Comments on the USPTO's "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products"

Point 1:

The following is a quote from the May 8, 2014 decision by the Federal Circuit in *In re Roslin Institute* (Fed. Cir. 2014).

> However, Dolly herself is an exact genetic replica of another sheep and does not possess "markedly different characteristics from any [farm animals] found in nature." *Chakrabarty*, 447 U.S. at 310; see Reply Br. 13 (stating that "the clones are genetic copies").
>
> Dolly's genetic identity to her donor parent renders her unpatentable. In *Myriad*, the Court concluded that "isolated," naturally occurring DNA strands are not eligible for patent protection. 133 S. Ct. at 2111. Here, as in *Myriad*, Roslin "did not create or alter any of the genetic information" of its claimed clones, "[n]or did [Roslin] create or alter the genetic structure of [the] DNA" used to make its clones. *Myriad*, 133 S. Ct. at 2116. Instead, Roslin's chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.

The Federal Circuit points to the "markedly different characteristic**s**" language of *Chakrabarty*, which the *Roslin* Court then notes does not exist because Dolly is genetically identical to her donor. Thereafter, the *Roslin* Court explains what it means by "genetic identity": 1) the patent holder did not modify the genetic *information* of the claimed clones; and 2) the patent holder did not alter the genetic *structure* of the DNA used to make Dolly. As such, the Federal Circuit refers to the information (function) and structure of the DNA used in the creation of the claimed subject matter. These "characteristic**s**," being identical to those of the donor parent (i.e., the natural product), render the claimed clones patent ineligible. This supports the concept that the "markedly different characteristic**s**" inquiry of *Chakrabarty* entails analysis of both the structure and the function of the claimed subject matter for comparison to the corresponding "natural product." If only the structure of the DNA in the claimed clones was relevant, then the Federal Circuit surely would have found it unnecessary to separately address the *genetic information* of the claimed clones.

As I discussed at the May 9, 2014 USPTO forum, the Court in *Myriad* completely conflated genomic DNA's structure ("sequence" to the Court) with its function ("information" to the Court), leading to one single, simple, question: " Has the genomic DNA's sequence changed from that which is found in nature?" Perhaps because the claimed subject matter in *Roslin* is a cloned animal and thus several steps removed from the DNA at issue in *Myriad*, or perhaps because the Federal Circuit is more comfortable with recombinant DNA technology, the *Roslin* Court was able to clearly articulate that both structure and function are considered in the analysis of subject matter eligibility when dealing with "natural products."

Point 2:

At the May 9, 2014 forum, I argued that characteristics, qualities, function and use of claimed subject matter have been historically considered as being quite relevant in determining patent subject matter eligibly of "natural products," finding root, at least in part, in Supreme Court tariff cases. At that forum, the Office asked how one might analyze characteristics, qualities, function and use when performing an analysis of subject matter eligibility for "natural products," because all function is "inherent." I would like to address that point using the following fact pattern:

Amazonic acid, found in a tree leaf, has the property of being able to inhibit receptor X if administered to humans. Inhibition of receptor X, at a certain level, would be useful to treat the common cold.

Imagine that a human must consume 10,000 pounds of tree leaf to treat the common cold. If one were to administer Amazonic acid in its natural leaf state to a human, Amazonic acid would indeed have the property of inhibiting receptor X, but it would not treat the common cold due to the inordinate (and impossible) amount of leaf that must be consumed. Thus, while one might argue that "function" is inherent, the ultimate "use" is not necessarily so. The use is merely a *potential* of the natural product.[1] Perhaps the distinction between "use" and "function" is

[1] Imagine the shells in *Hartranft v. Wiegmann*, 121 U.S. 609 (1877), the india-rubber in *Lawrence v. Allen*, 48 U.S. 785 (1849), and the orange in *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931). Surely the shell had the potential to become a button. Surely the india-rubber had the potential to become a boot. Surely the orange had the potential to become a softball. But conversion of a raw material to a "manufacture" only occurred when something had been done to the original object that gave it a new characteristic or use. For the shells, the Court

semantic, as the words “use”, “function”, “quality”, “character” and the like are blurred in the English language. Nevertheless, the fact is that purification, isolation, concentration, etc. of Amazonic acid from the leaf is what gives this object the use that is sought, and it is what gives this object value. Indeed, Mr. Hansen, attorney for Petitioner, at oral arguments in front of the Supreme Court in *Myriad* admitted exactly this, when he conceded that Amazonic acid, isolated from a leaf, could be patent eligible if, in concentrated form, it had a new function.

There are also simpler scenarios. For example, imagine that no amount of leaves would suffice to achieve treatment of the common cold because Amazonic acid, found in the tree leaf, exists in the presence of some other inhibitory substance. In such a case, Amazonic acid cannot function to inhibit receptor X when administered to a human in its natural state as part of a leaf. Here we might say that purification, isolation, concentration, etc. of Amazonic acid from the leaf gives it the function and the use that we seek. But whether we use the term “function” or “use,” the distinction is actually quite irrelevant. What is clear is that purification, isolation, concentration, etc. of Amazonic acid from the leaf is what makes this object useful and valuable.

Unfortunately, there are also far more difficult scenarios that the Office must address. For example, imagine that only 10 leaves would suffice to achieve treatment of the common cold. In this case, does purification, isolation, concentration, etc. of Amazonic acid from the leaf give it the use that makes it so valuable? What if only one leaf was required to treat the common cold? This begs the question - exactly *where* is the cut off – *at what point* does patent eligibility attach?

There is no bright-line answer to this question. There rarely is in patent law. But, balancing factors is not a new act for patent examiners, patent attorneys and courts. At some point, extraction, purification, isolation, concentration, etc. results in a “difference in kind, rather than degree.” The concept of a “difference in kind, rather than degree” has been used in “natural products” cases concerning patent eligibility, such as *Parke-Davis & Co. v. H. K. Mulford Co.*,

---

looked for a new “name, character, or use.” For the boot, the Court looked for “a new form capable of use and designed to be used in such new form.” For the orange, the Court looked for “a new or distinctive form, quality, or property.” These cases were not decided based on the *potential* of the object at issue, but whether the object had, in fact, been changed in such a way that something a new function arose. All objects have *potential*, but the question is whether the object has been changed in such a way that this potential is actually realized. The Office should not ignore the functional aspect of the “natural products” doctrine simply because natural products have potential.

189 F. 95 (C.C.S.D.N.Y. 1911) and M*erck & Co., Inc., Appellant, v. Olin Mathieson Chemical Corporation*, 253 F.2d 156 (4th Circ. 1957). These cases generally find that a "natural product" was essentially useless or largely ineffective in its natural environment, but was converted to something of high therapeutic value when removed from its origins. However, we should be careful not to understand the distinction between "kind" and "degree" as requiring conversion of a "natural product" to a different object (which, incidentally, would be more akin to a structural analysis) or strictly requiring a new use. The "kind"/ "degree" distinction requires nothing of the sort:

> [t]he point on the spectrum where the additional increase in purity ceases to be a distinction in degree and becomes a distinction in kind, is really just a matter of degree, because a distinction in kind is nothing more than an adequate distinction in degree. In this sense, there is no such thing as a distinction in kind. If there were, it would imply a discontinuity in purity. Therefore, one must be cautious in construing the meaning of the language used by the courts in describing the appropriate test for the minimal improvement in purity that will give rise to novelty.

Gipstein, R. (2002) 'The Isolation and Purification Exception to the General Unpatentability of Products of Nature', Columbia Science and Technology Law Review 4: 1–44.

The "kind"/ "degree" distinction for subject matter eligibility is simplest when a new use is effectively created (e.g., the 10,000 leaf hypothetical above), but more difficult when the change is related more to efficacy, convenience, etc. (e.g., the 10 leaf hypothetical, above). The "kind"/ "degree" distinction applies equally to compositions of matter and combinations (e.g., a vaccine having a combination of peptides is different in "kind" from the proteins from which the peptides originally derived due the completely new use of the combination, but *Funk Brothers'* collection of bacteria is merely a difference in "degree" because there is no expansion in their range of utility). In some cases, the conversion from "kind" to "degree" is quite apparent (e.g., gunpowder), in other cases it is a more difficult to ascertain (e.g., the 10-leaf Amazonic acid hypothetical above), and in some cases it cannot be found (e.g., a sea shell, ground and stripped in preparation for sale to button manufacturers). But it is knowable; it simply requires more effort than a structural analysis.

In addition to the "natural product" cases cited above, the Office might look, for example, to purification-based novelty cases such as *In re Merz*, 97 F.2d 599 (CCPA 1938), *Farbenfabriken of Elberfeld Co. v. Kuehmsted*, 179 F. 701 (7th Cir. 1910), and *Union Carbide Co. v. American Carbide Co.*, 181 F. 104 (2d. Cir. 1910) for help in determining what factors are relevant to patent eligibility. While these cases do not deal with the patent eligibility of "natural products," they do discuss the characteristics considered by courts in ascertaining whether a purified, isolated, or concentrated object has attained a difference in kind, rather than degree (relative to prior art). Finally, a "kind"/ "degree" test also exists in the obviousness context, meaning that there is an additional body of case law available for reference in establishing compliance with this standard. See, e.g., MPEP 716.02. These obviousness-based cases clarify that a "difference in kind, rather than degree" does not mean that a *different use* is required, but rather that an applicant can establish patentability in the obviousness context by showing an improvement beyond what is expected. While "unexpected" is too high of a standard for a "kind"/ "degree" test in the context of subject matter eligibility for "natural products," obviousness-based cases are nevertheless instructive because these opinions discuss whether a change shown for claimed subject matter rises to the level of patentable significance.

And finally, I note that a "kind"/ "degree" test is in compliance with the *Hartranft v. Wiegmann*, 121 U.S. 609 (1877), which asks whether an object has attained a distinct "name, character, or use" relative to the corresponding raw material. This standard has been endorsed, at least implicitly, in patent subject matter eligibility contexts by the Supreme Court in *American Fruit*, *Chakrabarty*, and *Myriad*.

Sincerely,

Dr. Leslie Fischer, Ph.D., J.D.
Senior Patent Attorney, IHC Franchise
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080 USA
Phone +1 862 778 9308
Mobile +1 862 210 0280
Fax +1 973 781 8064
leslie.fischer@novartis.com