31 July 2014

Via E-Mail Only: myriad-mayo_2014@uspto.gov
Raul Tamayo, Senior Legal Advisor
Office of the 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:

GlaxoSmithKline (hereinafter "GSK") is a research-based pharmaceutical company committed to improving the quality of human life by developing new pharmaceutical, vaccine, and consumer health care products. GSK supports the United States Patent and Trademark Office (US PTO) in its efforts to improve the quality of patent examination, and to provide guidance regarding the eligibility of inventions that relate to naturally-occurring substances.

The present paper provides comments on areas where GSK believes the US PTO's recent Guidance (the 'Guidance') regarding subject matter eligibility is overbroad and/or not consistent with relevant case law.[1] While the specific contributions of naturally-occurring products to the development of safe, effective medicines and vaccines has been addressed in detail elsewhere and, for brevity, will not be catalogued here, we refer to a review by researchers from the National Institutes of Health. This review, an analysis of natural-based therapies over the period of 1981 to 2010, concluded that "natural products play a dominant role in the discovery of leads for the development of drugs for the treatment of human diseases."[1]

---

[1] Memorandum from Andrew H. Hirschfeld, Deputy Comm'r for Patent Examination Policy, 2014 Policy 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").

[1] David J. Newman and Gordon M. Cragg, "Natural Products as Sources of New Drugs over the Thirty Years from 1981 to 2010", J. Natural Products 75:311-335, 330 (2012).

## I. The Constitutional Basis of Patents

> Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;
>
> U.S. Const. Art. I, §8.

The Supreme Court has previously noted that "[t]he subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal" of promoting the progress of science.[2] The PTO's recent Guidance, in contrast, imposes impermissibly broad *exceptions* on patentable subject matter, and is at odds with both statutory and Supreme Court case law.

Patents spur investment into and development of new pharmaceuticals to address evolving healthcare needs. For example, by the 1980s it was known that certain strains of bacteria had become resistant to penicillin antibiotics. [3]

Clavulanic acid, a compound naturally synthesized by the bacterium *S. clavuligerus*, was first identified by scientists at the Beecham Group (a predecessor company to both SmithKlineBeecham and GlaxoSmithKline). Clavulanic acid, a 'product of nature' has only "weak antibacterial activity."[4] However, the combination of clavulanic acid with a penicillin antibiotic had a surprising synergistic effect, and provided a powerful new weapon against infections caused by penicillin-resistant bacteria.

GSK undertook the expensive and time-consuming development of clavulanic acid at the time, with the prospect of a period of exclusivity provided by patent protection. GSK was granted U.S. Patent 6,051,703 to purified clavulanic acid. The combination of amoxicillin and clavulanic acid (marketed by GSK as Augmentin®), was a breakthrough medicine and remains a standard in antibiotic therapy. It is still on the World Health Organization's list of Essential Medicines, "a list of minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost-effective medicines for priority conditions."

Denying patent protection to naturally occurring compounds, such as clavulanic acid, will dis-incentivize research on natural products, adversely impact the development of new medicines, and negatively impact global health. Augmentin® is no longer patented and is

---

[2] *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S. Ct. 2204 (1980).

[3] See, e.g., Marks, Clin Pediatr (Phila) 23(10):535-41 (1984) (regarding the "increasing prevalence" of multiple antibiotic resistant forms of H. influenzae).

[4] Stein & Gurwith, Clin. Pharm. 3(6):591-9 (1984).

widely produced by generic manufacturers; society benefitted from the incentives created by the patent system.

## II. The Guidance is Not Supported by Case Law

The language of 35 USC §101 is broad, stating that patents are available for "any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof." In contrast, the *exceptions* to §101 are narrow.

A basic tenet of statutory interpretation is that exceptions should be interpreted narrowly. *Commissioner of Internal Revenue v. Clark*, 489 U.S. 726, 739 (1989) ("In construing provisions … in which a general statement of policy is qualified by an exception, we usually read the exception narrowly in order to preserve the primary operation of the provision," (citing *Phillips, Inc. v. Walling,* 324 U.S. 490, 493, 65 S.Ct. 807, 808, 89 L.Ed. 1095 (1945) ("To extend an exemption to other than those plainly and unmistakably within its terms and spirit is to abuse the interpretative process and to frustrate the announced will of the people."))).

The Guidance is stated as implementing "a new procedure to address changes in the law relating to subject matter eligibility under 35 USC §101 in view of recent court decisions."[5] The specific decisions cited are *Association for Molecular Pathology v. Myriad Genetic, Inc.*[6] *(Myriad)* and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[7] *(Mayo).*

As a starting point, the *Mayo* Court cautioned against an overly broad reading of the 'laws of nature' exception: "too broad an interpretation of this exclusionary principle could eviscerate patent law . . . all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract idea."[8] The *Myriad* Court repeated this concern.[9]

Each of *Myriad* and *Mayo* represents an *exception* to the statutory provision regarding subject matter eligibility, and is based on the specific facts of that case. The Guidance broadens these disparate cases into a "factor-based analysis" that impermissibly synthesizes the rulings of multiple cases. This cannot be justified by analogy to the enablement analysis based on the factors set forth in *In re Wands.*[10] Each of the *Wands* factors stem from that single decision, and thus it is appropriate to combine them into a single multi-factor analysis -- the factors were meant to be considered together and to carry equal weight. This is not the situation with the present PTO Guidance.

---

[5] See *supra* note 1, cover memorandum.
[6] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 566 U.S. ___, 133 S.Ct. 2107 (2013).
[7] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 569 U.S. ___, 132 S.Ct. 1289 (2012).
[8] *Id.* at 1293-94.
[9] See *supra* note 5 at 2116.
[10] *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (discussing the several factors regarding enablement analysis).

The Guidance sets forth a new "significantly different" standard for assessing patentable subject matter.[11] This standard is not found in any single court case, but instead combines the "*marked difference* from what exists in nature" standard from *Myriad* with the "addition of *significantly more* to the judicial exception" standard from *Mayo*.[12]

## III. The Guidance Improperly Extends the Holdings of *Myriad* and *Mayo*

The Supreme Court has addressed only limited, specific issues in each of *Myriad* and *Mayo*, and has made clear that it is §101 that is broad, not the exceptions to it.[13]

The Supreme Court's order granting *certiorari* in *Myriad* was limited to the question: "Are human genes patentable?"[14] The *Myriad* case addressed two specific questions: "whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U.S.C. § 101 by virtue of its isolation from the rest of the human genome," and whether "synthetically created DNA known as complementary DNA (cDNA), which contains the same protein coding information found in a segment of natural DNA," was patent-eligible.[15]

The Supreme Court expressed its holding narrowly, stating "(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."[16] Importantly, the *Myriad* Court noted "what is *not* implicated by this decision."[17] The Court pointed out that there were no method claims at issue, that the case did not pertain to "patents on new *applications* of knowledge" about naturally-occurring genes, and there were no claims to "DNA in which the order of the naturally occurring nucleotides has been altered."[18]

*Mayo* addressed whether a process claim directed to a method of optimizing therapeutic efficacy for treatment of a medical condition was patent eligible.[19] The Supreme Court reasoned that the process claims in question "purport[ed] to apply natural laws" and that "the claimed processes have [not] transformed these unpatentable natural laws into patent-eligible applications

---

[11] See *supra* note 1.
[12] *Id.*
[13] See *supra* notes 5 and 6.
[14] *Myriad*, 133 S. Ct. at 2111.
[15] *Id.*
[16] *Id.* (emphasis added).
[17] *Id.* at 2119.
[18] *Id.* at 2120.
[19] *Mayo*, 132 S.Ct. at 1289.

of those laws."[20] The Court found that "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field."[21] However, the Court in *Mayo* made a point of noting that it was *not* deciding whether, "were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them."[22]

In addition, the *Mayo* Court distinguished the claims at issue from what it viewed as a typical drug use patent: "Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims [at issue] do not confine their reach to particular applications of [the natural laws at issue]."[23]

In direct contradiction to the Supreme Court's stated intention, the PTO's Guidance has expanded *Myriad* and *Mayo* holdings to apply to every naturally occurring substance, and to almost everything that contains or could be derived from such a substance.

Further, the Guidance focuses solely on structural differences, ignoring other characteristics such as utility or function. *Myriad* is consistent with the position that a new characteristic, utility, or *function* could convert an otherwise 'naturally occurring substance' into patent eligible subject matter. *Myriad* uses the term "information" to refer to the *function* of DNA. For instance, *Myriad* states: "Sequences of DNA nucleotides contain the information necessary to create strings of amino acids."[24] The Court considered both functional (informational) and structural changes in assessing whether isolated human genes are patentable, and concluded that "Myriad did not create or alter either the *genetic information* encoded in the BCRA1 and BCRA2 genes or the *genetic structure* of the DNA."[25] Thus, *Myriad's* analysis takes both structure and function into consideration in determining patent eligibility, and cannot support a §101 analysis based solely on differences in structure.

*Myriad* does exclude eligibility for a genetic sequence where the only aspect supporting patentability is isolation from the natural environment. But *Myriad* does not provide authority for excluding eligibility for a naturally occurring sequence where there are additional reasons supporting eligibility, e.g., a new utility.

Finally, the "significantly different" standard promulgated by the Guidance improperly combines the patentability inquiries in *Myriad* and *Mayo*. Such inquiries should have been kept separate and aligned with the holdings in the Supreme Court decisions.

---

[20] *Id.* at 1294.
[21] *Mayo*, 132 S. Ct. at 1294.
[22] *Id.* at 1302.
[23] *Id.*
[24] *Myriad*, 133 S. Ct. at 2109.
[25] *Id.* (emphasis added).

The Supreme Court in *Mayo* presented a "significantly more" test as it relates to process or method claims.[26] Relying on *Diamond v. Chakrabarty,* the Supreme Court in *Myriad* presented a "markedly different" test with respect to product claims.[27] The Guidance should stay true to these tests as set forth in Supreme Court precedent.

The holdings of *Myriad* and *Mayo* simply cannot be combined and applied to inventions that were not addressed in those opinions.

## IV. The Guidance Factor-weighing Test Breaks from Former USPTO Guidance

### A. USPTO Guidance in past has closely tracked US Supreme Court decisions

*(1) Graham v Deere*

When 35 U.S.C. § 103 obviousness was addressed by the US Supreme Court in *Graham v. Deere*[28], the USPTO issued guidelines to Examiners on how to assess obviousness during examination of US patent applications. Those guidelines, incorporated into § 2141 of the Manual for Patent Examining Procedure (MPEP), built upon what became known as the "Graham factors", but are taken directly from the Supreme Court decision of *Graham v. Deere*. The § 103 Obviousness guidelines dealing with the Graham factors rely on a factual assessment of the claimed invention, but in every fundamental way those guidelines adhere to the Supreme Court-delineated Graham factors and secondary considerations[29]. The USPTO did not create any factors, and did not expand upon the Court's holding.

*(2) In re Wands*

When the Court considered Enablement under 35 § 112,[30] as expanded by the Federal Circuit in the decision *In re Wands*[31], the USPTO again issued guidelines to Examiners, this time regarding whether a claimed invention met the requirements of Enablement under section 112. Those guidelines were also incorporated into the Manual

---

[26] *Mayo*, 132 S. Ct. at 1294 ("The Court's precedents] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.").

[27] *Myriad*, 133 S. Ct. at 2117 ("The *Chakrabarty* bacterium was new 'with markedly different characteristics from any found in nature,' 447 U.S., at 310, due to the additional plasmids and resultant 'capacity for degrading oil." (citing *Diamond v. Chakrabarty,* 447 U.S. 303, 100 S. Ct. 2204 (1980))).

[28] *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966).

[29] See MPEP § 2141, II THE BASIC FACTUAL INQUIRES OF GRAHAM v. JOHN DEERE CO. "...As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated *in Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:..."

[30] *See Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916).

[31] *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

for Patent Examining and Procedure (MPEP).[32] As with the USTPO guidelines on obviousness, these Enablement guidelines relied on adherence to the Supreme Court's holding and consideration of the Federal Circuit's Wands factors[33].

*(3) KSR International*

When the Supreme Court reconsidered obviousness with the *KSR* decision, expanding on the *Graham* decision[34], the USPTO issued new obviousness guidelines, but again adhered to the actual *KSR* Supreme Court decision for creating the revised obviousness guidelines. Thus, in addition to the Graham factors and secondary considerations, the USPTO Examiners were now instructed to look at the rationale for obviousness that the Supreme Court set forth in the *KSR* decision that could support a *prima facie* case of obviousness during prosecution, which *prima facie* case could be rebutted by the inventor in a number of ways[35]. At no point did the USPTO create new factors, new rationale, new elements to consider, or stray from the actual Supreme Court holdings these USPTO Guidelines were based on.

In short, none of these guidelines expanded Supreme Court or CAFC holdings; these guidelines simply applied court holdings to the examination of patent applications to help Examiners determine whether the claimed invention met the requirements for §112 Enablement and §103 Non-obviousness.

In contrast, the newly proposed Myriad/Mayo Guidance moves into uncharted territory. The Myriad/Mayo Guidance memorandum contains non-judicially created factors, hypothetical examples unsupported by any language in the *Myriad* or *Mayo* decisions, and includes classes of inventions that, if one follows these guidelines, fall within a significantly expanded judicial exception for patent eligible subject matter. As the title itself expresses, the USPTO now considers the judicial exception of laws of nature to include any subject matter or process "Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products."

---

[32] See MPEP §2164.01 "The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

[33] See MPEP § 2164.01(a) "Undue Experimentation Factors", which states that "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: …"

[34] Section 2141 of the Manual for Patent Examining Procedure (MPEP) states: "As reiterated by the Supreme Court in *KSR,* the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966).

[35] See *Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.* 72 Federal Register 195 (Oct. 10, 2007) (Notices, pp 57526-57535)

Such an expanded scope for judicially excepted patent eligible subject matter was never considered in either *Myriad* or *Mayo*. As written, the Guidance and the expanded judicial exception now includes small molecule natural products, amino acid sequences, peptides with natural sequences, antigens and antibodies, and mixtures of elements/molecules (e.g. gunpowder). The new USPTO guidelines also broadly sweep methods for using a naturally occurring substance into the judicial exceptions, such that the use of vectors (and thus transformed cells), recombinant molecules and synthetic molecules could be considered patent ineligible subject matter according to the USPTO Guidance[36] [37]. As discussed in an online essay in response to the USPTO Patent Eligibility memorandum "…the position now adopted by the USPTO in the Myriad/Mayo guidelines seems clearly inconsistent with the understanding of the Justices of the Supreme Court."[38]

B. Myriad/Mayo Guidance creates factors/tests where none existed in original USSC decisions

*(1) New Factors*

The proposed USPTO guidelines created, *de novo*, an overly complicated and confusing "factor-based analysis" for determining whether a claimed invention meets the standards for patentable subject matter under 35 U.S.C. § 101. Six factors sprang up weighing in favor of eligibility, and six factors appeared weighing against eligibility.[39]

This USPTO-created factor-based analysis was synthesized from the partial holdings of a combination of cases[40], a broad reading of the case law, and without regard to the

---

[36] See slide 33 of the USPTO presentation titled "Evaluating Subject Matter Eligibility Under 35 USC §101", presented at the Biotechnology/Chemical/Pharmaceutical Customer Partnership (BCP) meeting on April 16, 2014, available at http://www.aipla.org/committees/committee_pages/Biotechnology/usptobcp/BCP%20Meeting%20Materials/BCP%20Site/041614/BCP%20Eligibility%20Slides%20(Apr%202014)%20FINAL.pdf

[37] http://www.patentdocs.org/2014/04/uspto-tries-to-address-public-misunderstandings-regarding-myriad-mayo-guidance.html ("[Ms. Cohan] also indicated that examiners had been warned not to jump to conclusions based on the inclusion of any particular claim terms (*e.g.*, cDNA) because there are no magic words for establishing subject matter eligibility. Examples of some of these terms were provided in one slide: "…- E.g. words such as "cDNA", "composition", "isolated", "primer", "purified", "recombinant", "synthetic", and "vector" (emphasis added) as quoted from "USPTO Tries to Address Public Misunderstandings Regarding Myriad-Mayo Guidance" – April 16, 2014 by Donald Zuhn)

[38] See IP Watchdog, March 10, 2014 "USPTO Patent Eligibility Guidelines: A Topsy Turvy Approach to Natural Products" by Paul Cole, http://www.ipwatchdog.com/2014/03/10/uspto-patent-eligibility-guidelines-natural-products/id=48451/

[39] See March 4, 2014 Memorandum to Patent Examining Corps.

[40] See "USPTO Tries to Address Public Misunderstandings Regarding Myriad-Mayo Guidance" – April 16, 2014 by Donald Zuhn", exemplified slide 19 titled "Supreme Court Eligibility Decisions are Interrelated" http://www.aipla.org/committees/committee_pages/Biotechnology/usptobcp/BCP%20Meeting%20Materials/BCP%20Site/041614/BCP%20Eligibility%20Slides%20(Apr%202014)%20FINAL.pdf

unique holding of each case as informed by the particular facts and limitations of each case.

Moreover, comparing these new § 101 factors to the 'Wands' enablement factors as a way to justify application of these new factors is not appropriate because (a) the Wands factors go to a requirement (enablement), not to an *exception* to patent eligibility; (b) the Wands factors are based on a single case, so the factors are meant to be considered as a whole; and (c) the present factors from the Myriad/Mayo Guidelines arise from an impermissible amalgamation of the holdings from multiple Supreme Court cases. These factors never existed as a discrete set of factors, created by statute or case law, as hurdle to be overcome to meet the requirement for eligible subject matter under § 101 of the Patent Act.

The judicial exceptions to patentable subject matter should be narrowly construed based on the limited and fact-specific court decisions that make up the 101 case law as it now stands – they should not be categorically expanded by way of an over-reaching Memorandum to the Examining Corps by the Deputy Commissioner for Patent Examination Policy at the USPTO.

(2) *New Tests - PTO Guidelines require "significantly different" to find patent eligible subject matter*

The "significantly different" standard for inventions based on a naturally occurring product is an improper misconstruction of the Supreme Court's holding in *Mayo* (which discussed a process having "significantly more" in the claimed method that applies or uses a law or product of nature, referencing *Parker* v. *Flook*, 437 U. S. 584, 594 (1978)) and the holding in *Myriad* (which discussed a claim to a product that was "markedly different" from substance found in nature, referencing *Diamond* v. *Chakrabarty*, 447 U. S. 303(1980)). Neither *Mayo* nor *Myriad* set this language out as a "test" for patent eligible subject matter, and nowhere in either decision do the words "significantly different" appear as a test of patent eligibility. Moreover, there is also no discussion of what "significantly different" would entail in either of these decisions, with respect to patent eligible subject matter, and how such a test would be assessed.

The guidance offered in *Mayo* is simply put: "...do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" (*see Mayo* at p. 1396). In *Myriad*, taking care to emphasize what the decisions does not cover, the Court states "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." *See Myriad* at p.2124, emphasis added. This narrow language does not state that a genomic DNA

sequence is never patentable, or its use in vectors or in bioprocessing methods. Nor does this narrow language state that other substances isolated from nature are not patent eligible. There are no broadly applicable factors to use, or a broad test to apply, that can assess patent eligible subject matter in either of the *Mayo* or *Myriad* Supreme Court cases.

C. Myriad/Mayo guidance confuses, rather than clarifies

The Memorandum to the Examining Corps contains hypothetical examples for products and methods, in which the USPTO analyzes claims under each category for patent eligibility. As stated in an online article after release of the Memorandum "one concern with the USPTO's factors is that they are written in sufficiently generalized language so as to require further explanation… factor j) provides no explanation as to the parameters of a well-understood, purely conventional, or routine element. It is likely that a differing of opinions will abound when determining whether a claim limitation meets these standards"[41].

## V. The Guidance Effectively Creates a New Legal Standard

The PTO's powers, as set forth in 35 U.S.C. § 2, include the granting and issuing of patents and the dissemination of information regarding patents to the public.[42] More specifically, the PTO "may establish regulations, not inconsistent with the law which (A) shall govern the conduct of proceedings in the Office; [and which] (B) shall be made in accordance with section 553 of title 5."[43] It is well established that the PTO does not have substantive rulemaking powers.[44]

Thus the USPTO is well within its authority to provide guidance to Patent Examiners regarding its interpretation of the law and, under the Administrative Procedures Act (APA), to engage in procedural rulemaking.

However, the present Guidance is substantive in nature. The Guidance sets forth a new standard for assessing patentable subject matter, and applies it beyond the scope of the Supreme Court rulings regarding exceptions to subject matter patentability. The "significantly different" standard of the Guidance is a combination of the "*marked difference* from what exists in nature" standard from *Myriad* and the "addition of *significantly more* to the judicial exception" standard from *Mayo*. This is an improper expansion of statute and the case law, and effectively creates a

---

[41] See the March 6, 2014 IP update by Leslie A. McDonell at http://www.finnegan.com/IPUpdtaeUSPTOIssuesNewGuidelinesonPatentEligibilityforSubjectMatterDerivedfromNature/.

[42] *See* 35 U.S.C. § 2(a).

[43] *See* 35 USC § 2(b)(2).

[44] *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

new legal standard for patentability. As an agency within the executive branch, the PTO does not have the power to create a new legal standard.

## VI. Conclusion

In view of the shortcomings of the March 4, 2014 Memorandum to the Patent Examining Corps from Deputy Commission Andrew H. Hirshfeld with the subject "2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products", GSK requests that the Office issue new Guidance regarding patent eligible subject matter under 35 U.S.C. §101 that adheres to established case law and does not impermissibly expand the judicial exceptions to patent eligible subject matter under 35 U.S.C. §101.

GlaxoSmithKline thanks the US Patent and Trademark Office for this opportunity to comment.

Sincerely,

Charles M. Kinzig
Vice President Patent Litigation and IP Policy,
North & South America
GlaxoSmithKline
709 Swedeland Road
King of Prussia, PA 19046