

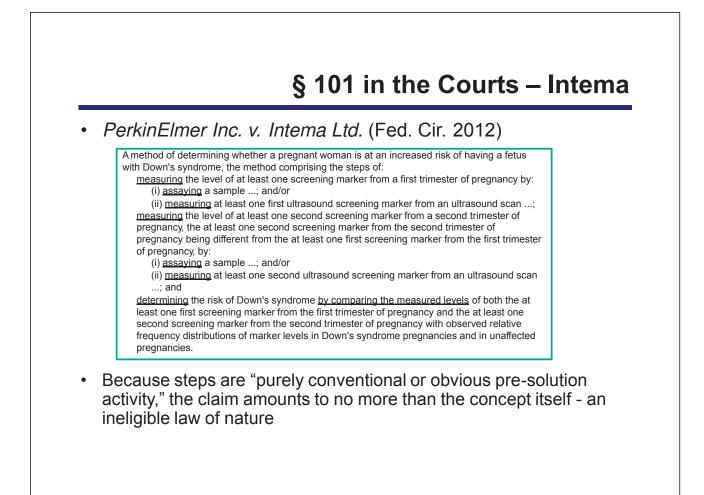
Recent Trends in Biotech Patent Law

Ana C. Ward Senior Vice President & General Counsel



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

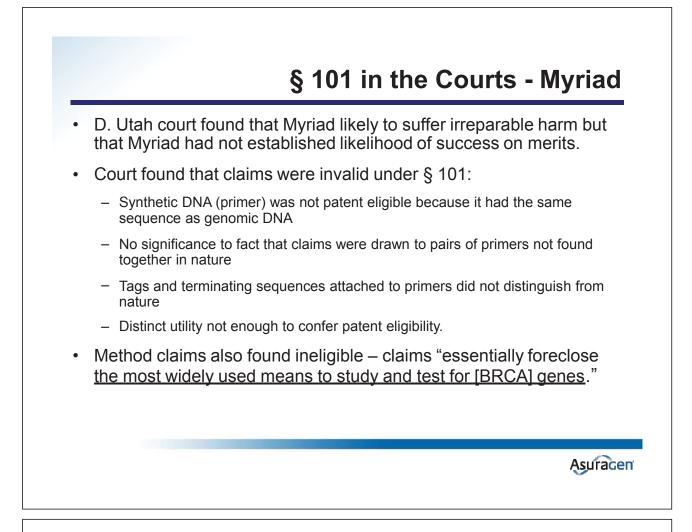
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§ 101 in the Courts - Myriad

- 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 <u>March</u>
 <u>2014.</u>
- Fed. Cir. denied Myriad's request for an expedited appeal.
- CAFC oral argument occurred on October 6. 2014.

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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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