21-Jan-2015

Remarks of Brian R. Stanton, Ph.D.

United States Patent and Trademark Office
Patent Eligibility Forum
Alexandria, Virginia

Good afternoon, ladies and gentleman.

First, I'd like to thank the Office for holding this forum and for giving me the opportunity to speak to you today.

My name is Brian Stanton and I am currently an independent intellectual property consultant. I previously worked at the PTO and during my tenure there, I coauthored the 2001 Utility and Written Description Examination Guidelines,

I laud the PTO's efforts in taking on the task of establishing subject matter eligibility guidelines.

Unfortunately, the guidelines seek to implement perplexing Court *dicta* whose underlying subjective reasoning almost belies such implementation.

Before getting to some detailed comments, I would like to propose a series of measures that, I believe, would serve both the immediate interests of the Office and the Public at large.

- First, the Office should reconsider their decision to interpret the recent Court decisions broadly. Instead, these decisions should be limited to their facts.
- Second, eligibility analysis should simply focus on the well-established notion of pre-emption, rather than on attempting to discern whether "sufficient" differences exist between what is claimed and what might be considered natural phenomena.
- Third, the Office should expand its public/private partnership efforts beyond the notice and comment methodologies and establish a working group composed of members of the public in addition to those of the Office.

Specifically, this group might:

- collect and use real-world claim sets to develop and publish examplars that provide guidance as to how to avoid claiming patent ineligible subject matter; and
- advise the Director in developing recommendations for legislative revisions that would serve the interests of the public and private sectors.

Finally, I encourage, the Office to establish a specific cadre of who would have the authority to review rejections and serve as applicant points of contact for resolving patent eligibility issues.

Now I'd like to move on to some specific comments.

First, the Myriad findings.

In this case, the Court was careful in crafting their decision. They ***did not state*** that all genes fail to meet the test of patent eligibility. Instead, they noted that "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on chemical changes that result from the isolation of a particular section of DNA."[1]

In fact, rather than asking whether a claim is "directed to" or "recites" a natural phenomenon, the reasoning of the Court would be better captured by having the Examiner ask whether or not "*a reasonable interpretation of the claim* as a whole *would imply that applicant seeks to encompass a natural phenomenon or abstract idea.*[2]

This proposed revision to eligibility inquire would more directly address the question of preemption that so concerns the Court and it would be on point to their finding that the Myriad flaw was the claims *failure to exclude* the natural product rather than a *per se* lack of eligibility for isolated nucleic acids

The Guidelines should be clear that it is the *scope of the claims* and what they encompass that is a key inquiry, not the fact that they employ some judicial exception *per se*.

Moving on the guidelines "additional elements" test, I would suggest that the "significantly more" inquiry suffers from irreconcilable ambiguity.

First, the subjective nature of determining what is "significant" makes it untenable as an examination standard. This judgmental, subjective standard begs arbitrary and conclusory analyses that will only continue to cloud prosecution records.

Second, the Guidelines use of a "markedly different characteristic analysis" is also unworkable. Specifically, the analysis requires comparison of the "nature-based product limitation to its naturally occurring counterpart."

First, it is noted that it is unclear how one would determine what an appropriate counterpart would be. Consider the following two examples:

In the first, imagine a specification that describes the identification of a new genetic locus and the use of its encoding protein for disease treatment. Such an

[1]Association for Molecular Pathology v. Myriad Genetics (Myriad) 569 U.S. ____ 2013, slip op., at 14.
[2]Proposed modification of language regarding determination that a claim is *directed* to a JE at 79 FR 74618, 74622, column 1, last full paragraph.

application might contain a claim to an isolated and purified human gene similar to the case in Myriad.

Now change the facts slightly to a specification that merely lists a nucleic acid's sequence as well as that of an encoded protein. Such an application might also contain a claim to an isolated and purified gene.

In the first example, the Specification provides that a naturally occurring gene exists that can be used in disease treatment. Based on this disclosure, the public would be informed of the discovery, its source, and its basis in nature. In this case, a comparison to a natural product is possible.

In the second example, however, the specification would provide no means for considering the source of the invention or whether or not it would exist in nature. The public would be denied any teachings regarding the science behind the invention even though a patent might issue.

Thus, the guidelines asserting a comparison to a natural counterpart would only encourage patent applicant's to avoid disclosing details of their invention and, by extension, deny at least part of the *quid pro quo* of the patent system.

Lastly, I would like to point out that one following the steps of the guidance document are as likely to emerge with conclusions that are in direct contradiction to Supreme Court findings as they are to agree with them.

Consider the Chakrabarty case, drawn to "a bacterium" that *contains* two plasmids. There is no functional requirement that the claimed bacterium actually perform the function of metabolizing oil. It is, at best, merely capable of performing this function.

The example in the Guidelines indicate that a markedly different characteristic test serves to help find the claim patent eligible. Unfortunately, the analysis suffers because all bacteria are **capable of** having the claimed characteristic that the Office finds distinguishing; that is to say, digesting oil.

Seeking a rationale for finding the Chakrabarty bacteria patentable, the guidelines compare them to a bacterium that only harbors one plasmid? Why is it not to a bacterium that contains two plasmids? Would not the difference between two bacteria each containing two plasmids merely be the information content in those plasmids? If so, would it be reasonable for an examiner to reject the Chakrabarty bacteria by finding that since the claimed bacteria and those in nature both have the same capability, they are products of nature?

Here, with the desire to reconcile their analysis with the Court's result, the Office has created an arbitrary application of a rule that is as likely to overturn the Supreme Court as it is to enforce their finding.

There are evident scientific and logic pages in the recent Supreme Court decisions. However, complex and subjective analyses only serve to aggravate these faults. While we cannot change the Courts findings, we can provide tenable extrapolation. Determining whether or a claim "encompasses" a product of nature is a tenable analysis. One would simply point to a species in the claim and compare it directly to that in nature. This would reconcile both Chakrabarty and Myriad and also provide guidance to an applicant as to what needs to be excluded from a claim while addressing the Court's concern with patents preempting nature.

These examples reveal that the Office's analytical framework only works as an *ex post facto* validation of reasoning. It is not tenable for adaptation to new situations and only serves to highlight that the Court's findings should be limited to their specific facts and other policy avenues pursued to reconcile the court's holdings.

I think I'll stop there and reserve more detailed remarks for my written comments.

Thank you.