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Recent Trends in Biotech Patent Law

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Asuragen is a molecular diagnostics company using genomics to drive better patient management through best-in-class clinical testing solutions.

Developments in Patent Eligibility Law/Policy

- § 101 in the Courts after *Mayo* and *Myriad*
- USPTO Interpretation of Supreme Court Decisions and Examiner Guidance
- Guidance in Practice by PTO Examiners

§ 101 in the Courts – Intema

- *PerkinElmer Inc. v. Intema Ltd.* (Fed. Cir. 2012)

> A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:
>
> measuring the level of at least one screening marker from a first trimester of pregnancy by:
>
> (i) assaying a sample ...; and/or
>
> (ii) measuring at least one first ultrasound screening marker from an ultrasound scan ...;
>
> measuring the level of at least one second screening marker from a second trimester of pregnancy, the at least one second screening marker from the second trimester of pregnancy being different from the at least one first screening marker from the first trimester of pregnancy, by:
>
> (i) assaying a sample ...; and/or
>
> (ii) measuring at least one second ultrasound screening marker from an ultrasound scan ...; and
>
> determining the risk of Down's syndrome by comparing the measured levels of both the at least one first screening marker from the first trimester of pregnancy and the at least one second screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies.

- Because steps are "purely conventional or obvious pre-solution activity," the claim amounts to no more than the concept itself - an ineligible law of nature

§ 101 in the Courts - Myriad

- Myriad sued Ambry Genetics, Gene by Gene, GeneDx, Quest Diagnostics, InVitae, and Lab. Corp. of America – District of Utah.
- D.J. action was filed by Counsyl, Quest Diagnostics, and InVitae on overlapping Myriad patents - N.D./C.D. California.
- Cases were consolidated in D. Utah.
- Myriad's motion for preliminary injunction was denied in March 2014.
- Fed. Cir. denied Myriad's request for an expedited appeal.
- **CAFC oral argument occurred on October 6, 2014.**

§ 101 in the Courts - Myriad

- D. Utah court found that Myriad likely to suffer irreparable harm but that Myriad had not established likelihood of success on merits.
- Court found that claims were invalid under § 101:
  - Synthetic DNA (primer) was not patent eligible because it had the same sequence as genomic DNA
  - No significance to fact that claims were drawn to pairs of primers not found together in nature
  - Tags and terminating sequences attached to primers did not distinguish from nature
  - Distinct utility not enough to confer patent eligibility.
- Method claims also found ineligible – claims "essentially foreclose the most widely used means to study and test for [BRCA] genes."

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§ 101 in the Courts - Sequenom

- *Ariosa v. Sequenom* (N.D. Cal.)
- Sequenom's patent cover methods of detecting paternally inherited DNA of fetal origin - based on discovery that cell-free fetal DNA is detectable in pregnant woman's plasma.
- On summary judgment, the District Court held that the patent was invalid under 35 U.S.C. § 101:
  - Claims applied routine, well understood steps to a natural phenomenon (presence of inherited cell-free fetal DNA in maternal plasma)
  - The patents carry a "substantial risk of preemption because there was no evidence that alternative methods available and "commercially viable" at the time the application was filed.
- **CAFC oral argument scheduled for November 7, 2014.**

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