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Patent Eligibility of BioPharma after Alice in light of Ariosa

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Mayo/Alice

- Mayo Two-Step for Section 101
  - Directed to a "judicial exception"
  - Additional steps "as an ordered combination" do "significantly more" than merely apply the exception
  - Concern underlying the exceptions is preemption
  - Looks a lot like obviousness analysis – except that the discovery itself is not prior art under Section 102 (but treated as such for 101?)

Myriad

- Application of "markedly different" test
- Isolation not a "marked" difference
- Natural/synthetic line not dispositive
- Incoherent treatment of iDNA v. cDNA differences
- Case focus on "information content" of DNA – extensions (e.g., all nature-derived products)?

Post-Mayo/Myriad/Alice Cases

- In re Roslin Institute (cloned sheep; phenoyptic differences must be claimed)
- In re BRCA1- Litigation (ssDNA primers and probes)
- SmartGene (computer assisted treatment methods)
- Becton-Dickinson v. Baxter (pharmaceutical supervision and verification methods)
- Cleveland Clinic (tests and test kits)
- Genetic Techs. v. Bristol Myers (discovered correlations of junk/coding alleles; amplifying and analyzing to detect allele)

PTO Guidance

- "directed to a judicial exception"
  - analogy from case law to recognize (particularly for abstract ideas)
- "significantly more"
  - continued confusion over the level of generality/specificity of implementing steps (particularly in computer technologies)
  - Preemption is purpose, but not the test
- "Markedly different" analysis for all modifications from nature (nature-based products)
  - Structural, functional, and "other property" differences if marked are sufficient (line drawing) – see Roslin
  - "Step 2A" analysis (2B "significantly more" still available)

Ariosa v. Sequenom

- Discovery of cffDNA; claims to diagnostic methods using discovery
- Additional steps in prior art; combination of steps not used with cffDNA until discovery
- Conflation of preemption concerns (or not) with the question of whether creative application of a discovery is required – why does specificity v. creativity of application matter? Go back to purposes of exclusions
- Jeffrey Lefstin, Inventive Application: A History, 67 Fla. L. Rev. 565 (2015)

Conclusions

- Unlikely to get clarity from SCOTUS but Ariosa presents best test case on facts to discuss treatment of discovery as prior art for application (or not)
- Unlikely to get clarifying legislation (too political)
- "Dr. Strangelove, or how I learned to stop worrying and to love the bomb"!

Joshua Sarnoff, Patent Eligible Inventions after *Bilski:* History and Theory, 63 Hastings L.J. 53 (2011)