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Diagnostic Tests – Is There Anything Left to Patent?

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The "Big Question"

- Are "simple" diagnostic claims – "If A, then B" patent-eligible? (Elevated Hcys = low cobalamin.)
- PTO – "No" (2014 Guidelines)
- Justice Breyer, "No" ("Metabolite Labs. Dissent")(2006)
- Fed. Cir.: "No" –Even if claim is drafted with specificity as to both the marker measured and the condition identified.(Cleveland Clinic)

Genetic Technol. Ltd. v. Meriel, LLC

- (Appeal no. 1215-, -1202, -1203 (Fed. Cir. April 8, 2016))
- Claims were to the use of law of linkage disequilibrium to the problem of detecting specific coding sequences of DNA.
- Claim 1 was directed to a method of detection of at least one coding region allele of a multi-allelic genetic locus via an amplification step and a detection step.
- Claim 15 reads: “The method of claim 9 wherein said allele is associated with a monogenic disease” (e.g., cystic fibrosis).
- The panel characterized the term “to detect an allele in the coding region” as a mental process step – a routine comparison that can be performed by the human mind.”(Emp. supplied)

Does Judge Dyk have a legal hangover post-Ariosa?

- "The inventive concept necessary at step 2…cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea itself. That is, under the Mayo/Alice framework, a claim directed to a newly discovered [PAIN] cannot rely on the novelty of that discovery for the inventive concept necessary for [PE]; instead the application must provide something inventive, beyond mere 'well-understood, routine conventional activity.'"[Citing Mayo, Myriad and Ariosa][Empasis supplied]

Rapid Litigation Mgmt. LTD v. Cellzdirect, Inc.

- Appeal no. 2015-1570 (Fed. Cir., July 5, 2016)(U.S. Pat. No. 7,604,929). Judges Moore, Stoll and Prost, Prost writing.
- Method to isolate "hardy hepatocytes" by subjecting hepatocytes, including pooled ones, to two freeze-thaw cycles, resulting in cryopreserved "hardy" hepatocytes that could be used without further selection of viable from non-viable ones.
- D.C. held claim was to law of nature - reversed

Rationale: Claims are directed to new and useful preservation technique

- Panel distinguished the method steps of Genetic Techs., Ariosa and Myriad I and II as involving nothing more than observing or identifying the ineligible concept.
- Funk Bros. was distinguished as involving product claims and not methods of selecting and testing the strains.
- The method claimed in Mayo amounted to an old use of an old compound

Routine and Conventional Steps or Unobvious Advance?

- Panel carried out a full-blown obviousness analysis of the claimed method at Step 2 of the Mayo test, although method was PE under Step 1.
- "The benefits of the improved process over the prior art methods are significant."
- Prior art taught away from multiple freezing steps; art is unpredictable; crowded art did not suggest the multicryopreservation method.

Panel Relied on Diehr

- "Just as in Diehr, it is the particular 'combination of steps' that is patentable here. 450 U.S. at 188. The inventors discovered that some percentage of hepatocytes can survive multiple freeze-thaw cycles and applied that discovery to improve existing methods for preserving hepatocytes. To require something more would be to discount the human ingenuity that comes from applying a natural discovery in a way that achieves a 'new and useful end.'" [citing Alice].

PTO Responds to CellzDirect

- Memo to Examiners from Robert Bahr of July 14, 2016.
- "The court determined that [the claims], like thousands of other claims that recite methods of producing things or methods of treating disease, were not directed to a judicial exception."
- Bad: Claims that "[amount] to nothing more that observing or identifying the patent ineligible concept itself."
- No mention of diagnostic claims
- PTO Guidelines are sufficient post-Ariosa and CellzDirect.
- May 2014 Guidelines state that simple diagnostic claims are not PE.

Are All "If (a) then (b)" claims doa?

- What is the "more" that is needed to get diagnostic claims into the Diehr safe harbor? Need "inventive concept" in the claim (A discovery of a natural correlation AND an invention apart from a practical application of the correlation to yield a diagnosis).
- The discovery of the effect or meaning of the in vivo correlation cannot provide the "inventive concept" (Dyk in Meriel).
- Can't be "what is well-understood, routine, conventional activity, previously engaged in by those in the field" pre- or post-solution. But need some "further act." Mayo 132 S.Ct. at 1298.
- BUT what if the assay techniques are not routine and/or the components are complex?

The Cleveland Clinic Foundation v. True Health Diagnostics

- Appeal No. 2016-1766 (Fed. Cir., June 16, 2017)
- Diagnostic test for cardiovascular disease based on determining MPO level in sample with levels in subjects diagnosed as not having CVD.
- "[After testing steps, the claimed] method then employs the natural relationship between those MPO values and predetermined or control values to predict a patient's risk of developing or having [CVD]….The presence of MPO in a bodily sample is correlated to its relationship to [CVD]. The claims are therefor directed to a natural law."

Practice of methods does not rise to the level of "inventive concept."

- "Cleveland Clinic does not purport to derive new statistical methods to arrive at the predetermined or control levels of MPO that would indicate a patient's risk of [CVD]. Known statistical methods can be employed, as described, for example, in the specification [quoting about 11 lines]."

Cleveland Clinic Should Have Purported More!

- This is not like discovering the correlation between high homocysteine and low cobalamin or measuring maternal cffDNA.
- The “hand of man” is required to weigh the importance of each of a myriad of variables to the presence or risk of CVD.
- The definition of the presence or risk of CVD depends on how CVD is defined, including exclusion/inclusion and diagnostic parameters.

A Conclusion that is based on Judgment is not a Natural Law or a "Bare Mental Process."

- U.S. Pat. No. 7,223,552; Cols. 22-24, Table 1.
- CVD is defined using many parameters, such as "greater than 50% stenosis in one or more coronary arteries."
- The exclusion criteria for controls is also complex, e.g., coronary stenosis of greater than or equal to 50%.
- At the least this is the application of known statistical methods to multiple parameters to achieve, "optimum specificity…and sensitivity."

Athena Diagnostics, Inc. v. Mayo Collab. Services, LLC

- Civ. Action No.: 15-cv-40075-IT (D. Mass., August 4, 2017)
- Claims 6-9 of U.S. Pat. No. 7,267,820 were directed to the diagnosis of MG by detecting autoantibodies that will bind to a receptor located on neuromuscular junctions ("MuSK").
- MuSK or MuSK was labeled with 125-I, was introduced into a sample and any complexes formed with the IgG autoantibodies were detected indirectly or directly.
- The court found that each assay "focusses on a natural occurrence, it is directed to a patent ineligible concept [a law of nature]".
- Predictably, the claims also failed Stage 2 of the Mayo/Alice test. Specification called the test techniques "standard."

What if claims were to novel compounds or complexes?

- The method of using a patentable compound is also patentable. In re Pleuddemann, 910 F2d 828 (Fed. Cir. 1990), even if the use is otherwise obvious.
- The judge conceded that I-125-MuSK and the Ab-MuSK complexes are not found in nature, but the judge noted that they were not claimed and fell back on "the focus of the claims…is the interaction of the I-125-MuSK and the bodily fluid, an interaction which is naturally occurring."

But what if the compositions had been patented?

- "An in vitro complex of an IgG antibody and a MuSK receptor protein comprising a detectable label."
- "Isolated, labelled MuSK receptor protein that binds in vivo to human IgG autoantibodies."
- "A tertiary complex comprising MuSK, a human IgG autoantibody bound to MuSK and an labelled anti-IgG autoantibody bound to said IgG autoantibody."
- Preparations of either antibody per se.
- Mayo claims did not comprise novel compounds; correlation was between metabolite conc. and efficacy or side effects.
- Old use of an old drug.

What about methods of medical treatment?

- The Prometheus claim could have easily been written as a "regimen" type method claim:
- "A method for treating an immune disorder comprising administering a 6-TP generating immunosuppressive drug to a human in need of such treatment so that the serum levels of 6-TP fall between concentrations x and y."
- "Unlike, say, a typical patent on a new drug or a new method of using an existing drug, the steps add nothing of significance to the natural laws themselves."(Mayo)
- Methods of treatment were assumed to be PE by Lourie and Moore in Myriad and by the panel in CellzDirect.

Watch this Space!

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Thank you for your participation.

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Thank you for your consideration

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