FÉDÉRATION INTERNATIONALE DES CONSEILS
EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF
INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION
VON PATENTANWÄLTEN

Julian Crump, Secretary General
Alder Castle, 10 Noble Street
London. EC2V 7JX United Kingdom
t. +44 20 7776 7302
f. +44 20 7776 7301
julian.crump@ficpi.org

30 July 2014

Mr. Andrew H. Hirshfield
Deputy Commissioner For Patent Examination Policy

via email: myriad-mayo_2014@uspto.gov

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

RE \\ FICPI's Comments on the Guidance Memorandum issued on March 4, 2014

Dear Sir,

On behalf of FICPI, the International Federation of Intellectual Property Attorneys, I have pleasure in submitting our comments on the guidance memorandum titled *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* ("***Guidance***"), issued by the USPTO on March 4, 2014.

Yours faithfully,

Julian Crump,
FICPI Secretary General

Enc.

FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

Comments on the Guidance Memorandum issued on March 4, 2014

FICPI, the Fédération Internationale des Conseils en Propriété Intellectuelle (International Federation of Intellectual Property Attorneys) would like to provide its comments on the guidance memorandum titled *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (*"Guidance"*)*, issued by the USPTO on March 4, 2014.

Founded over 100 years ago, **FICPI** represents IP attorneys in private practice internationally with almost 5,500 members in 86 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.

FICPI welcomes the compilation of the Guidance as a positive step by the USPTO to bring uniformity in examining patent applications in the field of life science-related inventions. The Guidance seeks to remove non-uniformity and ambiguity regarding examination of such applications, after the *Mayo*[1] and *Myriad*[2] Supreme Court decisions. The Guidance covers various areas where both Examiners and Applicants are currently unclear regarding the extent to which such patent applications are subject to restrictions under the provisions of 35 USC § 101.

Nevertheless, **FICPI** maintains 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. The effects of this "over-reaching" are extensive and undesirable, including discouraging foreign entities from pursuing patent protection in the U.S., and discouraging the investment 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. Indeed, the Guidance could be considered a violation of the Agreement on Trade-Related Aspects of Intellectual Rights (TRIPs), which defines the minimum standards for intellectual property rights in over 170 countries. TRIPs requires that:

> *…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial*

[1] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289, 101 USPQ2d 1962 (2012).

[2] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013).

> *application... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*

Article 27(1).

Furthermore, **FICPI** observes that the Guidance does not consider the holdings of the Supreme Court cases as a whole. As a matter of fact, the USPTO is not merely applying the principles of the *Mayo* and *Myriad* decisions to the examination Guidelines. To the contrary, the USPTO is reinterpreting these latest Supreme Court decisions by extending them well beyond limited holdings in much earlier Supreme Court decisions, a result expressly disavowed by the Supreme Court in each instance. Notwithstanding FICPI's disagreement with the Supreme Court decisions in the *Mayo* and *Myriad* cases, **FICPI** understands that, although the USPTO is bound to apply the decisions of the Supreme Court as such, it has no authority to reinterpret the same.

Funk Bros.

For example, in the *Funk Bros.*[3] case, the Court distinguished a "law of nature" from a "discovery":

> *If there is to be invention from such a discovery, it must come from the **application** of the law of nature to a new **and useful end**.*

Funk Bros. at 130.

Mr. Justice Frankfurter, in his concurrence, 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. On the other hand, the suggestion that 'if there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end' may readily validate Bond's claim. Nor can it be contended that there was no invention because the composite has no new properties other than its ingredients in isolation. Bond's mixture does in fact have the new property of multi-service applicability. Multi-purpose tools, multivalent vaccines, vitamin complex composites, are examples of complexes whose sole new property is the conjunction of the properties of their components. Surely the Court does not mean*

[3] *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440 (1948).

> *unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged. In finding Bond's patent invalid I have tried to avoid a formulation which, while it would in fact justify bond's patent, would lay the basis for denying patentability to a large area within existing patent legislation.*

Funk Bros. at 134-135.

Indeed, *Funk Brothers* **does not address the issue of whether an isolated natural product behaves differently from the product itself in its native environment**: it merely says that:

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

Funk Bros. at 131.

The above quote clearly implies that, in contrast to the subject matter claimed in *Funk Bros.*, a claimed isolated natural product or composition containing such a product may constitute patent eligible subject matter if it satisfies one or more of the following factors: (1) has a "different use" from its naturally occurring components; (2) provides for an "enlargement of the range of…utility" in contrast to its naturally occurring components; (3) exhibits a "different effect" in contrast to the effect that the naturally occurring components always had; (4) "improves in any way" the natural functioning of the naturally occurring components; (5) serves any ends other than the "ends nature originally provided"; and (6) acts together with another component such that the resulting function or property is dependent on the effort of the patentee. *Funk Bros.*'s conclusions are thus limited to whether a mixture of naturally occurring bacteria is or is not patent eligible, and cannot be expanded any further.

Chakrabarty

Likewise, in the *Chakrabarty*[4] case, the Supreme Court noted that legislative history supports a broad co*nstruction of what is patent eligible subject matter under 35 USC § 101"*

> *…In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.*

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

> *The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]…" The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." …Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man…"*

Chakrabarty at 308. (Citations omitted.)

With respect to *Chakrabarty*, this case likewise **does not deal with isolated natural products**, but only with genetically modified bacteria, namely a *"non-naturally occurring manufacture or composition of matter - a product of human ingenuity "having a distinctive name, character [and] use*." *Chakrabarty* at 309-310.

Moreover, although *Chakrabarty* states that *a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter*, no indication or suggestion can be found in the decision as to whether such a principle should or could be applied to a natural product isolated from its natural environment and which, once isolated, behaves in a different way than it did in its original natural environment. In fact, the entire quote above from *Funk Bros.* at 131 is cited and endorsed in *Chakrabarty* (*Chakrabarty* at 310). This is an autonomous interpretation made by the USPTO, which has no technical or legal basis in *Chakrabarty.*

Mayo

Similarly, the Court in *Mayo* noted that "the 'machine-or-transformation' test is an '*important and useful clue'* to patentability," but did not necessarily trump the law of nature exclusion. *Mayo* at 1303. The Court likewise noted that it is the job of Congress, and not of the Supreme Court, to tailor the statutes if it intended to exclude certain types of inventions from patent eligibility:

> *In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. See, e.g., Flook, 437 U. S. 584 (holding narrow mathematical formula unpatentable). And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern.*

Mayo at 1303.

> *…But §§102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections. Cf. Diehr, 450 U. S., at 188 (patent claims "must be considered as a whole"). And 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.

> *In consequence, we 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. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U. S. C. §§161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.*

Mayo at 1305.

Myriad

Finally, the Court in Myriad likewise stressed that there cannot be an absolute preclusion of patent eligibility for naturally occurring things:

> *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.

The Guidance extends the holdings of *Mayo* and *Myriad* such that it effectively ignores that part of 35 USC §101 relating to whoever "discovers any new and useful process, machine, manufacture, or composition of matter". For example, setting aside the prohibition on patenting "isolated nucleic acids" that was the inspiration for the Guidance, based on the Guidance, even a new drug isolated from a plant would not be patentable even if, once isolated, the drug behaves in a different way than it did in its original natural environment. Indeed, the "isolation" step is one on which the chemical and

biotechnology industry focuses and invests in heavily, and without patent protection, research into "isolating" new products will be stifled.

Clearly, the intent of 35 USC §101 was to make eligible for patent protection that which is newly discovered, in addition to that which is newly created. As such, both are entitled to patent protection. This practice, as also expressly acknowledged by the USPTO itself in the Forum of May 9, 2014, has been followed by the U.S. Examiners and Judges for more than thirty years, leading to the grant of thousands of patents covering isolated naturally occurring products, having both therapeutic and non therapeutic indications.

FICPI understands that the USPTO is now of the opinion that *Myriad* would have made clear that isolating a gene, even though it "creates a non-naturally occurring molecule", is not enough for eligibility. Instead, eligibility would require the creation of something which is "markedly different" from what exists in nature.

Although **FICPI** does not agree with the conclusions reached by the Supreme Court in *Myriad*, it respectfully observes that such conclusions are limited to genes:

> *Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.*

Myriad at 2118.

Otherwise stated, the Court conflates DNA's functional aspects (information) with DNA's molecular structure; and there is no guidance in *Myriad* that the conclusion about the patent non-eligibility of genes should or could be extended to all isolated naturally occurring products *per se* and, in particular, to isolated naturally occurring products not carrying any genetic information.

Neither *Funk Brothers* nor *Chakrabarty* provides any contrary indication.

Importantly, the Court in Myriad noted inventions specifically not contemplated by the Decision, including method claims:

> *It is important to note what is not implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents "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," 702 F. Supp. 2d, at 202–203, and are not at issue in this case.*
>
> *Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, "[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications." 689 F. 3d, at 1349.*
>
> *Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of §101 to such endeavors.* ***We merely hold that genes and the information they encode are not patent eligible under §101*** *simply because they have been isolated from the surrounding genetic material.*

Myriad at 2120. (Emphasis added).

Thus, FICPI is thus of the opinion that *Myriad*'s interpretation of both *Chakrabarty* and *Funk Brothers* is perfectly compatible with the patent eligibility of isolated natural products other than genes.

In addition to its over-reaching effects, the Guidance lacks indications on how an Examiner is to construe a claim as "significantly different" from a judicial exception to patentability. Indeed, the Guidance uses terms without defining those terms[5]. For example, a "marked difference" is defined circularly as "a marked or significant structural difference" from a judicial exception. The guidance the USPTO provides on "marked difference" and "significantly different" must be enhanced, including many examples.

Examiners need to be trained not to assume that just because a judicial exception appears to be included as one feature in a claim, the claim as a whole is automatically ineligible. Indeed, an aggregation of elements that would not normally be found together in nature should be patentable if that combination provides a different property or functional result (e.g., a specific technical or

[5] The same essentially also applies to the Memorandum issued by the USPTO on June 25, 2014, in connection to the Supreme Court Decision in *Alice Corporation Pty. Ltd. V. CLS Bank International, et al.* as far as the term "significantly more" is concerned

synergistic effect). This conclusion is strongly supported by the above-discussed quote from *Funk Bros.* (*Funk Bros.* at 131) which was fully endorsed in *Chakrabarty* (*Chakrabarty* at 310). Examiners must be trained to consider the claim as a whole and not merely address its isolated parts. *Diamond v. Diehr*, 450 U.S. 175, 188, 209 USPQ 1, 7 (1981).

In addition, Examiners must be trained not to assume that just because a judicial exception is recited in the claim, it is not patent eligible, particularly when the claim relates to the discovery of a practical application of a natural product or phenomenon.

In conclusion:

- **FICPI** maintains that the Guidance unjustifiably and undesirably over-reaches with respect to the holdings in the *Mayo* and *Myriad* decisions, to the extent that isolated natural products/compositions and diagnostic methods that are clearly eligible for patenting under a proper interpretation of these decisions, as well as other Supreme Court decisions, may now be rejected by USPTO Patent Examiners as failing to be eligible subject matter for patenting.

- With respect to patent claims directed to isolated natural products/compositions, contrary to the USPTO's positions as articulated in the Guidance, the USPTO must at least take into account whether the claimed subject matter has a different or improved use or function so as to satisfy one or more of the above noted six factors based on the quotation from *Funk Bros.* at 131.

- With respect to claims directed to diagnostic methods, the discovery that the variation of the amount of a given compound in the blood is associated to a pathological condition (and, consequently, a diagnosis may be based on such a variation) is not a natural phenomenon *per se* but is the discovery of and *practical application* of a law of nature. Consequently, a claim covering obtaining a blood sample from the body of a human being and screening it to determine whether a variation of the amount of such a compound has occurred, should be patentable even according to 35 USC § 101.

- With respect to claims directed to a method of manufacture, such claims should not be subject to the eligibility tests under the Guidance given that *Myriad*[6] and *Funk Bros.*[7] both expressly excluded this subject matter from the scope of the respective decisions. Also, with respect to

[6] "It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court," *Myriad* at 2119.

[7] "We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable," *Funk Bros.* at 131.

claims directed to a method of treatment, both *Mayo*[8] and *Myriad*[9] indicated that such claims would be eligible.

Specific Suggestions for Changes to the Guidance Materials

In addition to the above comments on the general legal principles, FICPI believes that the following specific changes should be made to the Guidance materials to clarify issues for both Examiners and Applicants.

1. The function of any claimed product, including an isolated naturally occurring product, must be considered in determining patent eligibility.

The Guidance materials list six factors (a) – (f) that weigh toward eligibility. Missing from that list of factors is any mention of the function of the claimed product. As discussed above, in *Funk Bros.* the Court clearly emphasized that the claimed product, as compared to the naturally existing species, did not acquire any "different use", did not "enlarge the range of utility", did not have any "different effect", did not perform in a non-natural way, and did not improve in any way the "natural function". The Guidance materials should include an explanation that one factor that weighs toward eligibility is evidence that the claimed product has or performs a utility that is not performed by the naturally existing product, or performs a wider range of utility, or improves the function of the naturally existing product.

2. Claims to methods of treatment should be clearly patent eligible and not subject to the analysis outlined in the Guidance materials.

The Court in *Myriad* was clear to note that "there are no method claims before this Court". Neither *Funk Bros.* nor *Mayo* provides any basis for even considering whether method of treatment claims might be patent ineligible. The Guidance materials should be made clear on this issue. Example B of the Guidance materials analyzes a claim to a "method of treating colon cancer", which claim also recites a dosage time and a dosage amount. This example has already created confusion within the Examining Corps with some Examiners suggesting that to be patent eligible a method of treatment

[8] "Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the [Prometheus] patent claims do not confine their reach to particular applications of those laws," *Mayo* at 1302.

[9] "...this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes…Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications," *Myriad* at 2120.

claim needs to include some dosage limitations. Example 3 should be revised to make clear that a claim to "treating colon cancer" is patent eligible because such a method is not "naturally occurring", so 35 USC §101 is not implicated by such a claim.

FICPI hopes that the above comments may be useful for amending the Guidance in a way that safeguards the interests of both Applicants and Third Parties.

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.

* * *

The Australian Federation of Intellectual Property Attorneys, FICPI Canada, Association of Danish Intellectual Property Attorneys (ADIPA), Suomen Patenttiasiamiesyhdistys ry, Association de Conseils en Propriété Industrielle (ACPI), Patentanwaltskammer, Collegio Italiano dei Consulenti in Proprietà Industriale, Japanese Association of FICPI, Norske Patentingeniørers Forening (NPF), Associaçao Portuguesa dos Consultores em Propriedade Industrial (ACPI), F.I.C.P.I South Africa, the International Federation of Intellectual Property Attorneys – Swedish Association, Verband Schweizerischer Patent und Markenanwälte (VSP) and the British Association of the International Federation of Intellectual Property Attorneys are members of FICPI.

FICPI has national sections in Argentina, Austria, Belgium, Brazil, Chile, China, Colombia, Czech Republic, Greece, Hungary, India, Ireland, Israel, Mexico, Netherlands, New Zealand, Peru, Singapore, South Korea, Spain and the United States of America, and individual members in a further 49 countries.

[End of document]