Patent Nation Seminar

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Gene Patenting – Defining a Potentially Pivotal Moment in Biotech

Patentable Subject Matter in U.S.

Association for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al., 702 F.Supp.2d 181 (S.D.N.Y. 2010)

("*Myriad v. ACLU*")

Presenters

Moderator:

- **Harold C. Wegner,** Partner, Foley & Lardner

Panelists

- **Kevin Noonan, Ph.D.**, Partner, McDonnell Boehnen Hulbert & Berghoff LLP
- **Joshua D. Sarnoff**, Associate Professor, DePaul University College of Law
- **Hans Sauer, Ph.D.**, Associate General Counsel for Intellectual Property, Biotechnology Industry Organization (BIO)
- **Jacqueline D. Wright Bonilla, Ph.D.**, Partner, Foley & Lardner LLP

35 U.S.C. §101

- **§101 Inventions patentable.**
  - Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
- Not to be confused with:
  - §102 (novelty)
  - §103 (non-obviousness)
  - §112 (sufficiency of disclosure)

Three Exceptions

- Laws of nature
- Physical phenomenon
- Abstract ideas

District Court (SDNY)

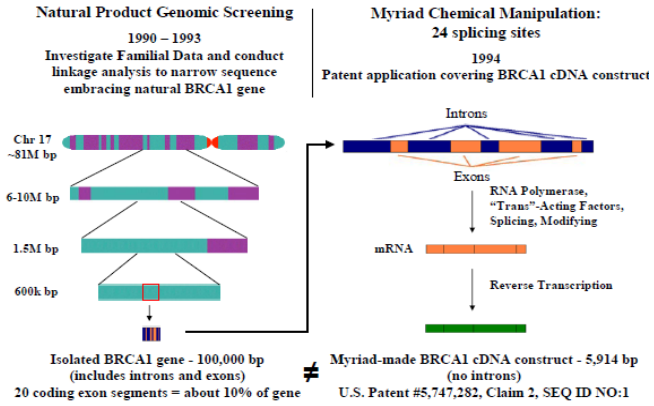
- 152 page opinion granting Plaintiffs' SJ motion
- Judge Sweet (March 29, 2010):
  - In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences [between native and isolated DNA] render the DNA "markedly different." . . .
  - The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.

Representative Claims from Myriad Genetics' Patent Applications

U.S. Patent No. 5,747,282

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having an amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

Genes, "Isolated DNA," and cDNA



Representative Claims from Myriad Genetics' Patent Applications

U.S. Patent No. 6,033,857

1. A method for identifying a mutant BRAC2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises **comparing** the nucleotide sequence of the suspected mutant BRAC2 allele with the wild-type BRAC2 nucleotide sequence wherein a difference between the suspected mutant the wild-type sequences identifies a mutant BRAC2 nucleotide sequence.

Appeal to Federal Circuit Fall/Winter 2010

- October 22: Brief filed by Appellants (Myriad)
- Late October/early Nov.:
  - 17 amicus briefs supporting reversal (4 rejected)
  - DOJ amicus brief supporting neither party
- November 30: Brief filed by Appellees (ACLU on behalf of Assn for Molecular Pathology, et al.)
- Early-mid December
  - 12 amicus briefs supporting affirmance (7 rejected)
- December 22: Reply Brief filed by Appellants

H.R. 977 - Genomic Research and Accessibility Act

- In 2007, Congressmen Xavier Becerra (D-Calif.) and David Weldon (R-Fla.) introduced a bill (H.R. 977).
- Purpose: to amend Title 35, United States Code, to prohibit "patenting of human genetic material."
- Key provision:

  "Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."
- Prospective only: "shall not apply to a patent issued before the date of the enactment of this Act."

Controversy Continues

DOJ: *What is NOT patent eligible*

- Genomic DNA merely isolated from human body, without further alteration or manipulation
- Unique chain of chemical base pairs that induces a human cell to express a BRCA protein is not a "human-made invention"
- Chemical structure of native human genes is a product of nature
  - No less a product of nature when structure is "isolated" from its natural environment

DOJ: *What is patent eligible*

- Man-made compositions of matter whose value derives from information-encoding capacity of DNA
- Nearly any man-made transformation or manipulation of raw materials of the genome
- "Human-made inventions" include:
  - cDNA and other "engineered DNA molecules"
  - Vectors and recombinant plasmids
  - Chimeric proteins
  - "Countless industrial products," such as vaccines and genetically modified crops, created with aid of such molecules

DOJ: *What is NOT patent eligible* (cont.)

- "Isolated DNA" molecule comprising a nucleic acid sequence of SEQ ID NO:1
  (SEQ ID NO. 1 = native genomic DNA sequence)
- Claim 1 of '282 patent
  - Encompasses ordinary BRCA1 gene isolated from a tissue sample taken from a woman in a hospital

DOJ: *What is patent eligible*

- Claim 2 in '282 patent = cDNA
- "Isolated DNA" comprising a nucleic acid encoding SEQ ID NO:3 *(SEQ ID NO:3 ≠ native DNA sequence)*
- A vector comprising an isolated nucleic acid having SEQ ID NO:1 *(SEQ ID NO. 1 = native genomic DNA sequence) (≈ claim 8 of Myriad '282 patent)*

DOJ: *What is patent eligible* (cont.)

- A microorganism or recombinant cell transformed with:
  - A nucleic acid encoding SEQ ID NO:3 or SEQ ID NO:1*; or
  - A vector comprising an isolated nucleic acid comprising nucleic acid sequence of SEQ ID NO:3 or SEQ ID NO:1

DOJ: *What is patent eligible (cont.)*

- Processes (or apparatus) for selecting, extracting and/or purifying native genomic DNA from its chromosome environment
- Method of treatment claims using DNA molecules
- Optimized pharmaceuticals (pills, vaccines)

AMA: *What is NOT patent eligible*

- "Isolated DNA" molecules ***and*** cDNA and synthetic genetic sequences that are not "markedly different" from the natural materials from which they derive – *Chakrabarty* standard (based on *Hartranft* and *American Fruit Growers*)
- **P.J. Federico acknowledgement** in 1937 (shortly after *American Fruit Growers*) that isolated natural materials (Pasteur's yeast and Hand's Parke-Davis decision on takemine) were not patent eligible even though had issued
- **DOJ current acknowledgment** that PTO has never had authority to grant isolated gene sequence claims – imposing avoidable costs to the medical system

AMA: cDNA v."markedly different" constructs

- **On-Line Medical Dictionary: complementary DNA** [is] *Single-stranded DNA* synthesized in the laboratory *using messenger RNA as a template and the enzyme reverse transcriptase*.
- **Wikipedia: Long interspersed repetitive elements** … are a group of genetic elements that are found in large numbers in eukaryotic genomes. They are *transcribed* (or are the evolutionary remains of what was once transcribed) *to an RNA*…. *The reverse transcriptase … makes a DNA copy of the RNA* that can be integrated into the genome at a new site.
- ***Cochrane v. Badische Analin* (1884):** "Calling it artificial alizarine *did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially*."

AMA: cDNA v."markedly different" constructs (cont)

- **Funk Brothers (1948):** *Human-created, novel, useful* bacterial combination was ineligible "product of nature" because each species ""ha[d] the same effect it always had…. [and] perform[s] in [its] natural way"
- **Chakrabarty (1980):** Distinguished synethetic, oil-eating plasmid-containing bacteria from *Funk Bros.* because it had "*markedly different characteristics* from any found in nature and … the potential for significant utility."
- **Ansonia Brass & Electric (1892):** *"non-analogous uses"* standard –not "similar"

AMA: Method claims are not eligible

- "Comparing" and "analyzing" claims are not limited to any specific methods of obtaining or using data or the information the patent itself discloses –no "machine" or "transformation" and claim to ineligible "phenomenon of nature" under *Bilski*
- Claims cover ineligible mental processes and speech (also posing First Amendment violations)
- Claims are directed to excluded natural phenomena –claiming medical fact as a process doesn't change its nature
- Even if construed to include data gathering steps, the claims would be ineligible – no specific method of data gathering required and would constitute only insignificant "pre-solution" activity under *Bilski, Flook,* and *Grams*

Gene Patenting Myths

- The Ownership Myth
  - Michael Crichton, ACLU and "Who Owns You"
- The Information Myth
  - "Physical Embodiment of Genetic Information"
  - "DNA is a chemical compound, albeit a complex one"

Gene Patenting Myths

- The "Natural Product" Myth
  - Isolated DNA not found in nature
  - cDNA not found in nature
  - Natural products not patent-ineligible
- The "Inhibits Research" Myth
  - The anti-commons are not tragic
  - Progress promoted by disclosure

Unintended (?) Consequences

- No remedy for women
  - Myriad patents expire in ~4-6 years
  - Test availability depends on insurance companies, not patents
- Financial impact on biotech industry
  - Burrill Report
    - http://www.patentdocs.org/2011/01/steve-burrill-makes-predictions-for-the-biotech-industry-in-25th-annual-report.html

Unintended (?) Consequences

- Patent ineligibility promotes non-disclosure
- Non-disclosure contrary to academic mission
- Academia (U.S. taxpayer) as uncompensated corporate R&D department (foreign and domestic)

Unintended (?) Consequences

- The future will be different from the past – much more complicated
- Trade secret protection perpetual (and biotech hard to reverse engineer)
- "Natural product" patent ineligibility extends to all medicinal chemistry and biologic drugs

Conclusions

- Be careful what you wish for
- Patent system not perfect but not pernicious, either
- Thirty years of biotechnology innovation based (in large part) on patent eligibility
- Do we really want to kill that golden goose?

Panel Q&A

- We welcome questions from our attendees. Please click “Q&A” on the menu bar and type in your question. The moderator will read questions as time permits. If time does not allow for your question we will follow-up with you individually.

Thank You

- An E-mail will be sent to when the presentation materials and recording are available online.