with misfolded protein P is present in the sample, said step of detecting including the use of flow cytometry; and diagnosing the patient as having degenerative disease X if misfolded protein P is determined to be present in the sample.

However, the specified epitope of misfolded protein P and the specific detection method of flow cytometry should not both be necessary to make the claim patent eligible. Either one of these two limitations without the other should be enough to make the claim patent eligible.

Other examples of diagnostic claims that describe a specific application of a law of nature or natural phenomenon that would be patent eligible would include but not be limited to limitations to treatments, to specific reagents, and to specific assays:

A method for diagnosing a patient as having degenerative disease X, comprising testing for the presence of misfolded protein P in a sample from said patient, diagnosing the patient as having degenerative disease X if misfolded protein P is determined to be present in the sample, and treating the patient with compound C.

In this case compound C limits the specific application of the law of nature because other compounds can be discovered to treat degenerative disease X.

A method for diagnosing a patient as having degenerative disease X, comprising testing for the presence of misfolded protein P in a sample from said patient by contacting said sample with reagent R, and diagnosing the patient as having degenerative disease X if misfolded protein P reacts with reagent R.

In this case the specific law of nature is limited by the reaction with reagent R as other future reagents may be discovered to react with misfolded protein P.

A method for diagnosing a patient as having degenerative disease X, comprising testing for the presence of misfolded protein P in a sample from said patient by analyzing the sample using ELISA assay E, and diagnosing the patient as having degenerative disease X if ELISA assay E is positive.

In this case the specific law of nature is limited by the ELISA assay E because other future assays may be discovered to test for misfolded protein P.

Thus there are several ways to limit the application of the specific law of nature but not all or even several should be required for patent eligibility.

The Guidance suggests that the only diagnostic claim that is patent eligible is one that is so limited as to be commercially irrelevant. Nothing in the Supreme Court precedent dictates that a diagnostic claim must be so narrow that it effectively dedicates the practice of the method to

the public. The Guidance should be revised to provide more examples of what reasonable levels of detail/limitation in the scope of the claims such that it does not completely eliminate all practical value.

VI. ADDITIONAL EXAMPLES

The USPTO has requested additional examples for consideration in revising its guidance.

Example 3 of the Guidance recites:

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

Such a claim would be of limited to no commercial value. An initial application claiming a method of treatment will often be filed prior to any human clinical trials. Thus, the applicant may not have the information such as period of time for treatment and specific, narrow daily dose at the time of filing. This should not prevent an applicant from obtaining a commercially reasonable claim. A more reasonable claim would include:

A method of treating colon cancer, comprising administering a pharmaceutically effective amount of purified amazonic acid to a patient suffering from colon cancer.

This claim is limited to a specific application of the natural product, i.e., treating colon cancer. It does not foreclose the use of the natural product as occurs in nature. Nor does it foreclose use of the natural product for any purpose other than treating colon cancer, such as, e.g., treating breast cancer.

Similarly, a pharmaceutical composition claim should be patent eligible without unreasonable limitations. Such a claim could recite, for example:

A pharmaceutical composition comprising a pharmaceutically effective amount of purified amazonic acid and a pharmaceutically acceptable excipient therefor.

This claim should be patent eligible because such a combination does not exist in nature. A pharmaceutically effective amount of a purified natural product in combination with a pharmaceutically acceptable excipient does not naturally occur. Thus, this combination is “significantly more” than what exists in nature.

If the USPTO does not agree to remove its requirement for “marked” or “significant” differences, additional examples should be provided to identify what is considered a significant structural difference, and precisely how “well understood, purely conventional, and routine in the relevant field” concepts should be applied to evaluation of claims involving a natural product, if at all. The Guidelines should make clear whether the following types of claims are patent eligible and why.

A [naturally occurring] nucleic acid linked to a fluorescent label.

Despite the fact that some compounds that may be used as fluorescent labels occur in nature, and the fact that adding such a label is routine and conventional, perhaps even extra-solution activity, the combination of a fluorescent label to the nucleic acid sequence (like cDNA) does not occur in nature. The labeled nucleic acid has a new utility, distinct from its utility in nature. And the physical combination of the components amounts to a structural alteration to one or the other component, which should meet the PTO imposed standard of “markedly different.”

Consider the following claim to a fusion protein:

A fusion protein comprising a fragment of a [naturally occurring] protein A and a fragment of a [naturally occurring] protein B.

The two proteins exist in nature, but their fragments do not naturally combine. The fusion protein has a new utility, distinct from the utility of either protein in nature. And the physical combination of the components amounts to a structural alteration to one or the other component, which should meet the PTO imposed standard of “markedly different.” Further, as specifically defined proteins, the fusion protein represents a specific application of the natural phenomenon and as such it should be patent eligible subject matter.

As discussed in the comments above, combinations of natural products that exhibit functional characteristics distinct from the individual elements in nature and/or exhibit a significant new utility should be considered patent eligible.

A mixture of saltpeter, sulfur, and charcoal [in a ratio that permits explosion upon ignition].

This claim should be considered patentable because the precise ratio of components needed to make this combination of natural products explosive does not occur in nature. The combination of elements has substantially different functional properties than the individual elements (in contrast to the bacteria in *Funk*) and provides a substantial new utility.

The Guidance does not include a single example of when a method claim satisfies factor e):

Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application

For example in the analysis of example B, claim 3, the Guidance concludes in one line, without analysis, that factor e) is not satisfied as “no machine or transformation is recited.” Guidance at 8. The Office provides no reasoning to back up this statement, and the

Office's conclusion is contrary to the case law. *See also*, Example C, Example F, and Example G, claims 1-3.

A "transformation," in the court-based "machine or transformation test," on which this factor is apparently based, is a transformation of some tangible thing into a different state, and it is meant to contrast with a change in something intangible such as data. *See* M.P.E.P. § 2106(II)(B)(1)(b). Thus, the presence of a machine or transformation is meant to contrast a step involving something tangible from a purely abstract, mental step. *See Id.* Moreover, the Supreme Court in *Mayo*, while finding a method claim ineligible under § 101 based on an analysis of the claim as a whole, acknowledged that the "administration" step in the claim is a transformation because it alters the body of the patient who receives the drug. *See Mayo v. Prometheus*, 130 S.Ct. at 1302-03 (referring to the "administration" step of Prometheus's claim as: "The first of these transformations . . .").

Accordingly, the IPL Section requests that the Guidance be modified to reflect that administration of a drug to a patient that results in a biological effect is indeed a "transformation" that satisfies factor e) or to provide sound reasoning as to why, particularly in view of *Mayo*, a step reciting drug administration to a patient is not transformative. The IPL Section appreciates the opportunity to provide the above comments. We hope for a continued dialogue to make sure that the Guidance provided by the USPTO is helpful to the Examiners, applicants and appropriately captures the Supreme Court precedent.

Sincerely,



Robert O. Lindefjeld
Section Chair
American Bar Association
Section of Intellectual Property Law