The *Myriad* ways that 35 U.S.C. §101 has been obscured for Biotech…

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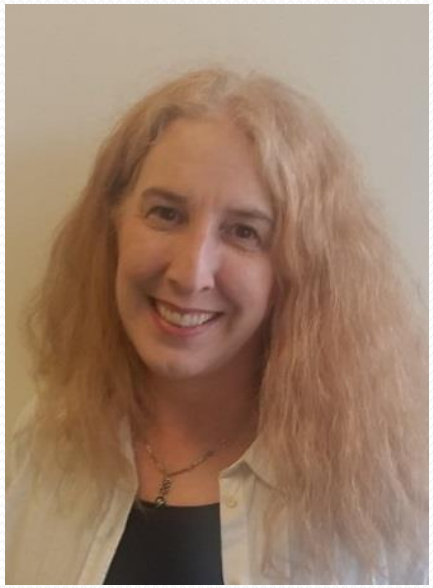

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Ms. Johnson is an experienced corporate and IP attorney with over 19 years of diverse legal experience in human biotechnology and agriculture companies. Prior to joining Blaze Bioscience, Ms. Johnson served as Head, IP Biology and Traits at Syngenta. Prior to Syngenta, she served in as Chief IP Counsel for ZymoGenetics. Previous to her life as a lawyer she was a researcher.

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The views expressed on this presentation are mine alone and do not constitute legal advice nor necessarily reflect the views of my employer, Blaze Biosciences, Inc., nor the views of any past employers, government agencies or other organizations.

Background – AMP v. Myriad (*Myriad I*)

- ***Myriad v. AMP (Oct. 2013)* SCOTUS *(Myriad I)***
  - **Held:** isolated genomic DNA is unpatentable subject matter - product of nature. (*Myriad I*)
  - **What is *not* implicated:** (i) innovative methods of manipulating genes (ii) new applications of knowledge about …genes, (iii) patentability of DNA in which order of naturally occurring nucleotides has been altered (e.g., cDNA).

"We merely hold that genes and information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."

- **Political Backdrop:**
  - Academics and Breast Cancer Patients (access to healthcare diagnostics)
  - Affordable healthcare at forefront of US Government debate
  - Aggressive Company perception
  - Industry pressure
    - Pressuring Myriad to withdraw patent to avoid creating bad precedent

CAFC: Myriad v. Ambry & Gene-by-Gene *(Myriad II)*

The case

- Myriad owns patents ('282 and '441 patents) claiming **compositions and diagnostic methods** for detecting human gene variants which increase cancer risk (BRCA1/2 genes).
  - Myriad sued Ambry for patent infringement based upon 4 broad diagnostic claims (use of DNA primers) and methods of BRCA1 and BRCA2 detection.
  - Sought to enjoin Generics: PI denied – Q of whether claims invalid under 101 (*Myriad*).
  - Myriad directly appealed to CAFC on the Q of patent eligibility.
- Composition Claim:

  "16. A pair of single stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of a DNA having all or part of the sequence of the BRCA1 gene."
  - Single Stranded DNA
  - Pair of Primers – functionally different purpose (application using DNA)

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The Court*(p. 9 of opinion)*

"A DNA structure with a function similar to that found in Nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature."

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- Method Claims 7-8 ('441) (summarized)

"7. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing [sequences…with wild type], wherein a difference in the sequence [between subject and wild type] indicates an alteration in the BRCA1 gene in said subject, wherein [identified by hybridization.]"

"8. A method for screening germline of a human subject for an alteration of a BRCA1 gene … wherein [identified by PCR.]"

- Ambry argues application of *Mayo*
- The Court takes further….

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The Court*(p. 13 of opinion)*

"We need not decide if Mayo *is directly on point here because the method claims before us suffer from a separate infirmity: they recite abstract ideas."*

Apply *Alice* two-step test to determine patent eligibility:

(1) **Are claims directed to a patent ineligible concept? If so,**

(2) **Then ask: "what else is in the claims before us?"** (whether nature of the claim is transformed it into something patent eligible)

- Abstract Ideas (comparing)
- With respect to research related to BRCA1 genes: *"it is antithetical to the patent laws to allow these basic building blocks of scientific research to be monopolized."*

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- **CAFC Panel Ruling (Dec 2014) on Patentable Subject Matter:**
- Broad "primer" and "method" claims held non-patentable. Myriad Settled the case in January.
  - Consequently, only the broadest claims have been challenged on the basis of non-patentable subject matter, leaving open (and ambiguous) patentable some narrower, and more specific claims.

- Compositions: Unless a unique structure - sequences and parts of sequences if identical to those found in nature are not patentable as "products of nature"

The issue

- Whether CAFC expansion of SCOTUS *Myriad* in light of *Alice Corp.* holding of non-patentable subject matter (product of nature) beyond isolated DNA is appropriate (adding routine elements or uses to novel unpatentable product of nature does not render patentable).
  - Tests scope of jurisprudence as applied to (i) methods of manipulating genes, (ii) new applications of knowledge about genes (methods of use).
  - Unclear whether narrowing use claim would overcome "product of nature" bar (not likely under *Alice Corp*. reasoning).
  - What makes our biotech claims unique? Sequences….

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- ***The risk***
- Myriad II has High Impact:
  - threshold "test" determining a "product of nature" is directed to the structure of novel genetic elements (or natural isolates) themselves (no matter how used, in part, or in combination)
  - Applies to any "natural" isolate: Biopharmaceutical proteins, cell-based expression of DNA, detection assays, GM plant microbial and animal, biocontrols, protein production strains, and hi-tech products (e.g., RNAi, antibodies), chemistry where gene, protein or active chemical is in whole or in-part non-modified (and identical to existing natural composition).
  - Impacts most biotechnology.

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- ***What can we do?*** What we patent attorneys typically do:
  - Crafting claims + Using attorney argument /finding ways to “distinguish” this line of cases
  - Increase use of Trade Secrets (we see this happening already in diagnostics)
  - Defined unique things about the sequences/etc. that are not found in nature (and hope that they are “different enough” to be considered patent eligible).
  - Advise clients to pursue novel structures (tweak your molecules)
    - Introduce changes in buried parts of proteins
    - Unique structures
    - Unique DNA sequences for cell lines used to express proteins
    - New cell lines for production methods
    - $$
- **None of the above changes the uncertainty of this line of cases and its impact on the Biotech business.**

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- ***What else can we do?***
- 3-Prong Strategy:
  - Work with USPTO to minimize the impact
  - Identify Test cases for Appeal to CAFC
    - With the right facts
    - To help shift law in a different direction
  - Start engaging in the dialog for a Legislative Correction
    - Advocacy as lawyers, companies, firms

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- ***What can we do?***
- Legislative Correction:
  - Precedent in the Plant Field (US Variety Patents)

- What might it look like?
  - Repeal 101!!! Do we really need it any more….
  - Repeal *Myriad* – make clear only exception is isolated DNA
  - Make carveouts (gets messy)

- **Legislative correction absolutely changes the uncertainty of this line of cases and would positively impacts Biotech business.**
  - Takes time and effort

Our role as attorneys in advising our clients

- **Political nature of cases**
  - Recognize a charged issue (breast cancer patients, academics, nonprofits, DOJ interest)
  - Public Policy at forefront pitted against private interest
    - Access to tests/medicine/healthcare v. Exercising an exclusion right / profit
  - Analysis/advice too theoretical: legal/technical without considering broader implications
- **Role in Litigation / enforcement**
  - Damage to reputation in light of political nature of case
  - Question whether to sue on what are realistically overly broad claims (create bad law?)
  - Impactful (advocacy to shape policy) v. Winning (advocacy without consequence)
  - What is the patent attorney role in the litigation team – only technical? Or more?
  - Focus shift: Winning wars rather than winning only battles
- **Leveraging the IP / Licensing**
  - If access important – is licensing a better option?
  - Part of the business case (as alternative to litigation)
- **Advocacy**
  - Legislation – as a real option…
  - Is it time to push this IP issue since it is now raised to the level of business importance?

Thank you!