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Still 101 (IN)Eligibility, maybe more or maybe less

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Over 4 years ago…

Mayo v. Prometheus was decided

And…

We know that well-understood, routine, and conventional activity is normally not sufficient to transform a law of nature into a patent eligible application of such a law.

But…

We don’t know what well-understood, routine, and conventional activity actually means.

And…

What about the use of the word “normally” in *Mayo*? Did anyone notice it? Is there a situation where well-understood, routine, and conventional activity is sufficient to render eligibility?

Over 3 years ago…

AMP v. Myriad was decided

And…

We know that naturally occurring DNA that is isolated is not patent eligible, and that some cDNA is eligible.

But…

We don’t know if this means other biomolecules isolated from nature such as non-naturally occurring fragments of proteins found in nature that exhibit the same properties as the full-length proteins are also ineligible.

Or…

If a protein having a given amino acid substitution, which was considered eligible because no mutations of that protein were known to naturally exist, later becomes ineligible upon the discovery of the same or different mutation in a naturally occurring protein (which mutation may have come into existence after the protein with the substitution was invented).

Over 2 years ago…

The Mayo/Myriad Guidance came out

And…

We were told that claims that recite something “significantly different” from a judicial exception would weigh towards eligibility, but that ineligibility factors could counterbalance eligibility factors and then render a claim ineligible.

But…

No one had a clue as to what things amount to something that is “significantly different”.

And…

We were also told that things like metal alloys were eligible, but compositions comprising mixtures of metals were ineligible even if the mixture resulted in a new and unexpected property.

But…

We all knew this was completely bogus and so the Mayo/Myriad Guidance became ineligible.

I mean…

We all knew this was completely bogus and so the Mayo/Myriad Guidance became inapplicable.

Almost 2 years ago…

Alice v. CLS Bank was decided

And…

We were told that, in the search for an "inventive concept", the elements of a claim must be considered both individually and in ordered combination to determine whether the additional elements transform the asserted judicial exception into a patent eligible application.

But…

We don’t know if, in the search for the “inventive concept”, claim elements containing the asserted judicial exception, may be considered as *a part of* or *apart from* the “ordered combination”.

Less than 2 years ago…

The Interim Guidance came out

And…

We were told that examination of a claim to something like an artificial hip coated with a naturally occurring mineral can proceed under a streamlined eligibility analysis and would be found eligible.

But…

We have been told that examination of a microneedle array having a naturally occurring peptide coated thereon is not analyzed under the “streamlined eligibility analysis”.

So…

I wonder what the difference is between an artificial hip coated with a naturally occurring mineral and a microneedle array coated with a naturally occurring peptide.

Almost one year ago…

The Update to the Interim Guidance came out

And…

It seems that the answer to the difference between a hip replacement and a microneedle array is somewhere in paragraph IV, “The Role Of Preemption, And The Streamlined Analysis” and that a hip replacement having the mineral coated thereon does not seek to preempt, *i.e.*, tie up all uses of the mineral.

But…

We’ve been told that even though preemption is a clue, preemption really has nothing to do with whether a claim is directed to a judicial exception.

And Now Comes

The Federal Circuit and

Ariosa v. Sequenom and GTL v. Merial

In *Ariosa*, the CAFC essentially held

- Claims to a method having steps in *an ordered combination that was actually unconventional* at the time that results in a groundbreaking technological improvement lack the requisite "inventiveness" under Step 2 of the Mayo/Alice Test *because the discovery of a judicial exception was the inspiration for the invention*—creating the ordered combination of steps.

The Convention and Discovery

- The convention was to look for fetal *cells* in maternal blood to then analyze fetal DNA in the fetal cells, thus the convention was to also throw away the maternal plasma and serum.
  - Plasma doesn't have blood cells, and serum doesn't have blood cells and proteins.
- The inventors surprisingly discovered that cell-free *fetal* DNA (cf**f**DNA) exists in the plasma and serum of the mother.
- However, cell-free *maternal* DNA also exists in the plasma and serum of the mother and the problem was that cell-free *fetal* DNA and cell-free *maternal* DNA were indistinguishable.

Until the Invention, US 6,258,540

- The inventors created a detection method whereby the cell-free DNA in the *retained* maternal plasma or serum is amplified and *paternal* sequences in the cell-free DNA is detected to thereby distinguish the cell-free *fetal* DNA from that of the mother.
  - Cell-free *paternal* DNA is not present in the plasma and serum of the mother.
  - So, any cell-free DNA having *paternal* sequences, must be from the fetus.

Convention Versus Invention

CONVENTION

- Keep the blood cells, throw away the plasma and serum;
- Amplify the cell-based DNA in in the blood cells; and
- Somehow try to distinguish the mother's DNA from the DNA of the fetus.

THE '540 INVENTION

- Keep the plasma and serum, and throw away the blood cells;
- Amplify the cell-free DNA in the plasma or serum; and
- Detect the presence of paternal sequences in the cell-free DNA to distinguish the cell-free *fetal* DNA from the cell-free *maternal* DNA.

And once the cell-free *fetal* DNA

- Is distinguished from the cell-free *maternal* DNA, the cffetalDNA can used to diagnose conditions of the fetus.
- But because cell-free *fetal* DNA naturally exists in maternal plasma and serum, the CAFC reasoned that with the discovery of cffetalDNA in hand, others skilled in the art would have been led to the particular combination of steps, such that the novel combination of steps is not inventive under the Mayo/Alice Test.

Huh? Really, Federal Circuit?

Isn’t all innovation inspired by the discovery of a law of nature, natural phenomenon, or an abstract idea?

In *Merial*, the CAFC essentially held

- Claims to an invention that is *founded upon* a discovery of a judicial exception are patent ineligible where conventional techniques are applied in an unconventional manner *even where the invention is a practical application of the judicial exception to solve a problem in the art*.

The Convention and Discovery

- The convention was to detect genes and their mutations directly
  - e.g., with a probe to the exact thing desired to be detected.
- However, when looking at all the genetic material in a subject, there is a lot of junk DNA and it is challenging to distinguish the junk DNA and find actual coding sequences, *i.e.*, genes.
  - Current estimates are that the human genome has about 20-25k protein-coding regions, which down from 100k or more as a result of improved methods for finding genes.
- The inventors surprisingly discovered non-coding sequences that are in "genetic linkage" with coding sequences that can be used to indirectly locate the coding sequences.

And then the invention, US 5,612,179

- The inventors created a detection method for detecting coding regions.
- A method for detection of at least one coding region allele of *a multi-allelic genetic locus* comprising:
  - a) amplifying genomic DNA with a primer pair *that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides* to produce an amplified DNA sequence characteristic of said allele; and
  - b) analyzing the amplified DNA sequence to detect the allele.

However, the Federal Circuit

- Considered the asserted claim limitations *apart from* the asserted JE—the relationship between non-coding and coding sequences in genetic linkage and the tendency of the non-coding DNA sequences to be representative of the linked coding sequences.
- Thus, the claim "as a whole" the Federal Circuit ended up evaluating for an inventive concept under Step 2 of the Mayo/Alice Test was completely stripped of the inventive concept itself.
- Unfortunately, the discovery of the JE is actually *a part of* the invention itself—integral to its practical and inventive application.

A *Part Of* Versus *Apart From*

A PART OF

- 1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:
- a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and
- b) analyzing the amplified DNA sequence to detect the allele.

APART FROM

- 1. A method for detection of at least one coding region allele [ ] comprising:
- a) amplifying genomic DNA with a primer pair [ ] to produce an amplified DNA sequence characteristic of said allele; and
- b) analyzing the amplified DNA sequence to detect the allele.

So, of course, the claim is ineligible

- As those skilled in the art were already detecting coding regions and alleles, by
  - a) amplifying genomic DNA with primer pairs, and
  - b) analyzing the amplified DNA to detect the alleles.

- And, of course, the performance of this stripped-down claim does not achieve the invention—the ability to search through a huge amount of junk and find a gem (gene).
- And so, this stripped-down claim does not even solve the problem in the art.

Federal Circuit, are you kidding?

Are you saying that any claim to an invention that is founded upon a scientific principle and integrates the scientific principle into the performance of the steps—is actually integral to the performance of the steps—to result in an inventive and practical application is ineligible?

USPTO and Additional Guidance

To the rescue… well, maybe

It seems the USPTO is trying

- Methods of detecting biomarkers are eligible
  - when the claim does not recite a law of nature

- 1. A method of detecting JUL-1 in a patient, said method comprising:
  - a. obtaining a plasma sample from a human patient; and
  - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

But diagnostic claims are ineligible

- 2. A method of diagnosing julitis in a patient, said method comprising:
  - a. obtaining a plasma sample from a human patient;
  - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
  - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

So…

What happens when claim 2 depends on claim 1?

2. A method of diagnosing julitis in a patient, said method comprising:
   - performing the detection method according to claim 1; and
   - diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

How can a claim that depends on and is narrower than an eligible claim all of the sudden become ineligible?

And…

Why isn't claim 2 simply eligible because we strip away the JE and consider what remains?

2. A method of diagnosing julitis in a patient, said method comprising:
   - a. obtaining a plasma sample from a human patient;
   - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody
   - [ ].

Isn't it then just like claim 1?

Oh…

Yes, Merck, treatment claims are eligible, or at least the USPTO thinks so.

What are markedly different characteristics?

- By the USPTO's own Dietary Sweetener fact pattern, claim 2 is ineligible, but it's a composition having 1-5% texiol and at least 90% water that has *a functional characteristic that is different* from that found in nature.
  - Specifically, a trained sensory panel, aka, experts in the field, determined that 1-5% texiol and at least 90% water "retains" the desired sweetness and bitter aftertaste and is preferred over higher concentrations.
    - The naturally occurring sap has about 10% texiol.
  - Thus, shouldn't something that has no more than HALF the concentration of texiol found in the naturally occurring sap, yet *retains* the sweetness and bitter aftertaste of the texiol *and has some different characteristic that makes it preferred over other concentrations*, be eligible?

So…

It seems the USPTO is comparing the functional characteristics of the *isolated* texiol with that of the texiol *isolated from* the composition *without regard to the effect of the concentration* in the composition that gives the composition a different character than texiol itself.

And…

What happened to looking at the claim *as a whole*?

What kind of evidence, if not that of an expert panel, is necessary to support markedly different characteristics?

What is a *Reasonable* BRI?

- In the Vaccine Example, is water really a *reasonable* broadest reasonable interpretation for a pharmaceutically acceptable carrier?
- There are innumerable forms and types of water that exist, some naturally occurring and some not:
  - Potable water
  - Contaminated water
  - Heavy water
  - Distilled water
  - Sterile water
  - Rain water
- But are *all* pharmaceutically acceptable, and of those, are they found in nature?

Peptide F and the Vaccine Example

- In the fact pattern, Peptide F is a naturally occurring fragment.
- What about *non-naturally occurring fragments* of proteins that *retain* substantially or all of the character/function of the full-length proteins?
  - Considering the structure-function relationship of biomolecules such as proteins, it is unexpected when a fragment has the same or similar function as the full-length protein despite its different structure (*i.e.*, truncation).

Again, what is the difference…

- Between a hip replacement and microneedles having a product of nature coated thereon?
  - Both are medical devices
- Is the difference in their intended use?
  - And if so, when did the USPTO start giving intended use (in)eligible weight but not patentable weight?

We still don't know

- The USPTO's position on "combination" biomarker assay claims and "weighted" biomarker assay claims.
  - Shouldn't the question for both be whether one in the art at the time would have combined or weighted the particular set of biomarkers together to result in an inventive concept?
  - In other words, shouldn't the *particular combination of biomarkers* in the given set of biomarkers be considered in the *ordered combination* part of the Mayo/Alice Step 2?

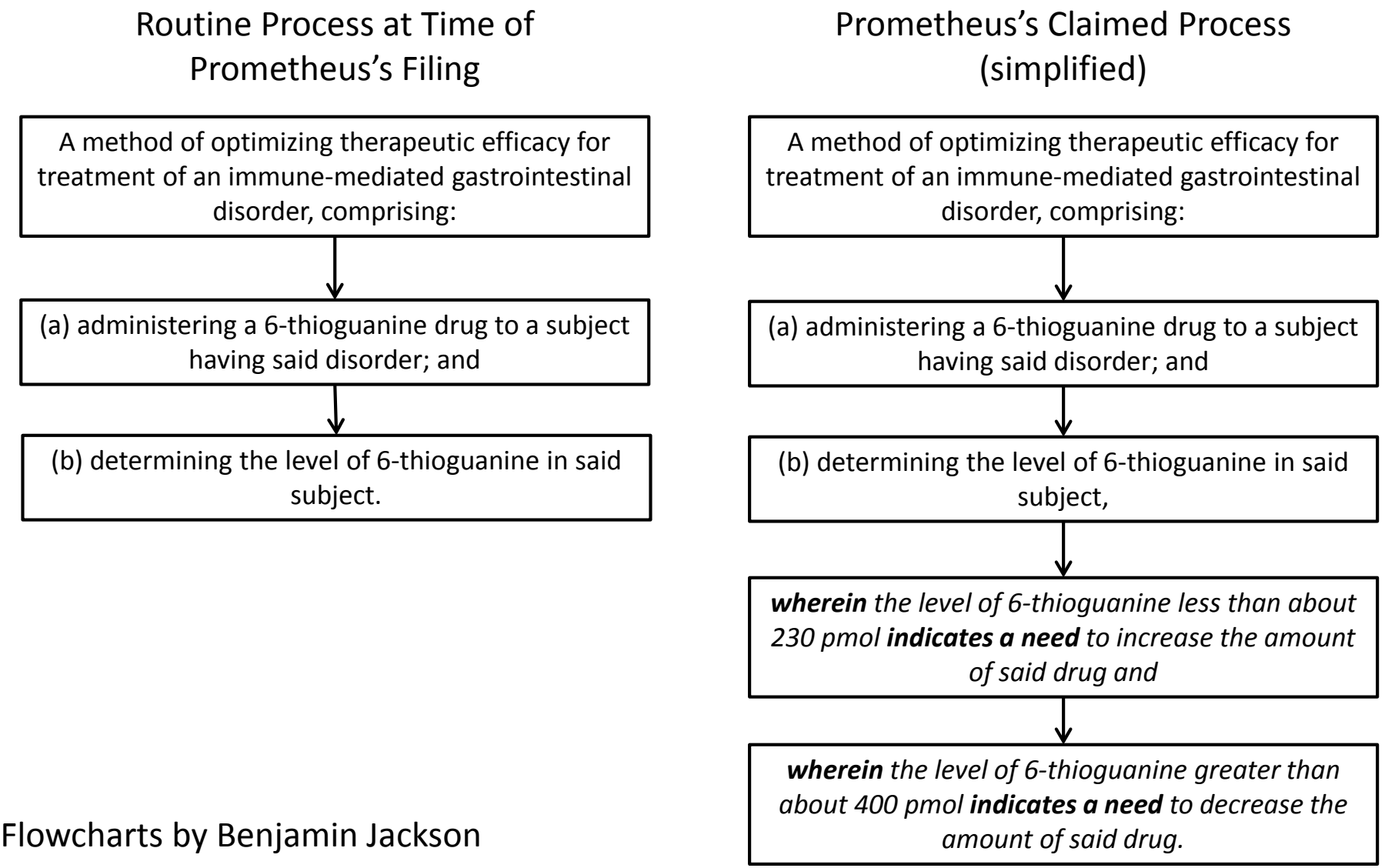
<sigh>…

I have so many more questions.

Now…

All I can say is that I knew more in kindergarten than I do now.

And when looking at *Mayo* again



Flowcharts by Benjamin Jackson

I agree with the *Mayo* Decision

But not with everyone's interpretation of *Mayo* to render meritorious inventions truly deserving of patent protection ineligible.

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