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Re: Comments on Laws of Nature/ Natural Products Guidance
Published March 4, 2014

Dear Sir:

I am a partner at Foley & Lardner LLP, with over 20 years' experience drafting, prosecuting, licensing, and evaluating patent applications and patents in the chemical, biotechnology and pharmaceutical arts. I am submitting these comments on my own behalf. These comments do not necessarily represent or reflect the views of any other member of Foley & Lardner LLP or any of its clients.

I understand that the USPTO needs to provide guidance to examiners on the implications of recent Supreme Court decisions addressing the patent eligibility of products of nature (*Myriad*) and claims related to laws of nature/natural phenomena (*Prometheus*). However, I believe that the Guidance published March 4, 2014 expands the exceptions to patent eligibility beyond that required by—or even supported by—relevant Supreme Court precedent. Moreover, the Guidance could significantly undermine investment and innovation in biotechnology, pharmaceuticals and personalized medicine by making it nearly impossible for innovators to obtain an adequate scope of protection for inventions in these fields. I therefore urge the USPTO to consider these alternative approaches to applying Supreme Court precedent to claims involving products of nature, laws of nature, and natural phenomena.

I. Single Element Product Claims

At the outset, I believe that the Supreme Court's recent decision in *Alice Corp. v. CLS Bank International*, shows that the general approach set forth in the Guidance is contrary to the guiding principles set forth by the Supreme Court. In particular, where the Guidance instructs examiners to identify any "judicial exceptions" recited in the claims and then consider whether any ***other*** claim elements show that the claim as a whole is directed to "significantly more" than the judicial exception, the Supreme Court decision in Alice demonstrates that all claim elements must be considered when evaluating a claim under 35 USC § 101.

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. .... If so, we then ask, "[w]hat else is there in the claims before us?" .... To answer that question, ***we consider the elements of each claim both individually and "as an ordered combination"*** to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. ....

Slip op. at 7 (emphasis added).

The USPTO must revise the Guidance to be consistent with this guiding principle, and to instruct examiners to consider every claim element "***both individually and 'as an ordered combination'***" when conducting a patent eligibility analysis.

II. Single Element Product Claims

Under the Guidance, single element product claims are patent eligible only if the product is "non-naturally occurring" and "markedly different in structure" from naturally occurring products. This test is too restrictive, as it prevents the patenting of products that may have a significantly different function or expanded utility than the corresponding "natural product."

Support for the patent eligibility of products that differ only in function or utility from the corresponding "natural product" is found, for example in *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911) (Hand, J.), where the compound adrenaline was deemed to be patentable even if it were considered to be "merely an extracted product without change" because it had become "for every practical purpose a new thing commercially and therapeutically." Under *Parke-Davis*, compounds isolated from natural sources that are determined to have therapeutic or industrial utility (for example) would be patent-eligible, such as drugs, bacteria, enzymes, vaccines and antibodies.

The USPTO has asked for comments on how a product that does not differ in structure from a product of nature could nonetheless have a different function or utility. There are many examples of areas of technology where the "function" of a product depends on the context in which it is used, for example. These include vaccines, small molecule drugs, protein drugs, antibiotics, and minerals.

Many vaccines are based on a protein present on the surface of the pathogen, such as a coat protein of a virus. In the context of the virus, the protein may protect the virus from the environment. Once isolated from the virus, the protein is useful as a vaccine, to induce antibodies that will protect the vaccinated subject from infection by the virus. Even better results may be afforded by a vaccine based on a fragment of the protein that more specifically induces protective antibodies. So, vaccines are one example of compounds that can have the same structure but a different function depending on the context (pathogen vs. vaccine).

Many small molecule drugs are isolated from plants or other natural sources (or are made synthetically after originally being discovered by isolating from a natural source). Such small molecules may have any number of functions in the plant, but once isolated from the plant and purified, are useful as drugs to treat patients suffering from a particular disease or condition.

So, small molecule drugs are another example of compounds that can have the same structure but a different function depending on the context (plant vs. drug).

Many protein drugs are isolated from human or animal sources, or made recombinantly, such as insulin, Factor XII, human growth hormone, erythropoietin, etc. Even when the protein drugs exhibit the same function as the naturally occurring protein, by isolating and purifying them or making them recombinantly, they can be used to treat serious diseases and conditions, thereby vastly expanding their utility.

Many antibiotics are produced by microorganisms. Antibiotics may inhibit the growth of other microorganisms that threaten the viability of the producing microorganism. When antibiotics are **isolated** and **purified** from culture, they can be used to prevent or treat infection in other organisms, including farm animals, pets and humans. So, antibiotics are an example of compounds that can have the same structure but vastly expanded function depending on the context.

Minerals may not perform any active function in their native state (other than contributing to the geological makeup of their surroundings), but can exhibit many different functions depending on the context in which they are used. For example, zinc oxide (which occurs naturally as zincite) has a high refractive index, high thermal conductivity, antibacterial properties and UV-absorbing properties. Thus, when zinc oxide is isolated and purified it can function as a sunscreen, as a pigment, or as a semi-conductor (to name a few), depending on the context. So, minerals are yet another example of compounds that can have the same structure but vastly different functions depending on the context.

III. Manufacture and Composition Claims

Under the Guidance, manufacture and composition claims are patent eligible only if the claim recites elements ***other*** than natural product(s) that support a conclusion that the claimed subject matter is significantly different from the natural product(s). As noted above, this approach is inconsistent with the approach set forth in *Alice*, under which all claim elements must be considered. Moreover, this test is too restrictive, because it prevents the patenting of subject matter that is significantly different from the natural product components when the claimed subject matter is considered as a whole.

This aspect of the Guidance is based on *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948), but *Funk Brothers* does not require—or support—an analytical framework that ignores any natural product components of a manufacture or composition. Nor does *Funk Brothers* stand for the proposition that a structural difference is the *sine qua non* of patent eligibility for claims reciting natural products. Rather, the analysis in *Funk Brothers* demonstrates that the

Court considered each of the natural product components of the claims and considered whether any of the bacterial strains (i) acquired a different use or (ii) an enlarged range of utility, (iii) exhibited any different effect, (iv) performed in any different way, or (v) exhibited any improved functioning. It was only after determining that the claimed inoculant did not exhibit any of these different functions or uses that the Court determined that the claims were not patentable.

When the analytical framework of *Funk Brothers* is followed, manufactures and compositions that include natural products would be patent-eligible as long as they differ in structure, function, or utility from the individual natural product components. Thus, for example, a vaccine composition comprising an antigen and a pharmaceutically acceptable carrier would be eligible because the antigen has a different function and use in the context of the vaccine than it does in the host organism from which it was derived. A juice composition comprising juice and a preservative would be patent eligible because the juice composition would have a different property (e.g., extended shelf life) than the naturally-occurring juice.

IV. Method Claims Reciting Natural Products

Under the Guidance, method claims reciting natural products are subject to the same analysis as method claims that recite a law of nature or natural phenomena. However, no Supreme Court decision undermines the patent eligibility of a method claim simply because it recites the manipulation or use of a natural product. Quite to the contrary, in *Funk Brothers* and *Myriad* the Supreme Court made clear that method claims were not under consideration, and even in *Prometheus* the Court distinguished the claims at issue from claims directed to "a new way of using an existing drug."

In *Myriad*, the Supreme Court made clear that it was not addressing the patent eligibility of 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. ....
>
> 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."

Association for Molecular Pathology v. *Myriad Genetics, Inc.*, 569 U.S. _, 133 S. Ct. 2107, 2119 (2013).

In *Funk Brothers*, the Supreme Court made clear that it was not addressing the patent eligibility of method claims:

> We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable.

Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

Even in *Prometheus* the Supreme Court distinguished the claims at issue from typical method of treatment claims:

> Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims [here] do not confine their reach to particular applications of those laws.

Mayo Collaborative Services v. *Prometheus Laboratories, Inc.*, 566 U.S. _, 132 S. Ct. 1289, 1302 (2012).

Moreover, in each of the recent patent subject matter eligibility cases (*Prometheus*, *Myriad*, and *Alice*), the Supreme Court has approached the exceptions to patent eligibility with caution. As the Court stated in *Prometheus*, for example:

> 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.'" .... It added that "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."

Mayo Collaborative Services v. *Prometheus Laboratories, Inc.*, 566 U.S. _, 132 S. Ct. 1289, 1293 (2012).

The USPTO should revise the Guidance to be consistent with Supreme Court, and indicate that method claims need not be subject to any patent eligibility analysis beyond step one of the Guidance simply because they recite the use of a product of nature. That is, the USPTO should revise the Guidance to provide that method of manufacture claims and method of use claims

(including method of treatment claims) are patent eligible regardless of whether the methods involve the use of natural products.

V. Method Claims Reciting Laws of Nature/Natural Phenomenon

Under the Guidance, a method claim reciting a law of nature or natural phenomena is patent eligible only if a multi-factored, *Wands*-type analysis leads to the conclusion that the claimed subject matter is "significantly more" than the law of nature or natural phenomena. While I understand the basis in Supreme Court cases for each of the factors included in the Guidance, I do not believe that Supreme Court precedent supports an analytical framework that requires "weighing" multiple factors. In this regard, I note that many of the factors that weigh against eligibility are the converse of factors that weigh towards eligibility, such that, unless a claim satisfies each and every one of factors (a) – (f) there will be factors that weigh against eligibility.

I believe that Supreme Court precedent supports an analysis that would find a method claim that recites a law of nature or natural phenomena patent eligible if any one of the factors set forth in the Guidance is satisfied, or if the claim is distinguished from the claims at issue in *Prometheus* on any other grounds. *Prometheus* itself supports this approach to eligibility, because the Court found that the claims at issue were ineligible only after determining that the claims did not satisfy any of the factors considered by the Court.

I also believe that the examples in the Guidance misapply the "machine or transformation" factor. For example, the "flow cytometry" recited in the method claim of Example F indisputably invokes the use of a machine, yet the commentary states that no machine is recited. Additionally, claim 2 of Example E recites that the reaction conditions "allow the Taq polymerase to extend the primers," yet the commentary states that no transformation is recited.

VI. Conclusion

I appreciate the USPTO's careful consideration of these written comments on the Guidance.

Because the Guidance is inconsistent with Supreme Court precedent for at least the reasons set forth above, the USPTO should immediately retract the March 4 Guidance, and issue new Guidance that heeds the Supreme Court's warnings that exceptions to patent eligibility must be applied with caution to mitigate the risk that "too broad an interpretation … could eviscerate patent law." Moreover, because of the substantive impact of the USPTO's interpretation and application of 35 USC § 101 and related Supreme Court decisions, the USPTO should use the notice and comment rulemaking process of the APA (e.g., 5 USC § 553) when promulgating new Guidance.

Sincerely,

/Courtenay C. Brinckerhoff/

Courtenay C. Brinckerhoff