Patentable Subject Matter, Part 2
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Statutory Language

35 U.S.C. § 101
“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 ….”

Business Method Patents

Business method patents disclose and claim new methods of doing business. It protects a process rather than a physical object. This may include new types of e-commerce, data security, finance, banking, or insurance.

Association for Molecular Pathology, Inc. v. Myriad Genetics, Inc., 569 U.S. 576 (2013)
**cDNA Synthesis**

1. The 1st strand cDNA synthesis by reverse transcription
2. The 2nd strand cDNA synthesis and PCR amplification
3. Attachment of adapter to 3’-end of cDNA
4. Synthesis of cDNA

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**Myriad’s BRCA Test**

- Relying on a large set of DNA samples from families with inherited breast and ovarian cancers, the inventors correlated the occurrence of cancer in individual family members with the inheritance of certain marker DNA sequences.
- This allowed the inventors to identify, or “map,” the physical location of the BRCA genes within the human genome and to isolate the BRCA genes and determine their exact nucleotide sequences.
- This in turn allowed Myriad to provide BRCA diagnostic testing services to women.

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**AMP v. Myriad Genetics**

**District Court**

- Rejects Learned Hand analysis in *Parke-Davis*
- Takamine’s “Glandular Extractive Product” patent
- Statement re: §101 was dicta there (same court)
- J. Hand: “While it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.” (189 F. 95, 103)

District Court

“In light of DNA’s unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA ‘markedly different.’”

“This conclusion is driven by the overriding importance of DNA’s nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its “isolated” form.”

AMP v. Myriad Genetics, 689 F.3d 1303 (Fed. Cir. 2011)

Federal Circuit

“[A]lthough the parties and the government appear to agree that isolated DNAs are compositions of matter, they disagree on whether and to what degree such molecules fall within the exception for products of nature.”

“The distinction, therefore, between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition’s identity compared with what exists in nature. [Patentable:]... compositions that human intervention has given “markedly different,” or “distinctive,” characteristics.”

AMP v. Myriad Genetics, 103 USPQ2d 1681 (Fed. Cir. 2012)

Federal Circuit

“In the limited questions before us, we conclude that the composition claims and the screening claim involving growing a transformed host cell meet the standards for patent eligibility, while the claimed methods for ‘analyzing’ or ‘comparing’ do not.”

“The isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity. While they are prepared from products of nature, so is every other composition of matter. All new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials.”

AMP v. Myriad Genetics, 103 USPQ2d 1681 (Fed. Cir. 2012)

Federal Circuit

“For example, virtually every medicine utilized by today’s medical practitioners, and every manufactured plastic product, is either synthesized from natural materials (most often petroleum fractions) or derived from natural plant materials. But, as such, they are different from natural materials, even if they are ultimately derived from them. The same is true of isolated DNA molecules.”

“BRCA1 and BRCA2 in their isolated states are different molecules from DNA that exists in the body; isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.”
AMP v. Myriad Genetics, 103 USPQ2d 1681 (Fed. Cir. 2012)

Federal Circuit

“[T]he patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material. The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact.”

AMP v. Myriad Genetics

Government Brief In Support of Certiorari

• Middle ground: cDNAs are patentable
• Isolated and purified “naturally occurring” DNA is not
• Degree of human intervention

AMP v. Myriad Genetics, 569 U.S. 576 (2013)

J. Thomas’ opinion for the Court (isolated DNA)

“[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated…”

• Longstanding USPTO practice to the contrary is not binding.
• Reliance interests in that practice are Congress’ problem, not ours.

AMP v. Myriad Genetics, 569 U.S. 576 (2013)

J. Thomas’ opinion for the Court (cDNA)

“…but that cDNA is patent eligible because it is not naturally occurring.”

• “[T]he lab technician unquestionably creates something new when cDNA is made.”
• cDNA “is distinct from the DNA from which it was derived.”

AMP v. Myriad Genetics, 569 U.S. 576 (2013)

J. Scalia’s concurrence

“I join the judgment of the Court, and all of its opinion except Part I-A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm...”

DEFINITELY NOT #PatentLaw
**In re: Roslin Institute (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014).**

**Background**
- Scientists generated clone “Dolly the Sheep” from adult somatic cell in 1996.
- Scientists “obtained [U.S.] patent on the somatic method of cloning mammals.”
- Patent application at issue here seeks claims on the clones themselves (restricted to “cattle, sheep, pigs, and goats”).

**PTAB Decision**
- Dolly the sheep was not patent eligible because a “cloned farm animal is exact genetic replica of another animal and does not possess ‘markedly different characteristics’ from any farm animals found in nature.”
- Essentially rejected on subject matter, novelty, and nonobviousness grounds.

**Scientific Disagreement?**
- “Some cloned mammals, including Dolly, have shorter telomeres than other animals of the same age. Telomeres are pieces of DNA that protect the ends of chromosomes. They shorten as cells divide and are therefore considered a measure of ageing in cells.” *New Scientist* 17:56 (2003).
- “Dolly was not quite a clone because the mitochondrial DNA came from the oocyte and not from the somatic cell.” Schon, E.A. et al. Mitochondrial DNA genotypes in nuclear transfer-derived cloned sheep, *Nature Genetics* 23:90-93 (1999).

**J. Dyk’s Opinion for the Court**
- “Roslin’s claimed clones are exact genetic copies of patent ineligible subject matter” and thus “not eligible for patent protection.”
- “[D]iscoveries that possess ‘markedly different characteristics from any found in nature’ are eligible …. [B]ut any existing organism or newly discovered plant found in the wild is not ….”
- Phenotypic differences are irrelevant in this case as they are unclaimed results “of ‘environmental factors’ un influenced by Roslin’s efforts.”

**Background**

- Canadian Patent Act defines “invention” as “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement” thereof. (R.S.C., 1985, ch. P-4, § 2)
- Canadian Patent Office denied application for patent on oncomouse.

**Statutory Interpretation**


**Line Drawing**

Acceptance of patenting of “lower life forms” “does not necessarily” mean “higher life forms are patentable.”

**Policy Questions & Deference**

“Owing to the fact that the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical and environmental concerns that the Act does not contemplate, I conclude that the Commissioner was correct to reject the patent application.”

**Patenting of Humans**

“[N]o patent may issue on a claim directed to or encompassing a human organism.”

Leahy-Smith America Invents Act, Pub. L. 112-29, §33(a) (Sept. 16, 2011).
**Alice v. CLS Bank, 573 U.S. 208 (2014)**

**Background**

- Patent claims involving business method for “settlement risk” mitigation via intermediary, understood to require use of computer
- 3 notable claim types
  - Process
  - Beauregard (computer-readable medium)
  - System

**Fractured Federal Circuit**

CAFC reviewed case en banc, produced 5 opinions:
- 5 judges concluding all claims invalid
- 2 concluding all but system claims invalid
- 3 concluding all claims s.-m. eligible.

**Results:**
- Process & medium claims invalid (7-3)
- District court’s invalidity ruling on system claims affirmed by equally divided court (5-5)

**J. Thomas’ opinion for the Court**

Endorsement of Mayo 2-Step
- Is claim “directed to … patent-ineligible concept[t]”?
- If so, does the claim feature “inventive concept”—“i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself’”?

Analysis of Process Claims
- Directed to “Abstract Idea”
  - “fundamental economic practice long prevalent”
  - “building block of the modern economy”
  - “organizing human activity” à la Bilski
- No “Inventive Concept”
  - “merely … generic computer implementation”
  - neither “improv[ing] the functioning of the computer” nor “effect[ing] an improvement in any other technology”

Analysis of Medium Claims
- Falling with Process Claims
  - Why didn’t Alice attempt to argue this? What would be arguments for and/or against a distinction here?

Analysis of System Claims
- Directed to “Abstract Idea” (as for process claims)
- No “Inventive Concept”
  - “[N]one of the hardware recited [e.g., ‘data storage unit’] ‘offers a meaningful limitation beyond generally linking “the use of the [method] to a particular technological environment,” that is, implementation via computers.’"

Alice v. CLS Bank, 573 U.S. 208 (2014)

J. Sotomayor’s concurring opinion

Business methods should not be considered to be subject matter eligible.

Recap: Patentable Subject Matter

- 4 Statutory Categories: “process, machine, manufacture, or composition of matter” (cover most inventions)
  - The Court’s statement in Chakrabarty that “Congress intended statutory subject matter to include ‘anything under the sun made by man’” isn’t accurate
    - “Laws of nature, physical phenomena, and abstract ideas” are “excluded from patent protection” (Diehr)
    - “A patent cannot ‘wholly preempt’ an idea or ‘in practical effect be a patent on the idea.’” (Benson)
  - Since 2010, 4 major Supreme Court cases:
    - Bilski and Alice have held computer implemented method claims invalid because they were directed to an abstract idea
    - Mayo and Myriad have held patents invalid because they were directed to a law of nature or physical phenomena

Recap: Patentable Subject Matter

- 4 Statutory Categories: “process, machine, manufacture, or composition of matter”
  - Viewed inclusively: “anything … made by man”; business methods & life not excluded (Bilski; Chakrabarty)
- Exceptions: “human organism” (USC); natural laws & phenomena; “abstract ideas”
  - “Whole Claim” Analysis (Diehr)
  - But Concern about Claim Drafter’s Art (Alice; Mayo)
    - No Preemption of Exceptions (Benson)
    - Not Mere Limitation to Technical Fields (Flook)
    - “Insignificant [extra]-solution Activity” Not Enough (Flook)
    - Isolation of Genetic Sequence Not Enough (Myriad)
    - Physical Apparatus/Change Only a “Clue” (Bilski)

Recap: Patentable Subject Matter

- Fit with statutory category? (cf. Bilski)
- If “Yes,” does exception to subject matter eligibility nonetheless apply? (Alice; Mayo)
  - Is claim significantly directed to ineligible subject matter?
    - If so, does claim feature enough, through individual elements or their combination, to ensure claim does not substantially equate to claim on ineligible subject matter?
      - Specific physical apparatus/change as “clue”
      - Not just “generic computer implementation”
      - Not preempting all substantial applications
      - Not just “insignificant [extra]-solution activity”
      - Not mere limitation to technological field
      - Probably not mere isolation of natural substance
      - Perhaps not total coverage of basic “building block”

Future Directions

- Artificial Intelligence?
- Blockchain?
- Cryptocurrency?
- Smartphones?
- Wearable devices?
- Other areas that are (or may become) contentious?

15 Minute Break