



FÉDÉRATION INTERNATIONALE DES CONSEILS
EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF
INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION
VON PATENTANWÄLTEN

Roberto Pistolesi, Secretary General
Via Nino Bixio, 7
20129 Milano
Italy
t. +39 02 2901 4418
f. +39 02 2900 3139
Roberto.Pistolesi@ficpi.org

27 October 2015

via email: 2014_interim_guidance@uspto.gov

United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314
USA

RE \\ FICPI Comments on the USPTO July 2015 Update: Subject Matter Eligibility

Dear Sirs,

On behalf of the Bureau of FICPI, I submit the attached comments in response to the notice entitled “2014 Interim Guidance on Patent Subject Matter Eligibility”, published in the Federal Register at 80 FR 45429 on 30 July 2015 and in the Official Gazette at 1417 Off. Gaz. Pat. Office 252 on 25 August 2015.

The USPTO’s kind consideration of our Federation’s attached comments is respectfully requested.

Yours faithfully,

Roberto Pistolesi
Secretary General

Enc.



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Comments on USPTO July 2015 Update: Subject Matter Eligibility

FICPI, the Fédération Internationale des Conseils en Propriété Intellectuelle (International Federation of Intellectual Property Attorneys) would like to provide its comments on the update memorandum titled *July 2015 Update: Subject Matter Eligibility* (“Update”), issued by the U.S. Patent and Trademark Office (“USPTO”) on July 30, 2015.

Founded over 100 years ago, **FICPI** represents IP attorneys in private practice internationally with over 5,200 members in 81 countries and regions, including all major countries. **FICPI** has strong US and European memberships and has recent and growing sections in India and China. **FICPI** aims to enhance international cooperation amongst IP attorneys, study reforms and improvements to IP treaties and conventions with a view to facilitating the exercise by inventors of their rights, increasing their security and simplifying procedures and formalities, and promote the training and continuing education of its members and others interested in IP.

The Update is the third in a series of publications by the USPTO in an effort to provide guidance in view of recent Supreme Court decisions, including *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289, 101 USPQ2d 1962 (2012), *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S.Ct. 2107, 106 USPQ2d 1972 (2013) and *Alice Corporation Pty. Ltd. V. CLS Bank International et al.*, 573 U.S. ___, 134 S.Ct. 2347, 110 USPQ2d 1976 (2014).

FICPI has previously provided comments on an initial USPTO publication titled *Guidance For Determining Subject Matter Eligibility OF Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* (“Guidance”), issued on March 4, 2014. The Guidance focused on how the USPTO would consider subject matter eligibility under 35 U.S.C. 101 in view of the *Mayo* and *Myriad* cases, which related to methods of optimizing therapeutic efficacy for the treatment of immune-mediated disorders (*Mayo*), and compositions (DNA sequences) useful for the detection of mutations in a BRCA gene (*Myriad*). It was **FICPI**’s position that “the Guidance over-reaches with respect to the



holdings in the *Mayo* and *Myriad* decisions, resulting in a prohibition on patenting subject matter in the U.S. that is patentable throughout much of the rest of the developed world” and could be considered a violation of the TRIPs agreement.

On December 16, 2014, the USPTO published the *2014 Interim Guidance on Patent Subject Matter Eligibility* (“2014 IEG”), which superseded the March Guidance, and took into consideration the holdings in the *Alice* case, which related to a method of exchanging credit obligations as between a stakeholder and an exchange institution. The 2014 IEG provided a framework for a two-step claim analysis involving a Step 1 of determining whether a claim was directed to a process, machine, manufacture or composition of matter, a Step 2A of determining whether the claim was directed to a law of nature, a natural phenomenon or an abstract idea, and a Step 2B of determining whether the claim recited additional elements that amount to “significantly more” than the judicial exception. A “streamlined analysis” was articulated where, in Step 2A, a claim could be qualified as subject matter eligible if the claimed invention had “markedly different characteristics” than that which existed in nature.

FICPI did not submit comments regarding the 2014 Interim Guidance, having favorably considered the advances made in instituting the “two-step analysis of patent eligibility,” the “streamlined analysis” and the acknowledgment that a natural product could be eligible for patent protection if the isolated natural product exhibited a difference in functional activity from its activity in nature.

FICPI welcomes the compilation of the Update as a positive step by the USPTO to bring uniformity in examining patent applications in the fields of “business method, graphical user interface (GUI), and software areas.” Specifically, the Update addresses previous comments on the 2014 IEG, including:

- (1) requests for additional examples, particularly for claims directed to abstract ideas and laws of nature;
- (2) further explanation of the markedly different characteristics (MDC) analysis;
- (3) further information regarding how examiners identify abstract ideas;
- (4) discussion of the *prima facie* case and the role of evidence with respect to eligibility rejections;
- (5) information regarding application of the 2014 IEG in the corps; and
- (6) explanation of the role of



preemption in the eligibility analysis, including a discussion of the streamlined analysis.

However, the Update notes that “[e]xamples in the biotechnology area, especially diagnostic and other method claims directed to laws of nature and natural phenomena, are in process in light of recent judicial developments.” The Update mentions a recent decision, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (Fed. Cir. 2015) (*en banc* petition 2015), in which the Federal Circuit found methods of detecting paternally inherited nucleic acid of fetal origin by amplification and detection to be ineligible subject matter.

The Update focuses on the issue of identifying claims directed to “abstract ideas” or “laws of nature,” which are said to represent “‘basic tools of scientific and technological work’ that lie beyond the domain of patent protection.” The intent of identifying claims that are directed to “abstract ideas” is to avoid the “considerable danger that the grant of patents would ‘tie up’ the use of such tools and thereby ‘inhibit future innovation premised upon them’” (i.e., preemption of the field). The Update notes that the courts have declined to define abstract ideas other than by example, and therefore, the Update provides further examples for examiners to use for comparison purposes. The Update provides four general descriptions of subject matter that could be considered to be an abstract idea: (1) fundamental economic practices; (2) certain methods of organizing human activity; (3) an idea of itself – “an uninstantiated concept, plan or scheme, as well as a mental process (thinking) that ‘can be performed in the human mind, or by a human using a pen and paper’”; and (4) mathematical relationships/formulas.

FICPI is concerned that these broad generalizations encourage examiners to reject claims as being directed to an abstract idea without a thorough analysis of the claims or a proper characterization of what “those in the art would recognize, as elements that are well-understood, routine and conventional.” The Update provides scant direction as to what, more than the mere opinion of the examiner, is required to present a *prima facie* case of ineligibility. As one example, the Update provides no direction to examiners regarding determining a level of skill for “those in the art” who might be capable of performing a claimed method in one’s own mind or by “using a pen and paper.”



The Patent Trial and Appeal Board (PTAB) has held that examiners must present a *prima facie* case of patent ineligibility, finding that an examiner’s mere “opinion” that claims are abstract is an “inadequate finding of fact on which to base the *Alice* analysis.” See *Ex parte Poisson*, No. 2012-011084 (PTAB Feb. 27, 2015). Rather, the “examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” See, e.g., *In re Oetiker*, 977 F.2d 1443, 1444 (Fed. Cir. 1992) (emphasis added); see also MPEP § 2106.III (citing *Oetiker*).

While the Update notes that examiners have been instructed to make such a *prima facie* case, and admits that the Supreme Court and the Federal Circuit have used textual evidence (e.g., books) to support that the claims are directed to an abstract idea, the Update stops short of identifying what is required from Examiners to present a *prima facie* case of ineligibility. FICPI is concerned that this will led to inconsistent and unpredictable results, neither of which is favorable to practitioners or the industry at large.

As noted in FICPI’s previous comments on the Guidance, courts have warned against over-application of finding claims directed to patent-ineligible subject matter. For example, Mr. Justice Frankfurter, in his concurrence in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440 (1948), anticipated the vagaries of terming something a “law of *nature*”:

It only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.

Funk Bros. at 134-135.

Furthermore,

...studiously ignoring all laws of nature when evaluating a patent application under §§102 and 103 would “make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.” *Id.*, at 189, n. 12...



Mayo at 1304. Likewise,

The rule against patents on naturally occurring things is not without limits, however, for “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and “too broad an interpretation of this exclusionary principle could eviscerate patent law.” 566 U.S., at ___ (slip op. at 2). As we have recognized before, patent protection strikes a delicate balance between creating “incentives that lead to creation, invention, and discovery” and “imped[ing] the flow of information that might permit, indeed spur, invention.” *Id.*, at ___, (slip op. at 23). We must apply this well-established standard to determine whether Myriad’s patents claim any “new and useful . . . composition of matter,” §101, or instead claim naturally occurring phenomena.

Myriad at 2116. Even the recent *Alice* case acknowledges the slippery slope:

At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. *Mayo*, 566 U.S. at ___ (slip op. at 2). At some level, “all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Id.*, at ___ (slip op., at 2). Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See *Diamond v. Diehr*, 450 U.S. 175, 187 (1981). “[A]pplication[s]” of such concepts “to a new and useful end,” we have said, remain eligible for patent protection. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

Alice, 573 U.S. at ___ (slip op. at 6).

FICPI recommends that the USPTO provide further guidance to avoid the present § 101 conundrum faced by applicants. The guidance should require that examiners thoroughly review the language of each claim and explicitly specify which elements make a claim drawn to an abstract idea. Examiners should be required to cite some evidence that the asserted abstract idea exists, including when the abstract idea is asserted to be “well known” or “conventional” in the field of art. Because of the absence of meaningful guidelines on identifying abstract ideas or other ineligible subject matter, and in light of the Supreme Court’s acknowledgement that all inventions embody such concepts at some level, it is difficult to persuade an examiner to reverse such a finding. When combined with the difficulties of addressing the “significantly more” aspect of the *Alice-Mayo* framework, the current environment places applicants between a rock and a hard place when responding to a § 101 rejection.



Moreover, the Update provides little, if any, direction regarding what would constitute a sufficient response by applicants to overcome a § 101 rejection. Examiners need to be instructed to thoroughly and objectively consider arguments regarding whether the claim language “confines the claim to a particular useful application” and “improves the technology,” thus demonstrating “significantly more.”

FICPI is pleased to see that the Update confirms that “examiners are to consider all additional elements both individually and in combination to determine whether the claim as a whole amounts to significantly more than a [judicial] exception.” (Emphasis in original.) However, **FICPI** is concerned that the Update does not sufficiently instruct examiners on how to objectively determine whether a combination of steps results in an overall function that is not generic, and thus demonstrates “significantly more.”

The Update refers to a “Streamlined Analysis” for examiners to utilize when the claims “clearly do not seek to tie up any judicial exception such that others cannot practice it.” **FICPI** is concerned that examiners will not take full advantage of the streamlined analysis in favor of shifting the burden to applicants to demonstrate that the claim amounts to “significantly more” than the alleged abstract idea. Indeed, page 9 of the Update states that “the results of the streamlined analysis will always be the same as the full analysis, in that a claim that qualifies as eligible after Step 2A or Step 2B of the full analysis would also be eligible if the streamlined analysis were applied to that claim.” (Emphasis added.) This appears to neuter, rather than encourage, the streamlined analysis presented in the earlier guidance.

FICPI therefore concludes that the Update, while advancing training on the two-step analysis, still does not provide sufficient instruction to examiners on how to present a *prima facie* case of patent ineligibility. Further guidance is needed on how to objectively analyze a claim by considering all of its elements in combination, and how to objectively consider rebuttal arguments and evidence by applicants. Overly broad application of § 101 rejections will result in a prohibition on patenting subject matter in the U.S. that is patentable in other jurisdictions of the developed world, and runs the risk of discouraging foreign entities from pursuing patent



protection in the U.S., and investing in research by U.S. entities who would no longer be entitled to the reward of a limited period of protection for potentially life-enhancing, if not life-saving inventions.

FICPI hopes that the above comments may be useful for further clarification of the two-step analysis for subject matter eligibility in a way that safeguards the interests of both applicants and the public at large.

IMPORTANT NOTE:

The views set forth in this paper have been provisionally approved by the Bureau of FICPI and are subject to final approval by the Executive Committee (ExCo). The content of the paper may therefore change following review by the ExCo.

The International Federation of Intellectual Property Attorneys (FICPI) is the global representative body for intellectual property attorneys in private practice. FICPI's opinions are based on its members' experiences with a great diversity of clients having a wide range of different levels of knowledge, experience and business needs of the IP system.

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