Sequenom's En Banc Petition

Sequenom's Petition for Rehearing En Banc - Panel Ignored "Inventive Concept" in Combined Steps of the Claimed Method.

For any of us practitioners encountering increasing numbers of s. 101 rejection rejections of diagnostic claims based on Mayo and the March 2014 PTO Guidance - and that is pretty much any life sciences patent attorney - this brief is a "must read." (A copy of this brief is available at the end of this post.) This brief puts it all out there, both criticizing the panel, proposing a new rule for method claims incorporating natural phenomenon and illustrating how the panel's application of the Mayo Rule threatens method of medical treatment claims as well as diagnostic method claims.

If I start trying to summarize the Brief, I will not be able to stop. Instead of arguing that the Mayo Supreme Court decision was wrong, the Brief distinguishes the regimen claims in Mayo from the Sequenom claims - that were based on the discovery of cffDNA in maternal serum which, in turn permitted the non-invasive determination of the condition of the fetus. The opinion of the Brief's authors is that the Sequenom claims adhere to the rationale of Diehr, a decision ignored by the panel. I will quote two paragraphs below, but picking just one to quote is like having to stop after eating a single M&M or one potato chip - nearly impossible:

"That the [Sequenom] inventors' discovery of a natural phenomenon motivated that new combination of steps makes this case no different that Diehr or any other invention. Indeed, while the *source* of [the inventors'] 'inventive concept' was of course the discovery of cffDNA in maternal plasma, it is indisputable that their inventive concept was ultimately embodied in a method that taught researchers to apply the combined techniques of fractionation, amplification, and detection to *waste materials* in essentially the opposite of the conventional fashion."

So the ultimate diagnostic conclusion is embodied in a method claim reciting steps that may all be available to the art, but add up to a patent-eligible method claim due to the embedded discovery of what the [per se unpatentable] natural phenomenon *means*.

This is a bit more sophisticated than my argument that the diagnostic conclusion should be viewed apart from the *in vivo* correlation and be given weight as a claim element, but it scales the same analytical mountain. Here is the next paragraph from the Brief:

"To see this more clearly--and demonstrate the problem in the panel's understanding of a method's 'inventive concept'--consider a case in which a researcher serendipitously discovers that a randomly-selected combination of well-known lab techniques allows him to reliably detect a disease from a urine sample, but he has no idea why. This method is plainly patent-eligible: It claims a highly novel and useful process, and recites no natural phenomenon apart from the fact that the method works.... Ironically, the panel's rule would hold that if this researcher *did* understand his method--if he knew the phenomenon that explained it, and the techniques involved would be routine to someone with that knowledge--the method suddenly becomes ineligible subject matter. This is absurd: No rationale patent system can punish inventors for understanding or explaining why their novel methods works. That is why, *per Diehr*, a method's 'inventive concept' inheres in the novelty of the combined steps, *not* the discovery that motivates them."

It only gets better. Now let's hope that the Fed. Cir. and the PTO can get it.