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The USPTO Guidelines do not follow Myriad and Prometheus and should be retracted

These comments relate to the USPTO's Guidelines entitled "2014 Procedure for subject-matter eligibility analysis of claims reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products".

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Introduction

The Guidelines purport to "implement[s] a new procedure to address changes in the law relating to subject matter eligibility under 35 U.S.C. §101 in view of recent court decisions including [Myriad] and [Prometheus]". However, neither Myriad nor Prometheus changed the law relating to natural products. Myriad was a very narrow decision relating only to genes and the information they encode, whereas Prometheus did not relate to natural products at all. Prometheus simply confirms that claims that "tie up" a law of nature are not patent eligible, but it does not go further than this.

By introducing the new Guidelines, the USPTO is making it very difficult, even impossible to obtain patent protection for many inventions that the US courts have not deemed non-patent eligible. In doing so, the USPTO is acting contrary to the Supreme Court's warning in Myriad that it would be dangerous to extend the existing exclusions to patentability as this could "eviscerate" patent law:

> *"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".*

Similarly in Prometheus, the Supreme Court warned against applying exclusions to patent eligibility too broadly:

> *"Phenomena of nature, though just discovered, mental processes and abstract intellectual concepts are not patentable as they are the basic tools of scientific and technological work. Gottschalk v. Benson, … And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.*
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> *The court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in Diehr the Court pointed out that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm" … "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection".*

The Guidelines are certainly in danger of eviscerating patent law for many inventions in the biotechnology field. Patent applicants have started to face §101 objections based on the new Guidelines in US office actions which are forcing them to incorporate arbitrary limitations in the

claims, unduly narrowing the scope of protection available. Rather than incorporating arbitrary limitations, many applicants will take these cases to appeal. The Guidelines are not based on any legal precedents and so the US courts are not bound to follow them. In particular, as will be explained below, the following aspects of the Guidelines are wrong:

- Application of Myriad to claims reciting products other than "genes and the information they encode";
- Application of Myriad to method claims;
- The "markedly different" test;
- The "significantly different" test;
- Application of a "more than well-understood, purely conventional or routine" test to product claims;
- Application of a "more than well-understood, purely conventional or routine" test to law of nature claims; and
- Application of Prometheus to method of treatment claims.

As is stated in Myriad:

> *"the PTO lacks substantive rulemaking authority as to issues such as patentability".*

The USPTO should not, therefore, be introducing these new concepts for assessing patent eligibility. The existence of the Guidelines is making it more procedurally complicated and expensive for applicants to get the protection that they are statutorily entitled to. The Guidelines should be retracted.

Myriad was a narrow decision

The USPTO is not obliged to apply the Myriad decision to natural products in general because the Myriad decision does not relate to all types of product claim. The Myriad decision was a very narrow decision relating only to "genes and the information they encode". This is explicitly clear from the decision which concludes that:

> *"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". (emphasis added)*

The Supreme Court in Myriad did not say that their decision should be extrapolated to other natural products and so there is no reason why the USPTO should require this to be the case. The Myriad decision does not change the law relating to natural products in general and the Guidelines are, therefore, wrong in asserting that the Myriad decision applies to all claims that recite a natural product.

There is a whole body of US case law which explicitly states that isolated natural products are patent eligible.[1] Myriad does not relate to anything other than "genes and the information they encode"

[1] For example, see Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958) holding Vitamin B12 active compositions patentable because they were an advance in purification, more than "merely in degree," from the "compete uselessness" of the naturally occurring compound to the "great and perfected utility" of the patented version; Bergstrom, 427 F.2d 1394, 1401 (C.C.P.A. 1970) ruling that "naturally

and so does not change the law relating to any of these other products. The Guidelines go too far in this respect and are in danger of eviscerating patent protection for a huge number of useful products.

Myriad does not even say that all DNA is not patent eligible

The Myriad decision does not even relate to all isolated DNA. The decision is not couched in terms of "DNA" but instead refers to "genes and the information they encode":

> *"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". (emphasis added)*

Although the Syllabus to the decision words the decision slightly differently in terms of "DNA" rather than "genes", the Syllabus does not constitute any part of the decision and so has no legal standing.

In addition, although page 1 of the opinion refers to DNA, this is inconsistent with the conclusion at the end of the opinion that is set out above. For reference, page 1 mentions:

> *"For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring"* .

The binding opinion of the Court can relate only to the claims in front of them. The Court interpreted these claims to relate to "genes and the information they encode", so this statement at page 1 is merely dicta.

Myriad does not say that chemically defined DNA is not patent eligible. On the contrary, it states:

> *"Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally 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."*

The Supreme Court therefore suggests that claims can be rescued from the exclusion if they are expressed in terms of chemical composition or otherwise rely in any way on the chemical changes that result from the isolation thereby distinguishing the product from a naturally occurring product. If the structure of the DNA had been defined more clearly, it is possible that a different decision would have been reached.

In support of this, it is clear from the Supreme Court's reasoning that their decision was heavily weighted on their concern that the information aspect of the genetic information was being tied up

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occurring" compounds that are new and "do not exist in nature in pure form" are patent-eligible under Section 101; Kratz, 592, F.2d 1169, 1174 (C.C.P.A. 1979) upholding claim to a substantially purified chemical compound naturally occurring in strawberries because the claims did "not seek to claim 2M2PA, per se, nor 2M2PA in its natural state, nor even a composition encompassing strawberries; but instead present[ed] claims to compositions containing "substantially pure" 2M2PA"; Doyle, 327, F.2d 513, 518 (C.C.P.A. 1964) ruling that 6-amino penicillanic acid extracted from penicillin producing moulds was patentable.

by Myriad and that the claims were not restricted to a chemically defined sequence. For example, it describes how Myriad's claim:

> *"… is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule".*

This is why the decision relates to "genes and the information they encode". It does not relate only to "genes" and certainly does not relate to DNA. Inventions which do not tie up the information encoded by genes are, accordingly, outside the scope of the Myriad decision.

In view of this, isolated DNA that forms short primers, for example, may be patent eligible. Such primers certainly have a "distinctive name, character and use" (this test will be discussed later) compared to a naturally occurring gene because a) their length is far shorter than a naturally occurring gene, b) the specific combination of two primer sequences is not naturally occurring and c) the combination does not exist in nature such that it can be used to amplify nucleotide sequences by way of polymerisation reactions. In addition, an invention which relates to short primers is not attempting to patent "genes and the information they encode". Patent eligibility of primers is entirely consistent with Myriad's very narrow decision. There is no need for the Guidelines to eviscerate patent protection for such primers.

The Supreme Court in Myriad explicitly states that non-natural DNA sequences are not excluded from patent eligibility:

> *"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 endeavours. 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".*

Accordingly, isolated DNA that comprises altered sequences is still patent eligible, as is, for example, an isolated DNA encoding a gene when present in a vector because the vector comprising the gene sequence is nonnaturally occurring.

<u>Method claims not impacted by Myriad</u>

Neither should the Guidelines be applied to method claims that recite natural products. Myriad explicitly states:

> *"It is important to note what is <u>not</u> 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. ...".*

Method claims only implicate law of nature case law, which is distinct from product of nature case law. As discussed below, law of nature case law and natural product case law are different and should not be arbitrarily combined. Accordingly, the USPTO does not need to attempt to apply Myriad to method claims.

"Markedly different" is not the correct test – eligibility factor a)

Eligibility factor a) of the Guidelines indicates that one way of determining whether a claim to a product satisfies the alleged "significantly different" test is to determine whether it is "markedly different in structure" from naturally occurring products. This is not based on the case law.

The USPTO believes this to be the test that was used in Myriad and Chakrabarty to determine whether the products of interest were patent eligible. For example, the USPTO's training slides from March 2014 state that:

> *"Myriad relies on Chakrabarty and serves as a reminder that Chakrabarty's markedly different criterion is the eligibility test across all technologies for product claims reciting natural products"* (see slide 28).

However, this is wrong because the Supreme Court did not use this test in Myriad or Chakrabarty, as explained below.

"Markedly different" in the Myriad and Chakrabarty opinions

Nothing in the legally binding Myriad opinion says anything about requiring an analysis of whether a product is "markedly different" from a naturally occurring product in order to determine whether it is patent eligible.

It is likely that the USPTO considers "markedly different" to be the test by referencing the Syllabus to Myriad, which states:

> *"Diamond v. Chakrabarty, 447 U.S. 303, is central to the patent-eligibility inquiry whether such action was new "with markedly different characteristics from any found in nature," id., at 310".*

However, the Syllabus is just a headnote that has been prepared by the Reporter of Decisions for the convenience of the reader. It does not form part of the opinion of the Supreme Court.

The term "markedly different" is mentioned only once in Myriad, when the Supreme Court discusses Chakrabarty. It is clear from their discussion of Chakrabarty that the question which interested the Supreme Court was whether Myriad's isolated DNA had "a distinctive name, character and use", not whether it was "markedly different":

> *"Myriad recognizes that our decision in Chakrabarty is central to this inquiry…. The Court held that the modified bacterium was patentable. It explained that the patent claim was "not to a hitherto unknown naturally phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use'" … The Chakrabarty bacterium was new "with markedly different characteristics from any found in nature " … due to the additional plasmids and resultant "capacity for degrading oil" … In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention". (emphasis added)*

Similarly, the Supreme Court in Chakrabarty did not ask whether the bacteria in question was "markedly different" but instead applied the "distinctive name, character and use" test. Specifically, it was held in Chakrabarty that:

> *"… respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity "having a distinctive name, character [and] use" …" (emphasis added)*

In the next sentence of its opinion, the Supreme Court in Chakrabarty contrasts the facts of Chakrabarty with the earlier Funk case in which Funk's bacterial mixture had not acquired a distinctive name, character and use and so was not patent eligible:

> "*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 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 functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee" (emphasis added).*

The Supreme court does then refer to Chakrabarty's bacterium being "markedly different", but only as part of its comparison to the Funk case:

> *"Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under §101" (emphasis added).*

The Supreme Court was merely commenting that Chakrabarty's bacteria happened to be "markedly different" from the bacteria that occurred naturally, contrasting it with Funk's bacteria which did not have any "new" or "different" characteristics/uses. It was not stating that "markedly different" was the test that needed to be applied to determine whether something was patent eligible. Even in Funk, the Supreme Court was not looking at whether the bacterial mixture had "markedly different" characteristics, but only whether it had a "new" or "different" character or a new or different use.[2]

It is clear from Chakrabarty and Funk that for a "manufacture" or "composition of matter" to be patent eligible, any difference from the naturally occurring product is enough provided that it means that the product is "a product of human ingenuity having a distinctive name, character [and] use". There is certainly nothing which says it must be "markedly different". Eligibility factor a) is, therefore, wrong.

[2] The Supreme Court's discussion of Funk in Myriad is misleading as it mentions only that "The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way". However, as already explained above, the Supreme Court in Funk found that the bacterial mixture was not patentable because it did not have a distinctive name, character or use, not merely because there were no structural differences. The absence of any differences in the use were discussed in detail in the Funk opinion.

Consistent with this, when coming to its conclusion that cDNA is patent eligible, the Supreme Court in Myriad did not consider whether cDNA is "markedly different" from naturally occurring DNA. Instead, they considered only whether it is the same ("indistinguishable from") or "distinct":

> *"cDNA is patent eligible because it is not naturally occurring".*
>
> *"… the lab technician unquestionable creates something <u>new</u> when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is <u>distinct</u> from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be <u>indistinguishable from</u> natural DNA". (emphasis added)*

There is no mention of "markedly different" in this discussion from Myriad. It just requires something to be "new" or "distinct", i.e. not the same as what exists in nature. Indeed, the question asked in Myriad was:

> *"… whether Myriad's patents claim a "new and useful … composition of matter," §101, or instead claim naturally occurring phenomena".*

Surprisingly, the "distinctive name, character [and] use" test does not appear anywhere in the Guidelines. Instead, the Guidelines teach to apply the "markedly different in structure" test to determine patent eligibility of a claim appearing to relate to a natural product such as a protein, RNA, etc. As explained above, this test has no basis in the case law. This test is in danger of eviscerating patent protection for chemical compounds, proteins, etc. which exist in nature but which acquire new and useful inventive characteristics when they have been isolated or purified. Both Myriad and Prometheus warn against interpreting the exclusions too broadly, but the USPTO is doing just that. The Guidelines need to be retracted.

The case law does not even state that it is necessary to determine whether something relating to any judicial exception is "significantly different" in order for it to be patent eligible. In particular, the "significantly different" test is not relevant to natural products. Question 3) as a whole is also, therefore, wrong.

<u>"more than well-understood, purely routine, conventional" – eligibility factor f)</u>

Eligibility factor f) states that one way of determining whether a claim relating to a judicial exception is patent eligible is to determine whether the claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field. This test was not discussed in Myriad in relation to the product claims so should not be applied to claims relating to natural products. Accordingly, the guidance in the USPTO's slides of March 2014 (see slide 35), which states that factors b) to f) and h) to l) should apply to all claims, is wrong.

It is clear that the Supreme Court in Myriad did not apply the "more than well-understood, purely conventional or routine" test to determine whether a product was patent eligible. cDNA was found to be patent eligible in the Myriad opinion. However, making cDNA is well-understood, purely conventional and routine once you are in possession of the naturally occurring mRNA.

Consequently, it is wrong for Examiners to apply the "more than well understood, purely conventional or routine" test to product claims to determine if they are patent eligible and the Guidelines should be updated to state that this is not a requirement for product claims. The only test for product claims should be the "distinctive name, character [and] use" test that is discussed above. This is not a new test and so there is no need for Guidelines to be introduced at the present time to set out this test. Instead, it would be simplest to retract the current Guidelines.

Law of nature case law and natural product case law are different and should not be arbitrarily combined

It is likely that the USPTO believes that the "more than well-understood, purely conventional or routine" test comes from the Prometheus decision. However, Prometheus related to an invention concerning a law of nature (or natural phenomenon), not to a natural product. The Guidelines incorrectly combine these two entirely separate lines of case law (laws of nature/natural phenomenon on the one hand and natural products on the other hand) and have applied them to *any* situation (natural phenomenon are not the same as natural products and are instead akin to laws of nature – e.g. see USPTO's March slides – slide numbers 17 and 20). There is no legal basis in the Myriad or Prometheus decisions to do this.

All the statements relating to "well-understood, routine, conventional activity" in Prometheus relate specifically to laws of nature and natural phenomenon. The Supreme Court in Prometheus does not extend these statements to natural products as well:

> *"… 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"*
>
> *"Purely "conventional or obvious" "[pre]-solution activity" is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. Floor, 437 US at 590, see also Bilski, 561, US at … (slip op. at 14)."*

Thus, eligibility factor f) should not be applied to product claims.

Prometheus does not use a "more than well-understood, purely conventional or routine" test

In any case, the Prometheus decision does not state that it is necessary to use a "more than well-understood, purely conventional or routine" test for all claims relating to laws of nature. Instead, Prometheus looks at whether the claims recite something that is "significantly more" than the law of nature:

> *"The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible process that apply natural laws?" (emphasis added)*

Prometheus does not state that in order to determine whether the claims recite "significantly more" than a law of nature the test to be applied is whether the claims recite "more than well-understood, purely conventional or routine" activity. It just so happened that in view of the facts of the Prometheus case, the Supreme Court considered that the claims did not contain any more than well-

understood, purely conventional or routine activity. However, the Supreme Court's concern was that the claims "tie-up" the law of nature because they did not instruct the doctor to change the treatment protocol dependent on the result of considering the law of nature:

> *"The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations"*
>
> *"… the steps add nothing of significance to the natural laws themselves. … The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusions that the processes described in the patents are not patent eligible …".*

The Supreme Court therefore indicates that the claims would have been saved from the patent eligibility exclusion if they had included a subsequent step of administering the drug according to the inference drawn using the correlation.

To summarise the Prometheus decision, it simply indicates that claims that tie up natural laws are not patent eligible:

> *"… to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it" (Benson)*

Here, the words "apply it" mean literally just that – apply it without saying how to apply it. This is reflected in the Supreme Court's conclusion:

> *"For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid".*

If the facts of the Prometheus case had been different, it is entirely possible that reciting well-understood, conventional or routine steps in the claims could have prevented the claim from tying up the law of nature, thereby ensuring that the claim did not fall within the exclusion.

Significantly, the Supreme Court in Prometheus acknowledges that claims to medical treatments do not tie up the laws of nature:

> *"… the steps add nothing of significance to the natural laws themselves. Unlike, say a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusions that the processes described in the patents are not patent eligible …".*

As explained above, medical treatment claims are distinguishable from the Prometheus claims because the Prometheus claims did not say what the doctor needed to do with the information once

it had been obtained. Instead, as explained in Prometheus, a claim to a medical treatment does not tie up the natural law itself. The USPTO intends to apply its Guidelines to medical treatment claims, thereby extending the applicability of the Prometheus decision beyond its legal scope. The Guidelines should not be applied to such claims and doing so risks eviscerating patent protection for many methods and products in this area.

To summarise, the USPTO does not need to make more than "well-understood, routine, conventional activity" a test compulsory for determining patent eligibility of claims reciting laws of nature or natural phenomenon and, in any case, the Prometheus decision does not state that this test must be applied. Instead, it is necessary to consider only whether the claim ties up the natural law. The Guidelines should be changed accordingly or retracted.

Conclusion

The Guidelines introduce new tests for patent eligibility (in particular the "markedly different in structure" and the "more than well-understood, conventional or routine" tests) that are not based on the case law of the Supreme Court. In attempting to follow *both* the Myriad and Prometheus decisions for all law of nature claims *and* natural product claims, two entirely separate lines of case law have been incorrectly combined and applied to situations which the Supreme Court never intended them to be applied to. The USPTO does not have the power to introduce new standards for patent eligibility. If Guidelines are essential then they need to be revised so that separate Guidelines are drawn up for natural products on the one hand and laws of nature/natural phenomena on the other. Better still, the Guidelines should be retracted and the USPTO should follow the Supreme Court's warning not to construe the exceptions to patent eligibility so broadly as to eviscerate patent protection.

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