

A Troubling Trend For Personalized Medicine Patents

Law360, New York (December 04, 2012, 12:45 PM ET) -- On Nov. 20, 2012, a three-judge panel of the Court of Appeals of the Federal Circuit, in *PerkinElmer Inc., and NTD Laboratories Inc. v. Intema Ltd.* (2011-1577), held that the claims in U.S. Patent 6,573,103 (the '103 patent") are invalid as drawn to noneligible subject matter under 35 U.S.C. § 101.

The '103 patent claims are directed to prenatal noninvasive diagnostic methods for risk of fetal Down syndrome. *PerkinElmer* is a nonprecedential decision that follows the *Ass'n for Molecular Pathology v. PTO*, 689 F.3d 1303 (Fed. Cir. 2012) ("*Myriad*") which was the first Federal Circuit decision to apply the U.S. Supreme Court's unanimous decision on the Section 101 validity of medical diagnostic/personalized medicine claims in *Mayo Medical Laboratories v. Prometheus Laboratories* 566 U.S. ____ (US 2012) ("*Mayo*").

PerkinElmer, like *Myriad*, concluded that the inventive features of the claims are ineligible mental or abstract steps. The tendency of the federal courts toward an expansive application of the abstract idea exception to patent eligibility, if widely adopted, will have a detrimental effect on the validity of broadly claimed diagnostics/personalized medicine patents.

PerkinElmer evaluated eligible subject matter of independent claims 1 and 20 of the '103 patent. Claim 1 is drawn to a method for determining whether a pregnant woman is at an increased risk of having a fetus with Down syndrome by (1) measuring at least one marker, by assay or ultrasound, during the first trimester, (2) measuring at least one marker, by assay or ultrasound, during the second trimester, and (3) determining the risk of Down syndrome by comparing the measured levels of the markers with the relative frequency distributions of marker levels in Down syndrome pregnancies and in unaffected pregnancies.

Claim 20 is similar but uses the first screening marker alone to compare to relative frequency distributions so as to screen individuals into positive or negative risk groups, wherein individuals in the negative risk group are further screened for a marker during the second trimester in order to determine risk.

The “determining” step of both claims was construed by the district court as follows:

1. determining the risk of Down syndrome by comparing distributions of marker levels in Down syndrome pregnancies, and in unaffected pregnancies; and
2. combining screening markers from the first and second trimesters into a single risk calculation.

The PerkinElmer court relied on the similarity of the ‘103 patent process claims to those at issue in Mayo and Myriad to find the claims invalid as directed to patent-ineligible subject matter. The guiding principle for the PerkinElmer court was Mayo’s “inventive concept” requirement which requires there to be significant additional steps in a claim beyond those representing laws of nature, natural phenomenon and abstract ideas to transform an unpatentable principle into a patentable process. PerkinElmer, at p.9. Post-solution activity that is purely conventional or obvious is insufficient to transform those laws, phenomena, and ideas patentable-eligible claims. PerkinElmer, at p.9-10.

The PerkinElmer court characterized the law of nature as the claimed relationship between screening marker levels and the risk of fetal Down syndrome. PerkinElmer, at p.11.

The court then evaluated whether the data-gathering steps (i.e. screening marker measuring steps) and/or the post solution “determining” step added enough to render the claims patent-eligible.

According to the court, the measuring steps of the ‘103 patent claims were insufficient to make the claims patent eligible because the patent merely tells the user to measure the screening markers using well-known methods. Id. at p. 11. In fact, the patent states that it was previously known to use the specified screening markers from a single stage of pregnancy (in addition to maternal age) to calculate a Down syndrome risk.

The determining step of the ‘103 patent was held to be a mental step and therefore insufficient to impart patent eligibility. PerkinElmer, at p.12. Furthermore, the court determined that the statistical information underlying this step was well known and conventional. PerkinElmer, at p.12.[1] Finally, the ‘103 patent claims, when considered as a whole, excluding the natural law and mental steps, also were adjudged by the court to lack sufficient patent-eligible subject matter.[2]

The PerkinElmer court concluded that the ‘103 patent claims also failed the machine-or-transformation test for subject matter eligibility. It reasoned that the measuring of biochemical markers may be done in the future without the need to transform a sample from the patent and that measuring of an ultrasound scan offers “no tangible output or visual depiction of the risk.” PerkinElmer, at p. 14-15.

The PerkinElmer court appears to extend into new territory beyond the facts in Mayo and Myriad when it evaluated subject matter eligibility of the ‘103 claimed requirement to base Down syndrome risk determination on a comparison of test results from both the first and second trimester. This concept, dubbed “two markers are better than one” by the court, was considered a mental step or abstract idea and thus ineligible subject matter, despite the patentee’s assertion that it was focus of the claims and rendered it new and inventive over the prior art single marker risk assessment.[3]

The court did not explain how it reached the view that the measurement of markers from two time points and the combination of the results into a single risk factor is a mental or abstract idea. It simply indicated that the two markers concept were mental or abstract steps similar to the findings of the Myriad court concerning the comparison of DNA sequences and the determination of the cell growth rates. PerkinElmer at p. 13. The “two markers are better than one” concept arguably is achieved by physical tasks, which include gathering the samples at each time point, processing the samples from each time point to obtain test results, and then using all the information mathematically to obtain a single risk score.

Too much should not be made of a nonprecedential decision however, in this instance, the impact of Mayo on the validity of medical diagnostic/personalized medicine patents is just beginning to take shape so the views of additional circuit justices is revealing of the direction the Federal Circuit may taking in the future. PerkinElmer seems to follow Myriad in concluding that certain claimed features are mental or abstract steps. The tendency to adjudge claim features in this manner may end up having a detrimental effect on the validity of broadly claimed inventions in diagnostics/personalized medicine.

Patent practitioners drafting and prosecuting method claims in diagnostics/personalized medicine may be advised to convert what may be considered a mental step into one more steps that embody physical actions to make is more likely that the claim will satisfy Section 101. Another approach is to add steps to the claim that utilize the information generated. In this regard, the PerkinElmer court hinted that the ‘103 patent claims may have fared differently had they included an additional step(s) that utilized the information generated but gave no indication as what additional steps may be sufficient. PerkinElmer, at p.12-13.

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[1] The court relied on admissions in the ‘103 patent at column 6 to support this conclusion.

[2] Like the Supreme Court in Mayo, the PerkinElmer court found that anyone wanting to use the mental step and natural law of the ‘103 patent claims would necessarily follow the claimed process. PerkinElmer, at p.12.

[3]The PerkinElmer court considered this argument in support of patentable subject matter to be the basis upon which the district court erred. The district court distinguished an earlier Federal Circuit decision, *In re Grams* 888 F.2d 835 (Fed. Cir. 1989) (“Grams”), prohibiting patent eligible physical data gathering steps from rendering eligible, non-eligible abstract ideas. In Grams, the sole physical process step in the claims, i.e., performing clinical tests on individuals to obtain data, was determined a mere data gathering step incidental to the algorithm to which the patent and claim were really focused on. The district court distinguished Grams by concluding that the data gathering steps in the ‘133 patent claims in which markers levels from the first and second trimester were combined to generate a risk were the “focus of the claimed method and not a mere antecedent step.” PerkinElmer at p. 14.