July 31, 2014

Dear Deputy Commissioner Hirschfeld:

I write to comment on the *Myriad* patent-eligibility guidelines.[1]

I was in attendance at your presentation at the BIO meeting last month, and thus I am aware that you and other USPTO employees spent a considerable amount of time developing those guidelines. Without wishing to belittle those efforts, I think the approach taken to developing the guidelines was misguided, and that the guidelines should be scrapped in their entirety.

In reading through the guidelines, it became clear to me that they were drafted based on the premises that (a) Supreme Court caselaw is cohesive and (b) it is the Office's duty to extrapolate from this purportedly cohesive caselaw and predict what the Supreme Court might say in a future case, and determine patent eligibility on that basis. I respectfully submit that both premises are false. There simply is no cohesion or consistency in Supreme Court caselaw pertaining to patent-eligibility.[2] So while it is admirable that the Office attempted to synthesize various Supreme Court pronouncements on patent eligibility, that effort was doomed from the start to be Sisyphean.

Moreover – and it pains me to say this – the *Myriad* and *Mayo* decisions themselves are predicated on intellectual sleight-of-hand on the part of the Court, at a number of levels. To name a few: (a) Congress amended the patent statute in 1952, among other things introducing section 101. Yet *Mayo* and *Myriad* rely on several pre-1952 decisions, such as Funk Brothers and Morse, for the proposition that there are certain judicially-created exceptions to patentability, in so doing ignoring the statutory change. (b) Additionally, *Myriad* and *Mayo* conflate the 102 novelty test and the 103 obviousness tests with the 101 patent-eligibility test. This makes no sense from a statutory interpretation perspective – why have separate sections for eligibility, novelty and non-obviousness if the latter two are part of the former – and indeed one of the reasons for the introduction of 101 was precisely to avoid such conflation. (c) *Myriad* and *Mayo* ignore the precise claim wording, derisively dismissing this as mere wordsmithing, part of the "draftsman's art", and look at a claim in pieces. But the statute says that it's the claims that define the invention for which exclusivity is granted, which means that for patent-eligibility each claim should be looked at as whole, not have various parts of the claim abstracted away on grounds that it constitutes mere information-gathering steps or post-solution activity. (d) *Myriad* says that the "information encoded" in isolated DNA is the same as that encoded in naturally-occurring DNA, and therefore the former is a natural

[1] I have a USPTO registration number, and a significant portion of the clientele that I represent before the USPTO work in areas that will be affected by those guidelines. All of the parties I represent before the USPTO are bricks-and-mortar enterprises, engaged in the development of physical products and processes for improving agricultural yields, diagnosing and/or treating medical conditions, digital printing, and many other useful activities. Other than universities, none of the clients that I represent before the USPTO are large in the sense of having 500 employees; most are also not large in the sense of having deep pockets. I note that I am writing of my own volition, and not on behalf of any particular client or group of clients, because I see these guidelines as harmful. I have not been and will not be remunerated for writing these comments.

[2] Anyone who understands the basics of molecular biology – a group to which Justice Scalia, at least, admitted he does not belong – need not even compare different decisions, but can simply look at the Myriad decision alone to appreciate that statement: for the molecular biologist, there is no logical reason to differentiate between isolated DNA and cDNA for patent-eligibility purposes (both have the same "information", in Justice Thomas' words), yet the Court said the former is not patent-eligible and the latter is.

product. Information, however, is a human construct; molecules in and of themselves do not contain information, and what a person may perceive as the information content of a molecule is not germane to the patent-eligibility of that molecule. Chemically, the isolated and the naturally-occurring DNA are different molecules, and the isolated DNA does not occur in nature. Thus the proper inquiry for its patentability is not under 101 but under 102, 103 and 112.

Because of the inconsistency in the Court's 101 caselaw, it is folly to even try to extrapolate from the *Myriad* and *Mayo* decisions. Because of the intellectual chicanery inherent in those decisions, it is wrong to try to so extrapolate.

Attempting to extrapolate from bad Supreme Court case law also does a disservice to the public, in that it will prevent patent applications on good inventions from even being examined on the merits, thus resulting in too many worthwhile inventions not receiving patent protection.[3] Inasmuch as the *Myriad* guidelines will mostly affect patent applications on diagnostic methods, new medicines and methods of treatment, and in these areas – as I see from the experience of my clients who are active these areas – patent protection is a key to obtaining the investment necessary to commercializing inventions in these areas, the guidelines will have a chilling effect on the development of new diagnostic methods and new drugs and treatments for diseases. This overreach is particularly egregious the post-AIA era, in which Congress has already given parties which feel they are adversely affected by improperly-granted patents many options for attacking those patents.

Finally, attempting to extrapolate from the Supreme Court's case law, and to force examiners and applicants to run through a complex series of analytical steps just to determine eligibility, wastes resources on both ends. To illustrate from a personal experience: I recently had a pre-first office action Examiner interview for a case for a solo inventor, with the inventor present. The invention involves taking an enzyme substrate that has been labeled in a non-natural way and feeding it to a sample suspected of containing the relevant enzyme. If the enzyme is present and digests the substrate, this is detected using an appropriate analytical technique. The Examiner, pointing to the *Myriad* guidelines, said that we probably have 101 issues. The inventor was stunned: as the substrates are all modified so that they are non-naturally occurring, how could such a method be considered patent-ineligible, he wanted to know. I've been working in the patent field for over 19 years, this is as elegant a method as I've seen. It deserves to be assessed under 102 and 103, not denied under 101. But now it appears that we will have to spend time – and my small client's money – dealing with what should be a no-brainer, viz. the patent-eligibility of the invention, because the guidelines are so much broader than they ought to be. And if the Examiner doesn't budge, the case will wind up before the BPAI on the 101 question. All this takes away from the inventor's time and money for commercializing the invention. That's hardly an optimal allocation of resources.[4]

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[3] That is akin to a legal rule that provides the public with too much protection, for example a strict liability rule that automatically places drivers at fault any time they hit a pedestrian. The result will be less driving than is socially optimal. See any of the standard textbooks on economic analysis of law for a discussion of this situation.

[4] For another recent anecdote illustrating the difficulties with the *Myriad* guidelines, I quote here from the July 30, 2014 installment of Mr. Greg Aharonian's newsletter, which, unfortunately, is available only in email format, and as far I as know is not indexed anywhere. (It is, however, received by at least some USPTO examiners.) While not a patent practitioner himself, Mr. Aharonian is an experienced prior art searcher and

Rather than attempt to generalize from the incoherent morass of Supreme Court precedent, when applying *Mayo* and *Myriad* the Office apply these decisions very narrowly, to claims that fit the precise contours of those two cases. In *Myriad* the Court said that isolated DNA was not patent-eligible. The Office should go no further than that: if there are still applications pending that claim

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has been following the USPTO for over 20 years; not being a practitioner, he uses somewhat more colorful language than most practitioners use in their communications with the Office.

"Today's real/honest/meaningful science news brings us an announcement of a breakthrough in cancer testing, A PURE PATENTABLE INVENTION in all senses of the meaning of what it is to be an inventor, that is going to lead to yet another round of 101 patent rejections upheld by federal judges who do not understand much about science, engineering, invention, technology, and spending their own money.

One news article on the breakthrough at:

http://scienceblog.com/73604/potential-universal-blood-test-cancer-discovered/

Abstract of medical journal article at:

http://www.fasebj.org/content/early/2014/07/24/fj.14-254748.abstract

Technically innovative scientists at the University of Bradford in the United Kingdom have developed what could be a universal, simple blood test for cancer. They have discovered that the damage patterns of white blood cells, when exposed to UV light, differ if the cells come from people who are healthy, people who are pre-cancerous, or people who have cancer. "We have found that people with cancer have DNA which is more easily damaged by UV light than other people." They have tested their methods so far on just three types of cancer: melanoma, colon and lung.

Now, if this important technological development is confirmed, and generalized to many forms of cancer, and it leads to cheap testing instruments, especially for developing countries,

I WANT THESE SCIENTISTS TO MAKE AS MUCH
[TERM REDACTED] MONEY AS POSSIBLE WITH THEIR PATENTS

This type of breakthrough is what the progress of sciences and arts is all about, not [REDACTED like "Yo". But there is a problem. A problem of idiots. A problem of people who don't spend their own money. Consider the following reasonable claim, which easily satisfies 102 and 103 (needs more work for 112):

A method of detecting cancer by measuring the amount of
damage caused by exposing white blood cells to UV light.

Is this discovery a law of nature? (And yes, ignore for this conversation that there is not a single judge who has any real understanding of what are laws of nature). If true for many forms of cancer, across many races of people, if not across many species of animals, then this is a fairly generalized discovery - broad in every sense of the word, enough to be a law of nature:

"White blood cells of animals with cancer are more susceptible to UV light damage"

But we have known about DNA, white blood cells, UV light, cell damage, etc., for over 50 years. If this really is a law of nature, why hasn't it flowed out of some paper in the Journal of Theoretical Biology years ago?

So good luck to Oncascan, the Univ. of Bradford spin-out company formed to commercialize the research, and to the Univ. of Bradford in their attempts to get a patent.

But a word of advice. If you could numerically measure the brilliance of your invention, and the importance to mankind of your invention, well, sad to say, that is how much patent law stupidity you are going to encounter."

DNA that has been isolated from a natural source, then the Office should say that those claims are not patent-eligible. Anything else should be subject to substantive examination.

Similarly, the claim at issue in Mayo recited a method having two physical steps (administering a particular drug that results in a known metabolite, and determining the level of that metabolite) and that contains two "wherein" clauses pertaining to the implications of the determined metabolite level, which the patentee sought to be construed as method steps. The Office should go no farther than saying that a claim worded in this exact manner is likewise patent-ineligible, but that any other claim, such as one that recites an additional step or which has "wherein clauses" that the applicant does not assert constitute actual method steps, is patent-eligible, and examine the claim under 102, 103 and 112.[5]

If the Office takes this approach, then the worst that can happen from the Office's perspective is that the courts – both the Federal Circuit, which at least counts some scientists and engineers among its judges, as well as the Supreme Court, which in recent years has not been shy about taking on patent cases – will tell the Office that it is wrong, at which time the courts can provide better guidance of their own as to how they understand the statute. Given the realities of commercializing new inventions in the biotech arena, that would be a far preferable result to foreclosing the possibility of commercialization by not even letting patent applications on new inventions get out of the starting gate.

Respectfully submitted,

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[5] Alternatively, I think all practitioners agree that it would have been better had *Mayo* been decided on the grounds that the "wherein" clauses did not constitute method steps, therefore the only method recited in the claims was administering the metabolite precursor and measuring the level of the metabolite, and therefore the claimed method was anticipated under 101; the Office could adopt that approach here.