

From: Nicole Palmer
Sent: Monday, July 28, 2014 1:08 PM
To: myriad-mayo_2014
Subject: BPLA Comments Submission re: Examination Guidance Pertaining to Patent-Eligible Subject Matter

Dear Sirs:
Please find comments attached for your consideration on behalf of the Boston Patent Law Association.

Sincerely,
Nicole

Nicole A. Palmer



One Main Street
Cambridge, MA 02142
Direct: +1-617-395-7009
Main: +1-617-395-7000
Fax: +1-617-395-7070
Email: NPalmer@LALaw.com
www.LALaw.com

*Confidentiality Note: This e-mail message and any attachments may contain confidential or privileged information. If you are not the intended recipient, please notify me immediately by replying to this message. Please destroy all copies of this message and any attachments.
Thank you.*

This email has been scanned for email related threats and delivered safely by Mimecast.
For more information please visit <http://www.mimecast.com>



THE BOSTON PATENT LAW ASSOCIATION

PRESIDENT

Donna M. Meuth
Eisai Inc.
4 Corporate Drive
Andover, MA 01810-2441
Phone: (978) 837-4862
E-mail: donna_meuth@eisai.com

PRESIDENT - ELECT

Gregory J. Sieczkiewicz, Ph.D.
Assuerus Strategic Consulting, LLC
Phone: (617) 407-6915
E-mail: greg@assueruslaw.com

VICE PRESIDENT

Erik Paul Belt
McCarter & English, LLP
265 Franklin Street
Boston, MA 02110
Phone: (617) 449-6506
Email: ebelt@mccarter.com

TREASURER

Monica Grewal
Wilmer Cutler Pickering
Hale & Dorr, LLP
60 State Street
Boston, MA 02109
Phone: (617) 526-6223
E-mail: monica.grewal@wilmerhale.com

SECRETARY

Rory P. Pheiffer
Nutter McClennen & Fish LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210-2604
Phone: (617) 439-2879
E-mail: rpp@nutter.com

BOARD OF GOVERNORS

Joseph M. Maraia
Burns & Levinson LLP
125 Summer Street
Boston, MA 02110-1624
Phone: (617) 345-3241
E-mail: jmaraia@burnslev.com

Deirdre E. Sanders
Hamilton, Brook, Smith
& Reynolds, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133
Phone: (978) 341-0036
E-mail: deirdre.sanders@hbsr.com

Michael Bergman
Bergman and Song LLP
P.O. Box 400198
Cambridge, MA 02140-0002
Phone: (617) 625-8870
E-mail: mbergman@bergmansongllp.com

Daniel W. Young
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210-2206
Phone: (617) 646-8245
E-mail: dwyoung@wolfgreenfield.com

July 28, 2014

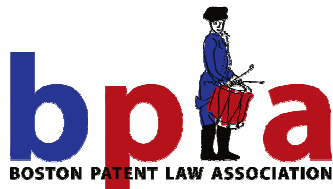
Via E-Mail: myriad-mayo_2014@uspto.gov
Raul Tamayo, Senior Legal Advisor
Office of Patent Legal Administration
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Comments on Examination Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena & Natural Products, in response to request for comments at 79 Fed. Reg. 21736 (April 17, 2014) and 79 Fed. Reg. 36786 (June 30, 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 Guidance for the examination of patent claims concerning laws of nature, natural phenomena, and natural products.¹ 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. These comments are submitted by the BPLA solely as its consensus view. They are not necessarily the views of any individual member, any firm, or any client.

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 (the “Guidance”).



THE BOSTON PATENT LAW ASSOCIATION

We appreciate the USPTO's efforts to further improve the examination of claims concerning laws of nature, natural phenomena, and natural products in the wake of the Supreme Court's recent patentable subject matter decisions. We offer the comments below in an attempt to assist the USPTO in these efforts.

I. THE GUIDANCE IS OVERLY RESTRICTIVE OF PATENTABLE SUBJECT MATTER

The Guidance, in striving to offer clarity in light of recent changes to the scope of patentable subject matter, appears to overreach in several key ways. First, the Guidance goes further than required by recent Supreme Court case law, sweeping too many types of claims into the detailed § 101 analysis, particularly those that merely “involve” natural products. Second, the Guidance unnecessarily suggests that claims to products that are functionally different from products found in nature are not patent eligible. Third, the Guidance has the potential to unnecessarily hinder inventive activity in important fields, and appears to contravene congressional intent with respect to certain classes of natural products.

A. Examining Man-Made Products Under the Guidance's Multipart Test Is Inconsistent with Supreme Court Case Law

The Guidance is overly broad to the extent that it pulls claims *involving* natural products into its scope. Such claims, including, for example, those directed to derivatives of natural products and methods of treatment using natural products, have not been the subject of the Supreme Court's recent patentable subject matter decisions. Accordingly, there is no reason for the USPTO to treat these claims differently in light of *Mayo* and *Myriad* than it did before these decisions.

A fundamental, and costly, shortcoming of the Guidance stems from the scope of its “Question 2,” which asks “Does the claim recite *or involve* one or more judicial exceptions?”² Nothing in the Supreme Court's holdings, however, suggests that the few judicial exceptions to patentable subject matter cast any shadows that render claims that merely *involve* these judicial exceptions ineligible for patent protection.

The Supreme Court has explained that § 101 was intended to, and does, have a “wide scope.”³ It has further cautioned against “read[ing] into the patent laws limitations and conditions which the legislature has not expressed.”⁴ Accordingly, the judicial exceptions to

² Guidance at 3.

³ *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

⁴ *Id.* (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)); see also *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012) (“[W]e must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another.”).



THE BOSTON PATENT LAW ASSOCIATION

patentability are narrow. “[T]oo broad an interpretation of this exclusionary principle could eviscerate patent law.”⁵

The Court’s recent patentable subject matter decisions have illustrated the narrow scope of these exceptions. *Myriad* involved claims to two types of products: naturally occurring, isolated DNA segments and man-made cDNA segments.⁶ Although the Court concluded that naturally occurring, isolated DNA segments are not eligible for patent protection under § 101, it concluded that cDNA segments do meet the statute’s eligibility requirements. It reached this conclusion with a straightforward analysis looking only at whether cDNA occurs in nature:

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring. . . . 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 § 101⁷

Having concluded that cDNA was not itself a natural product, the Court did not resort to a multifactor, totality of the circumstances analysis. Rather, it found the man-made origin of cDNA dispositive on its own.

Significantly, both *Myriad* and *Mayo* emphasized that their holdings should not be read to apply to other categories of claims not at issue in these cases. In explaining that it was “important to note what is *not* implicated by this decision,”⁸ the *Myriad* Court pointed out that no method claims nor patents on new applications of knowledge about the covered genes were before it. The Court noted that “[h]ad *Myriad* created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.”⁹ Similarly, it commended Judge Bryson’s conclusion, the Federal Circuit opinion, that *Myriad* could claim *applications* of knowledge about the covered genes, implicitly accepting that such applications are eligible for patent protection under § 101. Both method claims involving the covered genes and applications of knowledge about the covered genes *involve* a judicial exception. Yet, the *Myriad* Court assumed that such claims were patent eligible without any hint of a deeper, multifactor analysis.

⁵ *Mayo*, 132 S. Ct. at 1293; see also *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. ___, 2014 WL 2765283, at *5 (2014) (“[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law.”).

⁶ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2112-14 (2013)

⁷ *Id.* at 2119.

⁸ *Id.*

⁹ *Id.*



THE BOSTON PATENT LAW ASSOCIATION

The same is true of *Mayo*. The underlying judicial exceptions addressed in that case were natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that a drug dosage will be ineffective or induce harmful side-effects. In finding ineligible claims to methods instructing physicians to *apply* the natural law, the Court explicitly distinguished two types of claims that *involved* the natural law: claims to a “new drug” and claims to “a new way of using an existing drug.”¹⁰ *Mayo*’s holding was simply that a patent applicant cannot claim the natural law; it did not say that a patent applicant cannot seek claims that somehow involve the natural law, and it did not say that, if they did so, a multifactor test would be necessary to evaluate patent eligibility.

The Supreme Court’s most recent patentable subject matter opinion, *Alice Corp. v. CLS Bank International*, supports that only a subset of claims should be subject to *Mayo*’s “significantly different” or “inventive concept” analysis, *i.e.*, those *directed to* a patent-ineligible concept:

First, we determine whether the claims at issue are *directed to* one of those patent-ineligible concepts [laws of nature, natural phenomena, and abstract ideas]. . . . *If so*, we then ask, “[w]hat else is there in the claims before us?” . . . To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional elements “transform the nature of the claim” into a patent-eligible application.¹¹

The USPTO’s preliminary examination instructions in view of *Alice* appear to acknowledge this language in the Supreme Court’s opinion,¹² instructing examiners to “determine whether the claim is directed to a judicial exception,”¹³ and stating that “an invention is not rendered ineligible simply because it involves an abstract concept.”¹⁴

In contrast, by channeling claims that in any way *involve* natural products and natural laws into its “significantly different” test, the Guidance imposes a requirement that goes beyond, and contravenes, these Supreme Court holdings. By including broad “or involve” language in Step 2, and postponing the inquiry regarding the claims “as a whole” until Step 3 of its analysis, the Guidance sweeps many claims that plainly are not directed to natural products or natural laws into its costly multifactor test. A clear example of this is Example C of the Guidance relating to

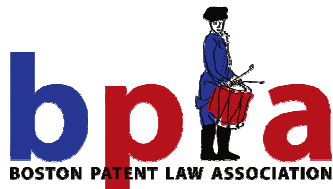
¹⁰ *Mayo*, 132 S. Ct. at 1302.

¹¹ *Alice Corp.*, 2014 WL 2765283, at *6 (quoting *Mayo*) (emphasis added).

¹² See Memorandum from Andrew H. Hirschfeld, Deputy Comm’r for Patent Examination Policy, Preliminary Examination Instructions in View of the Supreme Court Decision in *Alice Corporation Pty. Ltd. v. CLS Bank International*, *et al.* (June 25, 2014), available at http://www.uspto.gov/patents/announce/alice_pec_25jun2014.pdf.

¹³ *Id.* at 2.

¹⁴ *Id.*



THE BOSTON PATENT LAW ASSOCIATION

a claimed firework including a dual-compartment cardboard body with plastic ignition fuse housing a multi-component firework composition. Neither *Myriad* nor *Mayo* provides guidance regarding such a claim, let alone suggests any reason why such a claim should be subject to heightened scrutiny under a multipart test to determine whether it constitutes patentable subject matter simply because it recites the elements calcium chloride and gunpowder. The existence of the cardboard body with plastic fuse housing multiple components of the firework composition arranged in a particular manner should make clear, without applying a special test or weighing factors, that the claimed subject matter is not a product of nature. It is costly and unnecessary to sweep such claims into the multifactor test set forth in the Guidance.

Two other types of cases are illustrative: derivatives of natural products and method of treatment claims.

Example B of the Guidance discusses three claims: (1) a claim to “purified amazonic acid,” which contains a natural product compound; (2) a claim to “purified 5-methyl amazonic acid,” which contains a man-made derivative of a natural product compound; and (3) a method of treating colon cancer using a specific dose of amazonic acid at a specified frequency and for a specified period of time. The Guidance analyzes each of these three claims under the “significantly different” test, concluding that the first claim recites a judicial exception and that the second and third claims involve a judicial exception. Yet, subjecting these latter two claims to the “significantly different” test is unnecessary and inconsistent with the Supreme Court’s holdings.

Claim 2 of Example B recites a man-made derivative of a natural product. The Guidance concludes that it “recites (or may recite) a judicial exception, i.e., amazonic acid is a naturally occurring chemical found in the leaves of Amazonian cherry trees,” then proceeds to conclude (correctly) that the claim is directed to patentable subject matter under the “significantly different” test because it has both structural and functional differences from naturally occurring amazonic acid. Under the Supreme Court’s case law, however, these conclusions were unnecessary to resolve the § 101 question. 5-methyl amazonic acid “is not naturally occurring” and “is distinct from the [natural product] from which it was derived.”¹⁵ It, like all other derivatives of natural products, is analogous to the cDNA that the Supreme Court summarily found patent eligible in *Myriad*. Subjecting derivatives of natural products to the 12-factor “significantly different” test is therefore unnecessary and wasteful, at best (*i.e.*, if the examiner ultimately allows the claim), or directly contrary to *Myriad*, at worst (*i.e.*, if the examiner rejects the claim).

Claim 3 of Example B, which recites a specific method of treatment using amazonic acid, presents a similar problem. Again, the Guidance concludes that this claim “recites a judicial exception, *i.e.*, amazonic acid is a naturally occurring chemical.” It then proceeds to correctly conclude that this claim is to patentable subject matter, but it does so under the “significantly

¹⁵ *Cf. Myriad*, 133 S. Ct. at 2119 (discussing cDNA).



THE BOSTON PATENT LAW ASSOCIATION

different” test. The Guidance concludes that because the claim recites a “particular dosage of amazonic acid . . . for a particular length of time . . . to a particular patient,” and because “[i]t was not well-known, routine or conventional to use amazonic acid (either isolated or in leaf form) to treat colon cancer,” the claim is patent eligible under § 101. The Guidance, however, does not need to go through this analysis for this or many other method of treatment claims. *Myriad* distinguished method claims using a natural product from claims to the natural product itself, suggesting that method claims do not present the same § 101 problems.¹⁶ Indeed, the rigor of the analysis and the level of detail of the claim may improperly suggest to Examiners that method of treatment claims containing fewer limitations regarding the dosing regimen would not be patent eligible.

Similarly, the Guidance also suggests, without expressly saying, that claim 3 of Example B involves a law of nature (*i.e.*, that amazonic acid exhibiting efficacy against colon cancer is a law of nature). The Guidance ultimately concludes that this does not place claim 3 outside the scope of § 101. Yet, the lengthy analysis that led the Guidance to this conclusion was unnecessary. *Mayo* distinguished methods of using a drug that acted according to a natural law from a method of applying the natural law itself. Accordingly, the method of treatment claim in Example B is patent eligible under § 101 on its face; there is no need for examiners to subject it to the multifactor “significantly different” analysis. The Supreme Court’s case law provides no reason to find such a claim ineligible under § 101.

These examples are merely illustrative of how the Guidance’s overly inclusive Step 2 results in many claims that clearly meet § 101’s requirements, under existing Supreme Court case law, being subjected to the rigorous and costly “significantly different” analysis.

B. Functional Differences Between a Claimed Composition and a Natural Product May Satisfy § 101

To the extent that the Guidance suggests that claimed products that are only functionally, but not structurally, different from natural products are not patentable subject matter, this result is not required by Supreme Court or other case law. The USPTO’s position in the Guidance appears to be that a functional difference between a claimed product and a natural product is not, on its own, sufficient to make the claimed product patent eligible under § 101.¹⁷ This reading goes beyond the requirements of *Myriad* and other patentable subject matter case law in restricting patent eligible subject matter. Functional differences between claimed compositions

¹⁶ Although *Myriad* concludes that the specific method claims in its hypothetical (*i.e.*, claims to methods of isolating DNA) were likely not available because the methods “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach,” *id.* at 2119-20 (quoting the district court opinion, 702 F. Supp. 2d at 202-03), suggesting prior art issues, the opinion does not suggest that this presents a barrier under § 101.

¹⁷ See, *e.g.*, Raul Tamayo, Sr. Legal Advisor, Office of Patent Legal Admin, U.S. Patent & Trademark Office, Evaluating Subject Matter Eligibility Under 35 USC § 101, Presentation to Boston Patent Law Ass’n, at 26 (June 11, 2014).



THE BOSTON PATENT LAW ASSOCIATION

and natural products have long been held sufficient to support patentability, and nothing in the Supreme Court's recent decisions has changed that.

The USPTO has contended that a functional difference is insufficient to support patentability because briefs submitted in *Myriad* made this argument, yet the Court ignored it and rested its reasoning on the lack of a structural difference.¹⁸ This, however, reads too much into the Supreme Court's silence. The Court stated that the claims were "not expressed in terms of chemical composition," but rather "focus[ed] on the genetic information" in the claimed genes.¹⁹ Characterized in this way—as information, rather than a chemical compound—no functional difference existed between the isolated genes and the natural genes. Put differently, information is information, no matter how pure or concentrated its medium is. By construing the *Myriad* claims in this manner, the Court implicitly did away with the functional differences and therefore did not need to address them. Furthermore, in explaining why the *Chakrabarty* bacterium was patent eligible under § 101, the *Myriad* Court noted that this was "due to the additional plasmids **and resultant 'capacity for degrading oil.'**"²⁰ This reference to *both* structural and functional differences between the *Chakrabarty* bacterium and natural bacteria suggests that both may play a role in rendering a claimed invention patent eligible under § 101.

There is also little reason to conclude that the Court would dismiss established and much-cited case law recognizing that functional differences can impart patent eligibility without so much as a passing reference. Courts have long found functional differences between a claimed product and a natural product sufficient to meet § 101's requirements. For example, in *Parke-Davis & Co. v. H.K. Mulford Co.*, Judge Learned Hand addressed this issue in the context of a claim to purified adrenaline. He concluded that

[the inventor] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, ***it became for every practical purpose a new thing commercially and therapeutically.*** That was a good ground for a patent.²¹

Parke-Davis thus discusses functional, not structural, differences in finding the claimed subject matter patentable.

¹⁸ *Id.* ("Can A Functional Difference On Its Own Amount To A Marked Difference? Our interpretation of *Myriad* led us to conclude that the answer is no. Briefs submitted to the Supreme Court argued that the isolated DNA of *Myriad*'s claims performed new functions and new utilities that native DNA cannot perform. Arguments did not alter the Court's decision that eligibility hinged on a markedly different structural change.").

¹⁹ *Myriad*, at 2118.

²⁰ *Id.* at 2117 (quoting *Chakrabarty*, 447 U.S. at 305 n.1).

²¹ *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103-04 (C.C.S.D.N.Y. 1911) (Hand, J.) (emphasis added).



THE BOSTON PATENT LAW ASSOCIATION

Parke-Davis was not the only case to recognize that functional differences between a claimed product and a natural product may confer patent eligibility. In *Merck & Co. v. Olin Mathieson Chemical Corp.*, the Fourth Circuit concluded that “[t]he fact . . . that a new and useful product is the result of processes of extraction, concentration and purification of natural materials does not defeat its patentability.”²² Courts have repeatedly cited both *Parke-Davis* and *Merck & Co.* approvingly.²³

Because the Supreme Court has remained silent on whether a functional difference alone is sufficient to support patentability, the USPTO should not infer that decades of practice and highly regarded lower court precedent have been discarded. Accordingly, the Guidance should recognize that functional differences between a claimed product and a natural product may be sufficient, on their own, to meet the § 101 standard, unless and until the Supreme Court holds otherwise.

C. The Guidance’s Overbroad Approach Will Unnecessarily Hinder Inventive Activity in Important Fields and Conflicts with Congressional Intent

1. The Patent System Should Promote Inventive Activity to the Greatest Extent Possible, Particularly in Important Fields Such as Medicine

As the Supreme Court cautioned in both *Myriad* and *Mayo*, “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”²⁴ It is the role of the patent system to strike a balance between the inventions that are patentable and those that are not while preserving “incentives that lead to creation, invention, and discovery.”²⁵ Striking this balance requires tailoring the size of each of the patent system’s doors—not just § 101, but also the novelty requirement of § 102, the non-obviousness requirement of § 103, and the description and enablement requirements of § 112—as Congress has done.²⁶ Blocking any of these doors too much threatens to upset the delicate balance that Congress has struck to promote American innovation.

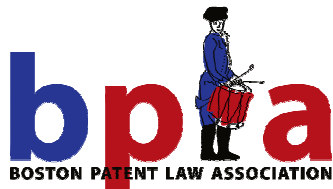
²² *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 163-64 (4th Cir. 1958).

²³ *In re Bergy*, 596 F.2d 952, 975 n.13 (C.C.P.A. 1979), *vacated in part sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028, *aff’d sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1328 (Fed. Cir. 2012), *cert. granted in part*, 133 S. Ct. 694 (2012), *aff’d in part, rev’d in part on other grounds sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

²⁴ *Myriad*, 133 S. Ct. at 2116; *Mayo*, 132 S. Ct. at 1293.

²⁵ *Myriad*, 133 S. Ct. at 2116; *Mayo*, 132 S. Ct. at 1305.

²⁶ *Cf. Application of Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979), *vacated in part sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028, *aff’d sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (Rich, J.) (“Achieving the ultimate goal of a patent . . . involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103 . . .”).



THE BOSTON PATENT LAW ASSOCIATION

By restricting patentable subject matter more than is required by Congress and Supreme Court case law, the Guidance threatens to suppress innovation in industries that are particularly dependent upon innovations relating to natural products and laws of nature for their breakthroughs. Notable examples are biotechnology and biopharmaceuticals. Compositions comprising natural products and their derivatives have historically been, and continue to be, vitally important as antibiotics and as treatments for cancer, cardiovascular disorders, visual disorders, and parasite diseases, among many other[s] important medical conditions.²⁷ Many of these areas are in desperate need of continued innovation. For example, antibiotic resistance will pose a profound risk to human health without the development of new drugs. The director of the U.S. Centers for Disease Control and Prevention (“CDC”) recently warned that “[w]e risk entering a post-antibiotic era where even simple infections can be deadly,” noting that, “[w]ith a few bacteria, we’re already there.”²⁸ Similarly, natural products and their derivatives lie at the heart of the biotechnology industry, which uses these molecules as tools and building blocks to improve human health and the human condition.

Unnecessary or overbroad changes to patent policy that restrict the scope of patent protection and introduce uncertainty in the patenting process threaten to slow innovation in these industries. To avoid that result, the USPTO should limit patentable subject matter no more than expressly required by Congress and Supreme Court case law.

2. Congressional Intent Supports Promoting Innovation, Particularly in Biotechnology

To the extent that the Guidance creates a higher burden for patenting biological products, it also conflicts with congressional intent. Section 287(c) of the Patent Act, which Congress passed in 1996, preclude actions against a medical practitioner for certain otherwise-infringing activities performed in the medical context. Congress expressly recognized the existence of “biotechnology patent[s]” in this statute,²⁹ implicitly ratifying the USPTO’s policy of granting such patents. The legislative history of § 287(c) makes clear that Congress understood “biotechnology patent[s]” to have a broad meaning, “includ[ing] . . . a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level.”³⁰

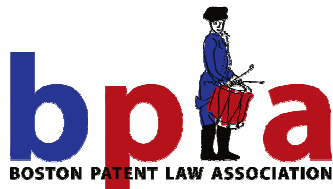
Other provisions of the Patent Act also show that Congress contemplated specific types of biotechnology patents. § 271(e)(1) carves out “new animal drug or veterinary biological

²⁷ See generally David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010*, 75 J. Natural Products 311 (2012).

²⁸ Centers for Disease Control and Prevention, Director’s Briefing: Serious Health Threat of Antibiotic-Resistant Germs (Sept. 16, 2013), <http://www.cdc.gov/about/cdcdirector/briefings.html>.

²⁹ See 35 U.S.C. § 287(c)(2)(A)(iii).

³⁰ See H.R. Rep. No. 104-863, 1996 WL 562036, at 855.



THE BOSTON PATENT LAW ASSOCIATION

product[s] . . . primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques” from the “patented invention[s]” that are subject to the regulatory submission safe harbor. § 271(g) likewise establishes a specific cause of action for infringement where a foreign manufacturer uses a patented “process of preparing a DNA molecule comprising a specific genetic sequence,” uses the DNA to make an unpatented protein outside the United States, and then sells the protein in the United States.

Congress also expressed support for biotechnology patents in responding to the USPTO’s interpretation of *In re Durden*³¹ with the Biotechnological Process Patents Act of 1995.³² The Act amended § 103(b) of the Patent Act to address the obviousness analysis of “biotechnological process[es],” including “process[es] of genetically altering . . . a single- or multi-celled organism,” “cell fusion procedures,” and methods of using products produced by such procedures.³³ This amendment again reflects a strong policy in favor of patents on biological products.

In light of this strong and clearly expressed congressional policy, the USPTO should go no farther than absolutely required by the Supreme Court’s decisions in restricting patentable subject matter, particularly as it relates to biotechnology.

II. A MORE NARROWLY TAILORED APPROACH WOULD BE CONSISTENT WITH CASE LAW AND LESS BURDENSOME ON THE USPTO AND PATENT APPLICANTS

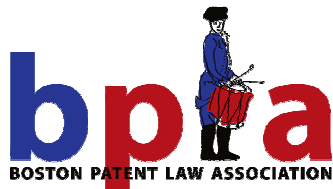
As discussed above, the Guidance adopts an approach that is broader than necessary in funneling many claims clearly directed to man-made products or processes into the multifactor “significantly different” analysis. This approach has at least two significant adverse effects on patent examination: increased prosecution costs and the potential for significantly increased delay.

The Guidance explains that the “significantly different” test will be applied in a manner similar to the *In re Wands* factors, such that the examiner has the initial burden to establish a reasonable basis to question whether the claimed invention is patentable subject matter. In the enablement context, an examiner is required to “explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable

³¹ 763 F.2d 1406, 1411 (Fed. Cir. 1985).

³² Pub. L. No. 104-41, 109 Stat. 351 (1995); 141 Cong. Rec. S11201-03 (1995) (statement of Sen. Orrin Hatch) (explaining that the Act was intended to “modif[y] the test for obtaining a process patent by clarifying *In re Durden*”).

³³ See 35 U.S.C. § 103(b) (2006). § 103 has since been further amended and the 1995 Act’s provisions have been removed as part of the sweeping changes implemented by the America Invents Act. However, nothing in the legislative history of the America Invents Act suggests a change in congressional policy toward biotechnology patents.



THE BOSTON PATENT LAW ASSOCIATION

evidence or reasoning.”³⁴ Although this does not require the examiner to go through each of the factors, it does require the examiner to “focus on those factors, reasons, and evidence that lead the examiner to conclude” that the claims are not patent eligible.³⁵ Enablement rejections commonly require several pages of analysis in office actions. Generating such rejections takes time, increasing the resources required for examination.

As in the enablement context, the Guidance suggests that the burden will shift to the applicant to establish patent eligibility after the examiner issues such a rejection. Because of the fact-intensive and multifactor inquiry required to overcome such a rejection, preparing such a response subjects the applicant to significant “trouble and expense.”³⁶ A diligent practitioner must consider and respond to each of the factors in the test, “present[ing] persuasive arguments, supported by suitable proofs where necessary,” including but not limited to factual affidavits and other evidence.³⁷ Preparing such a response is a labor-intensive task, requiring many hours of work from a patent agent or attorney and, accordingly, increasing the prosecution costs required to obtain patent protection.

Because multifactor analyses like the “significantly different” test increase the time and money required to obtain a patent, they should be deployed only in narrow circumstances. The enablement analysis turns to the *Wands* factors only if “there is a reason to doubt the objective truth of the statements contained” in a patent application,³⁸ expressly because of the “trouble and expense” required for an applicant to respond to a rejection under this test.³⁹ The Guidance’s “significantly different” test, however, appears to be overbroad by design and will capture many claims that ultimately are patent eligible, as the examples contained in the Guidance demonstrate.⁴⁰ Although any test by necessity must probe some breadth around the actual boundary of patent eligibility, broadly sweeping in claimed inventions such as fireworks containing a particular assembly of man-made components that happens also to include one or more natural products is unnecessarily overbroad. The adverse time and cost effects of this approach will act as a tax on America’s innovators, and it will unduly burden the USPTO’s own examiners. The USPTO should therefore seek to narrow the universe of claims that enter its multifactor test, such that these costs are minimized.

³⁴ MPEP § 2164.04 (emphasis added); *see also In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971).

³⁵ MPEP § 2164.04.

³⁶ MPEP § 2164.04 (recognizing trouble and expense of responding to enablement rejection); *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971) (same); *Ex parte Sredni*, Appeal No. 2001-0918, 2003 WL 23013217, at *3 (B.P.A.I. 2003) (same).

³⁷ MPEP § 2164.05.

³⁸ *Id.* § 2164.04.

³⁹ *Id.*; *see also Marzocchi*, 439 F.2d at 224.

⁴⁰ *See* Guidance Ex. A, cl. 2; Ex. B, cls. 2, 3; Ex. C; Ex. E, cl. 2; Ex. F; Ex. G, cl. 3 (all eligible under § 101).



THE BOSTON PATENT LAW ASSOCIATION

III. SUGGESTED ADDITIONS TO THE GUIDANCE TO PROMOTE UNDERSTANDING BY EXAMINERS AND PATENT APPLICANTS

BPLA suggests that additions to the Guidance, as outlined below, would further the important goal of consistency in patent examination.

A. Predictability and Consistency in Patentable Subject Matter Are Key Concerns for Innovation-Based Industries

The innovation industries, and particular the life science industries, heavily rely on the prospect of patent protection to justify significant investments in research and development. Patent protection is critical to attracting investments and recouping the significant early expenditures for the type of skill, hard work, and ingenuity required to create and develop inventions in these fields. Many years may pass between these research investments and their returns. Accordingly, predictability and consistency in the patent system are paramount concerns for these industries. The Supreme Court has recognized that these values are key for the patent system to function properly, recognizing in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* that “[f]undamental alterations in [patent] rules risk destroying the legitimate expectations of inventors in their property.”⁴¹ Accordingly, as the USPTO begins to implement the Supreme Court’s recent patentable subject matter decisions and craft its final Guidance (and the MPEP), it should take steps to maintain predictability and consistency.

B. Additional Examples Applying the USPTO’s Interpretation of Supreme Court Case Law Will Promote Consistent Examination

1. A Broader Scope of Examples Is Necessary for Examiners to Consistently Apply, and for the Innovation Industries to Understand, the Scope of the Guidance

Although the Guidance appears to affect nearly all inventions involving or touching on natural products, it offers few discrete hints of what inventions are patent eligible going forward and what inventions are not. Although they provide some assistance, the examples in the Guidance do not address a sufficient range of subject matter and claim language to afford sufficient guidance to examiners attempting to implement its broad scope. This inserts great uncertainty into the examination process. That uncertainty, in turn, casts a cloud over innovator companies, making it difficult for them to predict which projects may generate returns on investments and causing doubt among investors.

The following list summarizes just a few of the gray areas left by the examples in the Guidance. All of these technologies represent significant areas of research and development activity, underscoring the significance of predictability in the USPTO’s approach to patentable

⁴¹ 535 U.S. 722, 739 (2002).



THE BOSTON PATENT LAW ASSOCIATION

subject matter in these fields. BPLA suggests that the USPTO supplement the Guidance with additional concrete examples of patent eligible claims in at least the following areas.

- **Isolated or Purified Medicinal Substances.** The Guidance offers only one example of purified medicinal substances: Example B, dealing with “amazonic acid.” This single hypothetical example, however, provides insufficient guidance to this large field. First, purity is a relative concept, suggesting the presence of other components in the claimed substance. Many claims are therefore to *compositions* comprising an active substance of a certain purity. The Guidance is silent as to whether this distinction affects the new § 101 analysis, instead improperly implying to examiners that purified compounds generally are not patent eligible. Second, many claims are currently drafted to *pharmaceutical* compositions having a certain purity. Such compositions may have additional requirements that distinguish the claimed compositions from those that exist in nature. For example, pharmaceutical compositions generally should not contain toxic components. The Guidance does not address whether this distinction affects the patentability analysis.

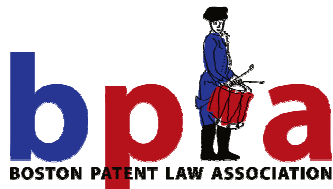
The USPTO has acknowledged, in training documents, that certain purification of natural products may be sufficient to create a patentable invention. In its March 19, 2014 training slides, the USPTO gave an example of a claim to pasteurized pomelo juice.⁴² Despite pomelo juice being a natural product, the slides deem the claim patentable under § 101 because “[n]aturally occurring pomelo juice contains vitamin C and flavonoids” and “[t]he specification describes the pasteurization process as damaging the chemical structure of the vitamin C and flavonoids in the juice.”⁴³ From this, the training slides conclude that “the pasteurized pomelo juice is markedly different in structure from what exists in nature.”⁴⁴ It remains unclear exactly how the pasteurized pomelo juice example in these slides is different from the purified amazonic acid claim in Example B of the Guidance. If the focus is on the specification, and what “purified” means in the particular specification, then further information and examples in this regard should be provided. The USPTO would help promote predictability by issuing additional examples addressing and explaining the distinctions. Further examples of patent eligible claims to purified compositions would be particularly useful for applicants.

- **Derivatives of Natural Products.** Natural products serve as lead compounds for countless areas of drug discovery. They serve as starting points for small molecule discovery; they are the proteins that many biologics seek to imitate; and they are the building blocks used for many vaccines and for gene therapy developments. The

⁴² U.S. Patent & Trademark Office, Evaluating Subject Matter Eligibility Under 35 USC § 101, at 75-78 (Mar. 19, 2014), available at http://www.uspto.gov/patents/law/exam/myriad-mayo_slides_20140319.pdf.

⁴³ *Id.* at 77.

⁴⁴ *Id.*



THE BOSTON PATENT LAW ASSOCIATION

Guidance offers only a single example addressing this important area: a methylated derivative of a small molecule natural product. Although useful, this example provides little certainty about the state of patent protection for the following other types of natural product derivatives:

- Stereoisomers of natural products, including both enantiomers and diastereomers;
- Fragment antigen-binding (Fab) fragments, which are derived from immunoglobulin monomers;
- Truncated peptides, such as epitopes;
- Antisense oligonucleotides, derived from naturally occurring genes;
- siRNA, which is derived from naturally occurring genes and is central to RNAi technology;
- Oligonucleotide primers, which are derived from naturally occurring genes;
- Aptamers, including both oligonucleic acid and peptide aptamers;
- Tagged proteins, including both recombinant tagged proteins and synthetically tagged proteins (*e.g.*, PEGylated proteins); and
- Fusion proteins.

All of these diverse types of molecules are derived, in some way, from natural products. Some add to the natural product, some take away from it, and some use it to guide the creation of an entirely new compound. The Guidance's single example of methylation is insufficient to allow for consistent examination and provide any degree of predictability in all of these related, yet distinct, areas. Again, additional examples of patent eligible claims would be useful.

- **Combinations of Natural Products.** Combinations of natural products with other compounds are also economically significant. These may include salts, powders, aerosols, suspensions, colloids, and other types of mixtures. Significantly, this category also includes pharmaceutical compositions, which frequently are mixtures of natural and man-made products. For example, a synthetic drug that is formulated in pill form commonly includes natural products in addition to the synthetic active ingredient. The natural products may include excipients—*e.g.*, disaccharides, polysaccharides, gelatin, and chemicals like magnesium stearate. Although the Guidance provides one example of a manufacture claim reciting a natural product, the chosen example—fireworks—offers little to inform examination in other fields, such as biotechnology and pharmaceuticals.



THE BOSTON PATENT LAW ASSOCIATION

This problem becomes more complex in situations where the combination consists of multiple natural products. A frequent embodiment of this problem will be formulated drugs where the active ingredient itself is a natural product. Although the Guidance includes one example discussing claims to combinations of natural products, that example (which is directed to a combination of bacteria) is of limited use to the industry because it merely recites the facts and outcome of one Supreme Court case.

Further examples confirming the patent eligibility of man-made compositions that include one or more natural components (like the firework, or a pharmaceutical composition) would be helpful to both applicants and examiners.

2. Examiners and Applicants Require More Complete Examples of How the Guidance Is to Be Implemented in Prosecution

The Guidance could also be enhanced by adding either stand-alone examples or additional material to the existing examples demonstrating what type of response by a patent applicant would be sufficient to overcome a rejection under the “significantly different” test. The examples, as written, focus on how the examining corps should review applications to make initial rejections for § 101 issues, but they provide little information regarding arguments or evidence that would be sufficient to rebut rejections under the Guidance’s test. The examining corps would benefit from additional instruction on how to apply the Guidance in back-and-forth exchanges with applicants.

The Guidance recognizes that “[t]he examiner’s analysis should carefully consider every relevant factor and related evidence.”⁴⁵ This makes clear that the Guidance contemplates some examination of material outside the claims themselves, and possibly even outside the four corners of the application, to determine patent eligibility under § 101. Accordingly, in response to a rejection under the Guidance’s test, patent practitioners will be faced with the decision of whether to argue based on the claim language or specification, and/or submit additional evidence, beyond that considered by the examiner, to make a case for patent eligibility. The examples, however, do not offer instruction on what evidence that might be or the threshold to which the evidence must rise in order to overcome the rejection. Without such examples, examiners will be left to develop their own standards, which may vary widely. The USPTO has provided such interpretive tools for examiners in related contexts, such as for rejections under § 112’s enablement requirement. *See, e.g.*, MPEP § 2164.05 (discussing types of evidence that an applicant may submit to overcome a rejection and explaining standard that such evidence must meet). To promote consistency and efficiency in prosecution, examples addressing how examiners should consider responses to rejections under the Guidance’s test is important.

⁴⁵ Guidance at 4.



C. Additional Explanation of How Examiners Are to Apply the Guidance’s Test Will Promote Consistency

The Guidance could be expanded in other ways to further promote consistency in applying the “significantly different” analysis, a standard that includes significant room for examiner discretion. Each decision point in the test represents another opportunity for reasonable examiners to differ, as does the outcome of the overall balancing between the 12 factors in the “significantly different” analysis.

To reduce potential inconsistency, more explanation could be provided regarding how the Guidance is to be used. First, to promote consistency in deciding what applications proceed to Step 3 of the Guidance’s flow chart, the Guidance could provide further definitions of the judicial exceptions—law of nature, natural principle, natural phenomena, and natural product—as they are to be applied by examiners. To the extent that these terms do not easily lend themselves to precise definitions, the Guidance could impose an interpretive methodology that examiners should use. For example, the Guidance could suggest that these terms be construed narrowly or broadly (although, for reasons noted above, a broad interpretation could promote unnecessary restrictions on the scope of patentable subject matter).⁴⁶ Such additional interpretive guidance could prevent the undesirable situation of two market competitors with similar technologies receiving markedly different levels of patent protection simply because of the examiners assigned to their applications.

Second, the Guidance could promote consistency by explaining in more detail how its examples are to be interpreted. Some examiners may see each example as reflecting a totality of the circumstances analysis, while others may see them as checklists for various types of claims. Example B, claim 3 is illustrative. One possible reading of this example is that a method of treatment claim using a natural product is permissible if it does not preclude all uses of a naturally occurring compound. Another reading, however, is that a method of treatment claim using a natural product is allowable under § 101 if it recites a narrow dose range, a narrow dosage period, and a specific type of patient, and is directed toward treating a disease that the natural product was not known previously known to treat. To the contrary, for example, a simple limitation as to a newly identified patient population should be sufficient to render a claim to administration of a natural product patent eligible. BPLA suggests that the Guidance emphasize that the examples are merely illustrative, and that many other similar or different types of claims with one or more limitations distinguishing the claimed subject matter from a judicial exception also can be patent eligible. As discussed above, providing further examples of patent eligible claims of varying scope and language relating to, for example, methods of treatment, would be helpful for applicants and examiners.

⁴⁶ As explained above, the BPLA suggests that the USPTO adopt a narrow construction of these threshold terms. Yet, even if the USPTO rejects that recommendation, it should expressly take a position on how these terms are to be interpreted to promote consistency.



THE BOSTON PATENT LAW ASSOCIATION

IV. CONCLUSION

The BPLA appreciates the opportunity to comment on the USPTO's proposed Guidance for the examination of patent claims concerning laws of nature, natural phenomena, and natural products. Thank you for considering our comments.

Sincerely,

Boston Patent Law Association

By: 

BPLA Patent Office Practice Committee Co-Chairs

Emily R. Whelan, Esq.

Nicole A. Palmer, Esq.