Making It Personal – Challenges and Strategies for Patenting Genetic Technologies

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B2PM
Best Practices in Personalized Medicine

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Incentivizing Investment

- Patents traditionally used to incentivize investment by providing limited period of exclusive rights in exchange for disclosure of invention to public.

- "The Congress shall have Power To promote the Progress of Science and useful Arts, by securing for limited Times to authors and Inventors the exclusive right to their respective Writings and Discoveries." U.S. Constitution Article 1 Section 8.

Patent Law Evolution Creates Uncertainty

- Rules of the game do not remain fixed over time
  - Legislation
  - Case Law
  - Patent Office Rule changes
- Long lag between preparing patent application and enforcement

Example — Medical Diagnostics — P4 Medicine

- Leroy Hood's P4 Medicine –
  - Predictive, Preventive, Personalized & Participatory
    - Dramatic cost reduction in DNA sequencing → individualized whole genome sequencing
      - Risk analysis based on mutations, SNPs, etc.
  - Impact of patents on delivery of P4 promise?

Association For Molecular Pathology et al.
v.
United States Patent and Trademark Office et al.

Significance of BRCA1/2 Genes

- BRCA1 & BRCA2 genes are responsible for the vast majority of hereditary breast and ovarian cancer
- Mutations in BRCA1/2 genes correlate with **increased risk of breast and ovarian cancer**
- Women with both BRCA1 and BRCA2 mutations:
  - 85% risk of developing breast cancer
  - 50% risk of developing ovarian cancer

Myriad's BRCA Products

- **Comprehensive BRACAnalysis** (Standard Test)
  - Detects 5 common large rearrangement mutations
  - Cost - ~$3000/test

- **BRACAnalysis Rearrangement Test**
  (Supplemental Test)
  - Detects virtually all large rearrangement mutations in BRCA1/2

Myriad's BRCA Patents

- **Myriad's BRCA Patents:**
  - Myriad's patents cover various permutations of isolated BRCA1 and BRCA2 DNA and their uses
  - 7 patents (15 claims) related to BRCA1/2 genes - challenged
  - 16 patents covering Myriad's BRCA-based tests - unchallenged

Myriad Genetics – Patentable Subject Matter Under 35 U.S.C.§101

- **Issue: Whether patents claiming isolated DNA sequences and related methods are patent eligible under 35 U.S.C.§101**
- Challenge was brought by patient advocates, scientists and public interest groups concerned about the availability of cancer treatments
- The Myriad patents claim the complete DNA sequence of certain genes that are significant in causing breast and ovarian cancer, and methods for comparing gene sequences to identify mutations that correlate with development of cancer
- Cannot patent naturally-occurring DNA sequences, which are products of nature
- District court held that DNA sequences isolated using well-known techniques should not be treated differently, and found the patents invalid

Myriad's Claims-in-Suit

- **Claims-in-Suit:**
  - **Isolated DNA** (related to human BRCA1/2 genes and mutants)
  - **Methods for analyzing** BRCA1/2 sequences for mutations
  - **Methods for diagnosing a predisposition** for cancer from BRCA1/2 mutations
  - **Processes for cell-based drug screening**, involving using a recombinant cell engineered to express BRCA1 to screen for potential cancer therapeutics

Primary Issues Presented

- Whether isolated gene patents are **unconstitutional**
- Whether claims directed to isolated DNA containing naturally occurring sequences fall within the **products of nature** exception to 35 U.S.C. §101
- Whether methods of analyzing/comparing DNA sequences are invalid due to indefiniteness, as well as being patent ineligible as being directed towards **abstract mental processes**

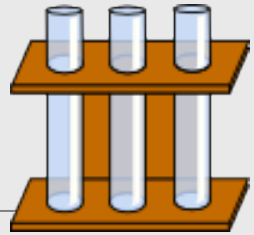
Holdings

- Judge Sweet
  - Products of nature do not constitute patentable subject matter absent a change that results in the creation of a new product
- **Isolated DNA:**
  - To be patentable, DNA must have "markedly different characteristics" from the naturally occurring sequence
  - Information-bearing is a key characteristic of both isolated DNA and the DNA located in a genome
    - **Chemical differences irrelevant, information-bearing characteristic of the gene is the same in both cases**
    - Differences in the presence or absence of introns in the genetic material does not make two pieces of DNA "markedly different"
  - **Isolated DNA is patent ineligible under 35 U.S.C. §101 because it is a product of nature**

Holdings, continued

- **What about cDNA?**
  - cDNA is non-naturally occurring DNA
  - Corresponds directly to naturally occurring mRNA and has the same informational significance
  - Also **patent ineligible** under 35 U.S.C. §101

Holdings, continued



- **Methods of Comparing / Analyzing:**
  - Court relied on *Bilski*'s machine-or-transformation test:
    - No transformative nature → merely data gathering steps
  - **Reconciling *Prometheus v. Mayo*:**
    - ***Prometheus v. Mayo*** – claims for analyzing body fluids for drug metabolites and adjusting dosage accordingly → patent eligible subject matter because "determining" metabolite levels involves a transformation
    - ***ACLU v. Myriad*** - No such "determining step" as found in *Prometheus*, only "analyzing" and "comparing" steps
  - Claims relate to methods of "comparing" or "analyzing" DNA sequences are abstract ideas and thus unpatentable under 35 U.S.C. § 101

Myriad Genetics Appeals District Court Ruling

- On July 15, 2010, Myriad filed a Notice of Appeal with the district court.
- Next stop, Court of Appeals for the Federal Circuit
- 29 *amicus* briefs were filed with the Court of Appeals.
  - 15 were filed in support of Defendants-Appellants and/or reversal,
  - 12 were filed in support of Plaintiffs-Appellees and/or affirmance, and
  - 2 remain to be determined
  - Department of Justice has filed an *amicus* brief arguing that genetically-engineered molecules should be given patent protection, but "isolated but otherwise unmodified" molecules should not

Likely Outcome of *Assn for Mol. Pathology v. USPTO & Myriad*?

- The status quo is the rule at the USPTO until the CAFC rules on Myriad's challenged BRCA patents
- The Supreme Court may grant *certiorari* given the importance of the issues
  - Outcome from Supreme Court less predictable
- First, stay tuned for CAFC decision

Dealing with the Uncertainty of *Assn for Mol. Pathology v. USPTO & Myriad*

- Recognize it exists, anticipate possible outcomes and prepare strategic patent filings that provide value in view of those possible outcomes
  - Include step that can be considered "transformation" – *e.g.*, contacting sample with reagent to form complex and measure complex
  - Describe machine-implemented steps (carrying out on a processor, web-based methods, software implementation)
- Participate in the policy debate through industry and lobbying organizations – consider standards setting and patent pools (as with high tech industry)

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Questions/Comments?

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