October 28, 2015

Via E-Mail Only: 2014_interim_guidance@uspto.gov
Hon. Michelle K. Lee
Under Secretary of Commerce
U.S. Patent and Trademark Office
Alexandria, Virginia

Re: Comments on USPTO July 2015 Update: Subject Matter Eligibility (80 Fed. Reg. 45429, July 30, 2015) (the 'Update')

Dear Director Lee:

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 ("Office") 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 comment concerns the Office's position on the prima facie case analysis set forth in the Update in Section IV (the "Update"). This comment explains why the Update's prima facie analysis is applicable to naturally occurring substance claims. It provides comments on areas where GSK believes the Update's prima facie analysis is overbroad and/or not consistent with the relevant law or past Office guidance. GSK urges the Office to revise the current prima facie guidance.

1. Outline of this comment

The Update is the first Office guidance after Alice[1] and Myriad[2] that explicitly discusses the prima facie evidentiary burden for examiners making a patent ineligible subject matter rejection. Although the Update cites primarily to cases discussing algorithmic and mathematical subject matter, the prima facie analysis of the Update explicitly states that it should be used to "…identify a law of nature, a natural phenomenon, or an abstract idea[.]"[3] Because natural products fall within the category of laws of nature or natural phenomena under the applicable guidance,[4] the Update's prima facie test applies to naturally occurring substances. This comment focuses on the deficiencies of the prima facie guidance as applied to naturally occurring substances and urges the Office to revise the guidance in accordance with applicable law.

To understand the Update's deficiencies, one must consider Section IV of the Update which states:

> For subject matter eligibility, the examiner's burden is met by clearly articulating the reason(s) why the claimed invention is not eligible, for example by providing a reasoned rationale that identifies the judicial exception recited in the claim and why it is considered an exception, and that identifies the additional elements in the claim (if any) and explains why they do not amount

[1] Alice Corp. v. CLS Bank International, 573 U.S. __, 134 S. Ct. 2347 (2014).
[2] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ___, 133 S. Ct. 2107 (2013).
[3] Update, p.7, first full para.
[4] 2014 Interim Guidance on Subject Matter Eligibility published on Dec. 16, 2014 (79 Fed. Reg. 74618, 74622)("IEG")

> to significantly more than the exception. This rationale may rely, where appropriate, on the knowledge generally available to those in the art, on the case law precedent, on applicant's own disclosure, or on evidence. Sample rejections satisfying this burden are found in the training materials, particularly the worksheets for Examples 5-8.[5] Once the examiner has satisfied her initial burden, the burden then shifts to the applicant.
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> The courts consider the determination of whether a claim is eligible (which involves identifying whether an exception such as an abstract idea is being claimed) to be a question of law. Accordingly, courts do not rely on evidence that a claimed concept is a judicial exception, and in most cases resolve the ultimate legal conclusion on eligibility without making any factual findings. For example:
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> *Alice Corp.*, *Myriad*, *Mayo*, *Bilski*, *Diehr*, *Flook* and *Benson* relied solely on comparisons to concepts found to be exceptions in past decisions when identifying judicial exceptions.

The Update then states:

> The 2014 IEG follows the analysis used by the Supreme Court and the Federal Circuit by comparing claimed concepts to prior court decisions to identify a law of nature, a natural phenomenon, or an abstract idea for Step 2A.[6]

This guidance suffers from vagueness because it fails to clearly explain when an examiner may rely solely upon case law precedent and when additional analysis (in the form of general knowledge, the applicant's disclosure, or documentary evidence) is required. It is overbroad because it does not emphasize that the inquiry relates to narrow exceptions to § 101 eligible subject matter identified by the Supreme Court. As written, the Update leaves the impression that examiners may forego providing evidence that a claimed concept is a judicial exception, may resolve the ultimate legal conclusion on eligibility without making any factual findings, and may rely solely on comparisons to concepts found to be exceptions in past decisions.

For reasons explained herein, the lack of a factual finding requirement departs from Supreme Court precedent, violates the Administrative Procedure Act (APA), and contradicts the Office's own past guidance with respect to examination. As a consequence, the Office's guidance accords scientific references and Rule 132 declarations an improperly diminished value in the examination of claims to naturally occurring substances. Confusion over the role of facts in the eligibility analysis already impacts practitioners and applicants during prosecution. The Update will only broaden that confusion, rather than assist examiners to resolve it. Section 2 of this comment treats each point in turn.

The Update's prima facie case improperly creates an over-arching, fact-free eligibility analysis rather than heeding the Supreme Court's caution that court-made exceptions to eligibility are narrow and applicable to the facts of the specific cases. The Update creates a new standard for eligibility contradicting the APA's prohibition against agency-derived law. The Update also encourages examiners to synthesize the holdings of various court cases and apply the result by analogy to an applicant's claims, unlike past Office guidance that depends on the use of a factual analysis. The result is that any claim can be found ineligible under the Update since it is always possible to generalize a given application to the point that it is analogous to some Supreme Court or Federal Circuit decision. Section 3 of this comment elaborates on these issues.

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[5] Update, p.6 (emphasis added). The examples from the training materials relate to claimed subject matter that may or may not be an abstract idea, not the prima facie case applicable to an alleged natural product.

[6] Update, p.7. It is not clear what the Update intends with this statement, as appellate courts review evidence and factual findings and evidence from the trial courts. In contrast, no such records exist for examiners so examiners cannot perform an analogous role.

The Office has announced that it plans to provide additional biotechnology-related examples for demonstrating prima facie rejections under § 101.[7] In view of the problems with the Update's guidance, we urge the Office to revise the guidance in conjunction with the addition of biotechnology-related examples.

Any revised guidance should avoid a § 101 synthesis that neither the legislature nor the courts have endorsed; rather, the Office should provide guidance that relates to specific case law developments – as it has successfully done in the past. For instance, the Office drafted the KSR Guidelines[8] with specific factual examples exemplifying the new Supreme Court law which the examination corps was able to use to analogize specific factual situations to claims under examination. In contrast, the Update's prima facie case analysis references various elements from a multitude of cases and instructs examiners to apply them by analogy to claims under examination. The Office should return to the successful model exemplified by the KSR Guidelines by drafting specific factual examples applying the rule stated by the Supreme Court in Myriad, and instructing personnel how to apply that guidance to naturally occurring substance claims.

2. The Update Provides Insufficient Guidance for Establishing and Rebutting a Prima Facie Case

Despite its title, "Requirements of a Prima Facie Case," Section IV of the Update provides few details about the actual elements of a prima facie case. The Update provides insufficient guidance regarding establishing a prima facie case for natural products under § 101 because it fails to address the Supreme Court's Myriad analysis, the requirements of the APA, and even fails to reference its own previous guidance for making a prima facie case of ineligibility under § 101. These issues are explained in subpart (A)(i)-(iv) of this Section of the comment. Moreover, the Update provides no guidance for assessing rebuttal evidence, or the determination whether rebuttal evidence overcomes a prima facie case. This issue is discussed in subpart (B) of this Section of the comment. The Update also encourages the examining corps to engage in legal analysis by comparing the claimed concepts under examination to prior court decisions to identify natural products. This issue is discussed in subpart (C) of this comment.

(A) The Update Does Not Correctly Reflect the Factual Requirements of a § 101 Prima Facie Case

The requirements of a prima facie case that examiners must have to support a claim rejection are well established. Under the Administrative Procedures Act and controlling federal case law, examiners must provide "substantial evidence" in support of all rejections.[9] Federal Circuit case law sets forth the procedure for examiners to use when making a rejection, and in this regard "[t]he examiner bears the initial burden…of presenting a prima facie case of unpatentability" before the burden shifts to the applicant to present reasons that the claimed subject matter is patentable.[10] The Office recognizes that the requirement to make a prima facie case applies to all statutory provisions, including 35 USC §§ 101, 112, 102, and 103 and that only after examiners confirm that they are able to set forth a prima facie case of unpatentability should any rejection be imposed in an Office action.[11] The findings, conclusions and

[7] Update, p.1.

[8] See the Examination Guidelines for Determining Obviousness Under 35 USC § 103, The KSR Decision and Principles of the Law of Obviousness, Manual for Patent Examining Procedure (MPEP) 2141 ("KSR Guidelines").

[9] See Administrative Procedure Act, 5 USC 500 et seq.; In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000); In re Dembiczak, 175 F.3d 994, 999-1000 (Fed. Cir. 1999) (broad conclusory statements about the teaching of references are not "substantial evidence").

[10] In re Oetiker, 977F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

[11] See MPEP 2104, stating:

reasons which support them must be clearly stated.[12] With respect to § 101, in past guidance the Office has instructed its personnel to "…review the totality of the evidence (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter."[13] Indeed, this last aspect of the prior Office guidance is even referenced in the IEG.[14]

The Update restates the existence of the prima facie case requirement and describes some aspects of the initial burden it places on the examiner. It further notes that "This rationale may rely, where appropriate, on the knowledge generally available to those in the art, on the case law precedent, on applicant's own disclosure, or on evidence." But there is no guidance with respect to a *requirement* for evidence. For example, how does the examiner establish some concept or claim element is "knowledge generally available to those in the art" and equally important, how is an applicant supposed to challenge that assertion? The prima facie analysis in the Update also omits the "markedly different characteristics" analysis for examining naturally occurring substances. Accordingly, the Update should provide guidance as to the development of appropriate factual evidence to support a prima facie case.

From this point forward, the Update departs from precedent and states that a 101 decision is a question of law and that *"[C]ourts do not rely on evidence that a claimed concept is a judicial exception*, and in most cases resolve the ultimate legal conclusion on eligibility without making any factual findings."[15] It then states that "*Alice Corp., Myriad, Mayo, Bilski, Diehr, Flook,* and *Benson* relied solely on comparisons to concepts found to be exceptions in past decisions when identifying judicial exceptions."[16] The Update concludes that the guidance "…follows the analysis used by the Supreme Court and the Federal Circuit by comparing claimed concepts to prior court decisions to identify a law of nature, a natural phenomenon, or an abstract idea for Step 2A."[17] Taken together, these statements imply that an examiner may typically identify judicial exceptions without factual analysis and reject claims by comparing them to judicial exceptions identified in past decisions, even in situations where the markedly different characteristics analysis is employed. As discussed in subparts (i)-(iv), the standard set by the Update is incorrect.

(i) The Update Does Not Follow the Supreme Court Precedent of Myriad

Contrary to the Update, the Myriad court did not rely solely on comparisons to previous rulings upon judicial exceptions when holding isolated genes to be unpatentable subject matter. In fact, while the Myriad Court looked to prior decisions for illustration of the type of analysis that should be performed, it did not rely on the factual or legal findings in past decisions when determining whether the claimed substances were naturally occurring. Rather, when deciding whether the claimed isolated genes were a natural product, Judge Thomas' majority opinion was predicated on pages of factual analysis about the nature of DNA, what happens to isolated DNA, the differences between cDNA and genomic DNA, and so on, all in order to reach a conclusion on the issue of whether there was anything

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> Once USPTO personnel have concluded the above analyses of the claimed invention under all the statutory provisions, including 35 USC 101, 112, 102, and 103,they should review all the proposed rejections and their bases to confirm that they are able to set forth a prima facie case of unpatentability. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions and reasons which support them.

[12] Id.
[13] See MPEP 2106.
[14] See IEG, 74624-74625.
[15] Update, p.6 (emphasis added).
[16] Id.
[17] Id. at p.7.

markedly different about the claimed subject matter from naturally occurring genes.[18] These facts largely came from 15-plus pages of fact finding made by the trial court.[19]

As written, the Update encourages the resolution of the eligibility question – without any factual findings – by comparing claimed concepts to prior court decisions. The Update allows examiners to make rejections by conjecture and analogy, rather than by sound argument based in fact. Without the establishment of a factual record, it is not possible to credibly evaluate whether the claimed invention presents markedly different characteristics from a naturally occurring substance. In this regard, the Supreme Court in Myriad highlights the problem with conclusions regarding the eligibility of naturally occurring substance claims that are divorced from the relevant factual context, stating: "The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable."[20] If the Court had not been able to establish that the phenomenon at issue was "unusual" and "rare" (both of which are factual findings), the Supreme Court may conceivably have arrived at a different – and incorrect – conclusion regarding the eligibility of cDNA.

But instead of following the Myriad analysis, which was grounded in a factual record that enabled the evaluation of whether various claims at hand were directed to naturally occurring products, the Update allows examiners to support a prima facie case by making comparisons to concepts found to be exceptions in past decisions without making any factual findings about the claimed inventions or the relevant context. We submit that the identification of an alleged natural product must follow the Myriad analysis such that any rejection is (1) supported by evidence in the form of factual findings, (2) presents conclusions stemming from these facts, and (3) articulates the reasons connecting the two. In this regard, revised guidance should specify that a prima facie case of ineligibility based on application of the markedly different characteristics test must clearly communicate findings, conclusions and reasons that – if unchallenged – are sufficient to support a conclusion that the claimed invention does not include markedly different characteristics. The Office should accordingly provide revised guidance.

(ii) The Update Does Not Follow the APA in Accordance with Controlling Supreme Court Precedent

Under the Administrative Procedures Act, examiners must provide "substantial evidence" in support of all rejections. The Supreme Court has held that the Office is bound by the APA standards of review, noting that "[t] he parties agree that the [Office] is an 'agency' subject to the APA's constraints."[21] The Update, however, does not mention the required evidentiary standard, nor does it explain how to satisfy the requirement for evidence. It states only that "The 2014 IEG follows the analysis used by the Supreme Court and the Federal Circuit by comparing claimed concepts to prior court decisions to identify a law of nature, a natural phenomenon, or an abstract idea for Step 2A."[22] Such a comparison does not satisfy the APA requirement for substantial evidence.[23] The Office should provide revised guidance that the identification of an alleged natural product must be supported by substantial evidence.

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[18] Myriad, pp.2-18.
[19] Association for Molecular Pathology v. United States Patent and Trademark Office, 702 F. Supp. 2d 181, 192–207 (SDNY 2010).
[20] Myriad, n.8.
[21] Dickinson v. Zurko, 527 U.S. 150, 152 (1999).
[22] Update, p.7.
[23] Nor does the Update statement accurately reflect the Office's own examiner training materials. See "Examples: Nature-Based Products" (issued December 16, 2014), available at http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf.

(iii) The Update Does Not Follow Federal Circuit Case Law

In case after case, the Court of Appeals for the Federal Circuit has repeatedly held that the PTO cannot rely on an "assessment of basic knowledge and common sense not based on any evidence in the record."[24] "[R]requisite findings" must be "based on the evidence of record."[25] Any suggestion that determinations under § 101 can be distinguished from such determinations under § 103 because § 101 is a "question of law" must be rethought. Like § 101, § 103 is a question of law as well based upon underlying facts.[26] Further, Examiners should be required to provide factual evidentiary support for a § 101 rejection in accordance with 35 USC § 132. That Section "is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection."[27]

Indeed, in keeping with such Federal Circuit precedent, the PTAB has found that Examiners must come forward with facts and evidence to support a § 101 rejection, reversing a rejection where "the Examiner merely expresses an opinion that "a set of rules qualifies as an abstract idea."[28] In short, "[t]he PTO bears the initial burden of establishing a prima facie case of patent-ineligible subject matter under 35 USC § 101." Id.

(iv) The Update Does Not Follow Existing Office Guidance

The Update encourages the examining corps to identify natural phenomenon by comparing the claimed concepts to prior court decisions under the analysis set forth in Step 2A without documentary evidence. This contradicts the Office's own guidance that provides the circumstances in which personnel may take official notice in place of providing factual evidence are rare: "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known."[29] The Office should provide revised guidance that all steps in the identification of an alleged natural product – including the prima facie case and any rebuttal – must be supported by documentary evidence unless the examiner can establish that the facts are so well-known as to be unquestionable. If that is the case, it should not be a burden on the examiner to recite documentary evidence to support the proposition at the outset. Doing so would facilitate compact prosecution.

(B) The Update Provides No Guidance Relating to Rebuttal Evidence

The Update lacks guidance for examiners facing an applicant's challenge to the factual basis of a prima facie case. In past guidance the Office itself recognized that "[i]f applicant challenges a factual assertion as not properly officially noticed or not properly based upon common knowledge, the examiner must support the finding with adequate evidence."[30] Thus, if an applicant challenges the examiner's assertion that the claimed subject matter is a judicial exception, the examiner must support the

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[24] In Re Zurko, 258 F.3d 1379, 1385 (Fed. Cir. 2001); In re Sang-Su Lee, 277 F. 3d 1338, 1344-1345 (Fed. Cir. 2002) ("the law requires authority" be provided to support a rejection); Velander v. Garner, 348 F. 3d 1359, 1380-1381 (Fed. Cir. 2003) ("requisite findings [must be] based on the evidence of record"); Perfect Web Technologies, Inc. v. InfoUSA, Inc., 587 F. 3d 1324, 1328 (Fed. Cir. 2009).

[25] Velander, 348 F. 3d at 1380-1381; see also Perfect Web, 587 F. 3d at 1328 ("basic knowledge and common sense [must be] based on … evidence in the record.'").

[26] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966) .

[27] Chester v. Miller, 906 F.2d 1574, 1578 (Fed.Cir.1990).

[28] See In re Renald Poisson, Appeal 2012-011084 (Feb. 27, 2015) (non-precedential) (http://e-foia.uspto.gov/Foia/RetrievePdf?system=BPAI&flNm=fd2012011084-02-26-2015-1)

[29] See MPEP 2144.03A.

[30] See MPEP 2144.03C.

allegation that it is a judicial exception with adequate evidence. As the APA provides, the substantial evidence standard must be met. Broad conclusory statements are not "substantial evidence."

The Office should revise the guidance to require examiners to provide supporting evidence and, where an applicant challenges any aspect of the prima facie case, include a finding under the materially different characteristics test.

(C) The Update Encourages Office Personnel to Engage in Legal Analysis

The Update states that its prima facie analysis may rely, where appropriate, on the knowledge generally available to those in the art, on the case law precedent, on applicant's own disclosure, or on evidence. But the Update then states that its guidance "…follows the analysis used by the Supreme Court and the Federal Circuit by comparing claimed concepts to prior court decisions to identify a law of nature, a natural phenomenon, or an abstract idea for Step 2A." This implies that an examiner should build a prima facie case upon the comparison between claimed subject matter and prior court decisions, and erroneously encourages the mixing of concepts and facts from multiple cases. Any comparison to the facts in prior precedential cases should be based upon the facts of a single case, and the use of mere concepts or facts synthesized from multiple cases, is inappropriate, as discussed above. The Update fails to emphasize the strengths of examiners: the technically trained examining corps is expert at interpreting scientific evidence to reach a conclusion on patentability.

The prima facie analysis set forth in the Update should be revised to prohibit a rejection founded solely on comparison to case law except when it is factually demonstrated that the claims are drawn to the same subject matter and similar facts that past cases specifically held to be an ineligible judicial exception. Otherwise, examiners run the risk of improperly and impermissibly extending and/or broadening the courts' holdings. Moreover, the Update's prima facie guidance should incorporate by reference those portions of the Manual for Patent Examining Procedure (MPEP) that require office personnel to "review the totality of the *evidence* (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter,"[31] as well as those that require office personnel to support challenged elements of the prima facie case with adequate evidence. [32]

Without such revised guidance, examiners may justify a rejection solely by stating that the claimed subject matter is "really nothing more than a claim to an isolated natural molecule," and that "after Myriad, molecules isolated from nature are not patentable." Such conclusory reasoning could be improperly extended and impermissibly applied across technology areas as diverse as vaccines, industrial enzymes, and therapeutic peptides. Although such reasoning should be found insufficient and overturned on appeal, an applicant would have to commit roughly 30 months to the appellate process. The Update should be revised in accordance with the foregoing suggestions to avoid such needless delay for applicants who are claiming products that have never previously been found to be judicial exemptions, but which are vulnerable to a fact-free rejection under § 101.[33]

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[31] See MPEP 2106(III).

[32] See MPEP 2144.03C.

[33] See "Request for Comments on 2014 Interim Guidance on Patent Subject Matter Eligibility 79 Fed. Reg. 74618 (December 16, 2014)" American Intellectual Property Law Association (AIPLA), available at http://www.aipla.org/advocacy/executive/Documents/AIPLACommentstoUSPTO-InterimGuidance-PatentSubjectMatterEligibility-3.16.15.pdf stating: "However, in practice, examiners are making conclusory statements that shift the burden to the patent applicant … with no requirement that the examiner cite a reference (or references) to support an assertion that a process is a law of nature or an idea is a 'fundamental practice long prevalent in the field.'"

3. A Universal Prima Facie Analysis Misrepresents Supreme Court Eligibility Holdings

The Update attempts to create a uniform prima facie analysis for discerning judicial exemptions from eligible subject matter. In particular, the Update states:[34]

> [M]ost cases resolve the ultimate legal conclusion on eligibility without making any factual findings. For example:
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> *Alice Corp.*, *Myriad*, *Mayo*, *Bilski*, *Diehr*, *Flook* and *Benson* relied solely on comparisons to concepts found to be exceptions in past decisions when identifying judicial exceptions.

This premise is incorrect. In these Supreme Court cases, the Court drew upon prior principles, but in each case provided a factual explanation and analysis of the specific subject matter at issue. Moreover, that the Supreme Court would decide a case without fact-finding itself is not only unsurprising, it is reflective of the nature of the United States judicial system: the trial court has the role of primary fact finder, not the Supreme Court.[35] The appropriate absence of fact finding in these Supreme Court cases cited in the Update does not prove that eligibility was determined without factual evidence.

That the Update missed the central role of fact finding in the eligibility analysis is attributable to the difficulty of creating a universal test for all judicial exceptions. In setting forth a test of universal applicability, the Update omitted a role within its prima facie case for the markedly different characteristics inquiry of Diamond v. Chakrabarty, 447 U. S. 303 (1980), which Myriad found to be central to determining whether a claimed product is patent eligible. If the Office wishes to create a universal prima facie analysis for eligibility, it must clearly indicate the evidentiary burden placed on examiners for all applicable eligibility tests within the prima facie analysis, including the markedly different characteristics test from the Myriad and Chakrabarty line of cases. Where the specification recites characteristics of the product, the guidance should make clear that the examiner bears the initial burden with respect to the markedly different test characteristics and that in most cases factual finding will be required. The Office should recognize the primary importance of fact finding in revised guidance.

Revising the Update would be consistent with the Supreme Court's warning to "...tread carefully in construing this exclusionary principle lest it swallow all of patent law."[36] The cases in which the courts have found claims ineligible represent distinct exceptions to the statutory provision regarding subject matter eligibility and each is based on the specific facts of that case. A basic tenet of statutory interpretation is that exceptions should be interpreted narrowly.[37]

The Update does not tread cautiously; it creates a vague, purportedly universal rule for establishing a prima facie case with no specific enumerated elements, and incorrectly asserts that the ultimate legal conclusion on eligibility is typically reached –without any factual findings – by comparison to concepts (not facts) previously held to be exceptions. A universally applicable, fact-free test for the identification of judicial exceptions is not supported by statute or case law and represents a substantial broadening of the exception to eligibility.

When it revises the guidance, the Office should remove the implication that a complete analysis typically relies solely on comparisons to concepts found to be judicial exceptions in past decisions, as this

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[34] Update, p.6 (emphasis added).

[35] See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 123 (1969) (explaining that reviewing courts must recognize that their function is not to decide factual issues de novo).

[36] See Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. __, 134 S. Ct. 2347, 2354 (2014); Myriad at 2116; Mayo at 1293-4.

[37] 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").

encourages examiners to engage in legal analysis by applying court holdings to "claimed concepts" while foregoing engaging in fact finding. This approach ignores a role (fact finding) for which examiners' technical training is particularly suited.

4. The Office Should Provide Guidance Specific to the Prima Facie Case for Natural Products Based Upon Myriad and in Compliance with the APA

The Office has announced that it plans to provide additional biotechnology-related examples for examiners to follow when making a prima facie case to support a rejection under § 101. Given the pitfalls of a universally applicable eligibility analysis, it seems most practical for the Office to revise the current Update to provide a prima facie analysis specific to naturally occurring substances; such an analysis should rely on the Myriad and Chakrabarty line of cases, which enumerate the elements of a prima facie case including the proper treatment of the materially different characteristics inquiry and the proper role for fact finding. Guidance specific to naturally occurring substances should be presented with the upcoming biotechnology guidance.

The Update must also be revised to comply with the APA. Although the Office is well within its authority to provide guidance to examiners regarding its interpretation of the law and, under the APA, to engage in procedural rulemaking,[38] the Update's prima facie case guidance is substantive in nature. The Update sets forth a new fact-free path for assessing eligible subject matter, and applies it beyond the scope of the Supreme Court rulings regarding exceptions to eligibility. This is an improper expansion of law, and effectively creates a new legal standard for eligibility. As an agency within the executive branch constrained statutorily to procedural rulemaking, the Office does not have the power to create a new legal standard.

The past is replete with examples where the Office has appropriately provided guidance restricted to each new case. Until now, the Office has set guidelines for examiners based on the holding of a case, and without combining elements from different holdings to develop a new hybrid standard that was not endorsed by the courts. For instance, when the Supreme Court reconsidered obviousness with the KSR decision,[39] the Office issued new obviousness guidelines, but adhered to the actual KSR Supreme Court decision in creating the revised obviousness guidelines.[40] At no point did the Office create stray from the actual Supreme Court holding the Guidelines were based on.

Rather than designing a legal analysis that departs from the applicable law, the Office should revise the present Update to reflect the holdings of the Supreme Court. A revised prima facie analysis for alleged natural products is required.

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[38] The PTO's powers, as set forth in 35 USC § 2, include the granting and issuing of patents and the dissemination of information regarding patents to the public. See 35 USC § 2(a). 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 § 553 of title 5." See 35 USC§ 2(b)(2). It is well established that the PTO does not have substantive rulemaking powers. 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).

[39] The MPEP states in § 2141: "As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 USC 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

[40] See Examination Guidelines for Determining Obviousness under 35 US. 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. 5752657535).

5. Conclusion

In view of the shortcomings of the July 2015 Update: Subject Matter Eligibility (80 Fed. Reg. 45429), GSK requests that the Office issue revised guidance regarding the prima facie case for patent eligible subject matter under 35 USC §101. Revised guidance should adhere to established case law and not impermissibly expand the judicial exceptions to patent eligible subject matter under 35 USC § 101. Preferably, the Office will present guidance specific to the analysis for naturally occurring substances according to the Myriad and Chakrabarty line of cases that enumerates the elements of a prima facie case, includes the materially different characteristics inquiry, and the provides a proper role for fact finding. This guidance should be presented with the upcoming biotechnology-related examples.

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

Sincerely,

Charles M. Kinzig
Vice President, Global Patents
GlaxoSmithKline
709 Swedeland Road
King of Prussia, PA 19046