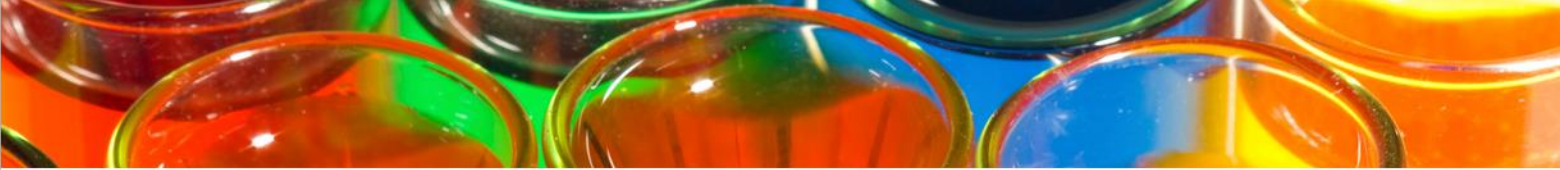




What You Need to Know About Recent Changes in Patent Law

Thursday, December 7, 2017



What You Need to Know About Recent Changes in Patent Law

Speakers:

- **Karen E. Brown**, PhD, JD, Vice President & Chief Intellectual Property Counsel, Ironwood Pharmaceuticals
- **Jennifer Elliott**, PhD, JD, Director, Intellectual Property, The Broad Institute
- **Claire M. Vasios**, PhD, Vice President, Head of Intellectual Property, Alkermes, Inc.

Co-moderators:

- **Mike Biro**, PhD, JD, Senior Counsel, CRISPR Therapeutics
- **Konstantin Linnik**, PhD, JD, Partner, Nutter McClennen & Fish LLP



Changes in Patent Law - Sources

- Legislation
 - America Invents Act (2011)
 - Biologics Price and Competition Innovation Act (2012)
- Courts
 - Active Supreme Court – 23 patent cases since 2010
 - US Court of Appeals for the Federal Circuit (~1,500 cases per year)
 - Other federal courts
- UPSTO
 - Implementation of the AIA above
 - Patent Trial and Appeal Board (7,500 IPRs since 1/2013)



Major Shifts – America Invents Act

- From First-To-Invent to First-Inventor-To-File
 - Phasing out of interferences
 - Introduction of “derivation” proceedings
- New “fast-track” challenge proceedings at the USPTO
 - Inter Parte Re-exams (“IPRs”)
 - Post-Grant Reviews similar to European oppositions
- Diverging interests of high tech industry vs. biopharma; small vs. large entities; generics vs. innovators/brand; FTO vs patentability



High-impact US Supreme Court cases

- *Myriad, Prometheus, Alice* – 101 patent eligibility
 - Isolated, naturally occurring substances (genes, Tx)
 - Correlations and laws of nature (Dx)
 - Software patents (bioinformatics)
- *Integra v Merck*
 - Research exemption
- *Oil States* (pending)
 - Are IPRs constitutional?



The State Of The Patent System

- The America Invents Act and court decisions have had a major impact on the US patent system, potentially impacting US competitiveness
- Abuses of the IPR system have surfaced, calling for calibrated adjustment to protect good-faith patent holders.
- Confusion and unpredictability stemming from court decisions regarding Section 101 also calls for congressional consideration.
- Concerns generally are surfacing that our patent system may have been overcorrected and excessively weakened, discouraging investments in innovation.



Upcoming MassBio Forums

Save the Date

January 18, 2018; 4-6pm:

2018 JP Morgan Recap: An Insiders View

BD/Fin & EU