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The Supreme Court's *Myriad* Decision and What It Means for Your Business

Bryan W. Jones, M.S., J.D.
D. Christopher Holly, Ph.D., J.D.

Intellectual Property Group
Washington, D.C.

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Roadmap of § 101 Jurisprudence in the Robert's Era

I. Statutory Text and Background

- Statute
- The beginning of the "biotech" era
  - *Chakrabarty and "anything under the sun made by man"*

II. John Roberts and the Solar Eclipse

- Setting the table for the main feast
  - *Bilski*
  - *Prometheus*

III. The Main Event: *Myriad*

- A trip to your undergrad days and freshman biology 101
- The Court's decision
- Practical implications

IV. Audience Questions

Patentable Subject Matter: 35 U.S.C. § 101

• Whoever **invents** or **discovers** a new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

- 35 U.S.C. §101: two prongs
  - Utility
  - Patentable subject matter

But Exclusive of (via *stare decisis*):

- Laws of Nature
- Natural Phenomenon
- Abstract Ideas

Public Policy Rationales For Exclusions

➢ Assure basic tools of scientific and technological work are available to all to support innovation

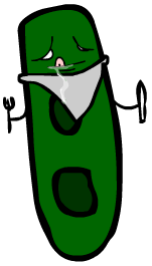
- Article 1, § 8, US Constitution: *To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries*

➢ Prevent "preemption" of an entire field

- Problem: "entire field" is difficult to determine

The beginning of the "biotech" era

- *Diamond v Chakrabarty* (SCOTUS, 1980)
  - Ananda Chakrabarty genetically engineered a bacterium capable of breaking down crude oil
  - Differentiated naturally occurring organisms and natural phenomena exclusions from transformed cell lines
    - "Anything under the sun made by man" concept introduced



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John Roberts and the Solar Eclipse

- Post *Chakrabarty* 35 USC § 101 Was Boring For Biotech Until…

- A solar eclipse for "anything under the sun made by man"?
  - *Bilski*
  - *Prometheus*
  - *Myriad*

Bilski v. Kappos (SCOTUS, 2010)

- **Claim 1 (paraphrased)**
  - A method for managing risk comprising the steps:
    - initiating a series of transactions between providers and consumers wherein consumers purchase a commodity at a fixed rate;
    - identifying market participants for the commodity having a counter risk position to the consumers; and
    - initiating a series of transactions between commodity providers and the counter risk market participants at another fixed rate so that the positions for risk between consumers and other market participants are balanced.

Bilski: Prosecution and Court History

- During prosecution the claims were rejected by the Examiner
  - ➢ abstract idea not implemented on an apparatus
- During administrative appeal the BPAI rejected the claims and upheld the examiner
  - ➢ mental step directed to abstract idea
- On appeal to the Federal Circuit, the CAFC *en banc* affirmed and held: NOT PATENT ELIGIBLE
  - ➢ Holding that the Sole Test for Method Eligibility is the Machine or Transformation Test (**MOT**):
    - Must be tied to a particular **M**achine or apparatus, or
    - Must **T**ransform an article into a different state or thing

Legal Theories For Non-patentable Claims Before SCOTUS

1. Method not tied to a machine and does not transform an article

2. Method involves a method of conducting business

3. Method is merely an abstract idea

SCOTUS: The MOT is Not the Sole Test for Process Patent Eligibility

- SCOTUS rejected the CAFC concept that a process/method must be tied to a particular machine or apparatus or must transform an article into a different state or thing
- MOT concept is an important clue but the *per se* rule is not valid
- Business methods are patentable and the standard for patentable processes are:
  - Definition of process in § 100(b) that does not mention a machine or transformation and
  - Guidepost in *Benson, Flook, and Diehr*
  - Consider the claim as a whole

SCOTUS Affirms CAFC: Not Patentable

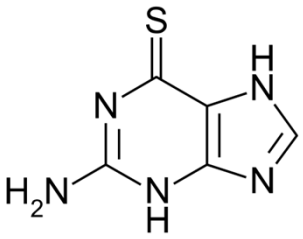
- Unanimously found claims **Not Patentable** because they claim an **abstract idea** instead of a process

Precedent is:

1. *Benson* (SCOTUS, 1972)
   - algorithm to convert binary coded decimal numbers into pure binary code is abstract idea
2. *Flook* (SCOTUS, 1978)
   - method for updating an alarm limit in a catalytic chemical conversion of hydrocarbons is an abstract idea
3. *Diehr* (SCOTUS, 1981)
   - method for molding rubber into products using a formula in a computer connected to molding press is patentable

Mayo v. Prometheus (SCOTUS, 2012)

- U.S. Patents 6,355,623 and 6,680,302 are directed to methods for calibrating the proper dosage of thiopurine drugs used for treating both gastrointestinal and non-gastrointestinal autoimmune diseases.



Nestlé

Prometheus' Claims

- Claim 1 of the '623 patent is representative:
  - A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

    (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

    (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

    wherein the level of 6-thioguanine less than about 230 pmol per 8×108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

    wherein the level of 6-thioguanine greater than about 400 pmol per 8×108 red blood cells indicates a need to decrease the amount of said drug subsequently ad ministered to said subject.

The District Court Southern District of California

- Prometheus brought a patent infringement suit against Mayo
- D. Ct. Granted summary judgment in favor of Mayo
- Holding that the claims of the '623 and '302 patents are invalid under § 101
  - the patents effectively claim natural laws or natural phenomena
  - namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs

- *Prometheus* appealed

Federal Circuit I

- The Federal Circuit reversed the District Court.
  - held that the claimed methods satisfy the Circuit's "machine or transformation test" for patent-eligible subject matter under § 101
  - the administering and determining steps are transformative, not merely data-gathering
  - the presence of mental steps (the final wherein clauses) do not detract from patentability; a subsequent mental step does not, by itself, negate the transformative nature of prior steps
- Mayo filed a petition for *certiorari*

Supreme Court I

- The Supreme Court granted *certiorari*, vacated the Federal Circuit judgment and remanded the case to the Federal Circuit for further consideration in light of *Bilski.*

Federal Circuit II

- On remand, the Federal Circuit again held that *Prometheus*' asserted method claims are drawn to statutory subject matter, and again reversed the district court's grant of summary judgment of invalidity under 35 U.S.C. § 101.
- The Federal Circuit reaffirmed that
  - the methods claimed in the '623 and '302 patents satisfy the transformation prong of the machine or transformation test
  - the claims recite specific treatment steps, not just the correlations themselves and involve a particular application of the natural correlations
  - the claims do not preempt all uses of the natural correlations; they utilize them in a series of specific steps
- Mayo again filed a petition for *certiorari*.

Supreme Court II

- Opinion by Justice Breyer
- Unanimous court
- Questions to decide
  - "whether the claims do significantly more than simply describe these natural relations"
    - relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage will prove ineffective or cause harm
  - "do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?"

Supreme Court II

- The Court's focus is on the difference between
  - claims to laws of nature themselves - not patent eligible and
  - claims to specific applications of such laws - patent eligible.

- Monopolization of laws of nature, mental processes and abstract intellectual concepts through the grant of a patent might tend to impede innovation more than it would tend to promote it.
- An application of a law of nature or mathematical formula to a known structure or process may be deserving of patent protection.
- However, to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it."

Supreme Court II

- Analysis relied on *Diamond v. Diehr*, 450 U.S. 175 (1981) and *Parker v. Flook*, 437 U.S. 584 (1978) to show the difference between a non-patentable method and a patent-eligible method that represents an application of a natural law.
- The methods in *Diehr* and *Flook* were analyzed by examining each step of the method separately to determine its effect and to determine whether it was well-known or conventional in the relevant art, and examining the steps of the method as a whole.

Court's analysis based on *Diehr* & *Flook*

Diehr process – patentable

Method for molding raw, uncured rubber into cured, molded products.

The process

(1) continuously monitoring the temperature on the inside of the mold,

(2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and

(3) configuring the computer so that at the appropriate moment it would signal a "device" to open the press.

Flook process – not patentable

Method for improved system for adjusting "alarm limits" in the catalytic conversion of hydrocarbons.

The process

(1) measuring the current level of the variable, *e.g.*, the temperature;

(2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and

(3) adjusting the system to reflect the new alarm-limit values.

Court's analysis based on *Diehr* & *Flook*

Diehr process – patentable

The combination of steps was NOT obvious, already in use or purely conventional.

The additional steps of the process integrated the equation into the process as a whole.

Flook process – not patentable

The steps of the method were well-known to the point that, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula.

The process did not limit the claim to a particular application.

"The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*."

Court's analysis of the claims

Analysis of the claims went through four steps:

- 1. the Court observed that the administering step just defines "the relevant audience"— doctors who treat patients with thiopurine drugs.
- 2. "the 'wherein' clauses simply tell a doctor about the relevant natural laws."
- 3. the determining step does not specify any particular process, but merely invites doctors "to engage in well-understood, routine, conventional activity."
- 4. "to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately."

Court's analysis of the claims

- Concluded that these instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field; and
- the steps of the method, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.
- The effect of the steps is simply to tell doctors to apply the law of nature somehow when treating their patients

Summary

- In sum, "the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlation."
- The three steps "are not sufficient to transform unpatentable natural correlations into patentable applications."
- To allow such a patent could "inhibit further discovery by improperly tying up the future use of laws of nature."
- Application of a law of nature is patentable, but
  - "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."
  - When "putting" the law of nature step "to the side, there was no 'inventive concept' in the claimed application" of the law of nature and "the other steps in the process did not limit the claim to a particular application."
  - something more is required.

Supreme Court II – Guidance?

- Not much specific guidance of what would constitute "enough" or "sufficient" to "transform the nature of the claim" from an unpatentable law of nature into a patentable application of such a law
- Backed away from making a determination of whether the additional steps relating to the use of the laws of nature if less conventional would be sufficient or not to invalidate the claims
  - "[w]e need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them."

Supreme Court II – Guidance?

Examples of what the Court considered as not being "enough" or "sufficient":

- the process should not "depend simply on the draftsman's art" and would need additional features to make the process more "than a drafting effort designed to monopolize the law of nature itself."
- just to "limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity'" would not be sufficient, *i.e.* "post-solution activity" that is purely "conventional or obvious . . . can[not] transform an unpatentable principle into a patentable process."
- "additional steps, apart from the natural laws, must not just involve well-understood, routine, conventional activities"
- simply a suggestion to consider tests results for decisions was not sufficient, *i.e.* "[t]he "wherein" clauses simply tell a doctor about the relevant natural laws, adding, at most, a suggestion that they should consider the test results when making their treatment decisions."

Supreme Court II – Guidance?

- The Court included 102/103 concepts into analysis of § 101
- Although the Court quoted *Diehr* for indicating that the claims "must be considered as a whole," the analysis appears to look at each element separately and dismiss them as routine and well known in the art.
- In its analysis, the Court separated the steps of the process into 2 groups: (1) the steps relating to the law of nature itself; and (2) the additional steps relating to the use or application of the law of nature.
  - With the emphasis that the additional steps would need to be "unconventional" or "inventive in some way," which appears to indicate that novelty must be integrated into a section 101 analysis

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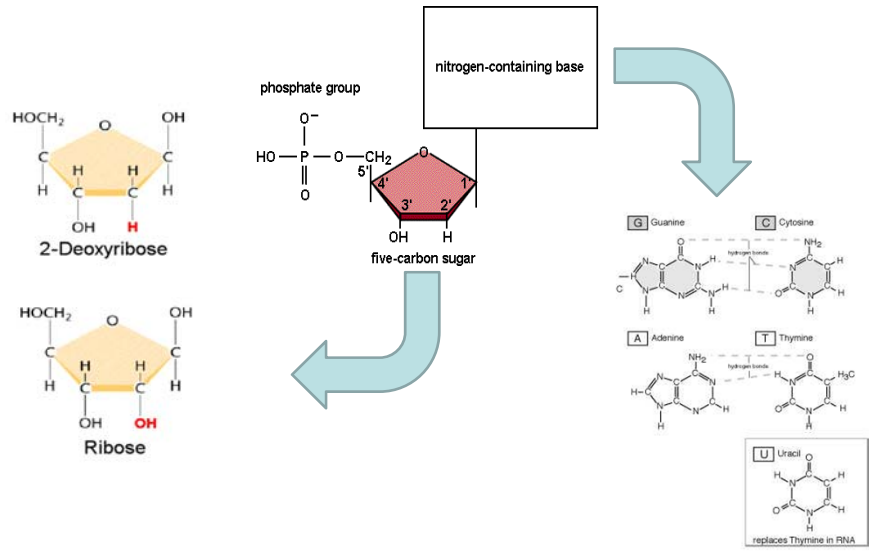
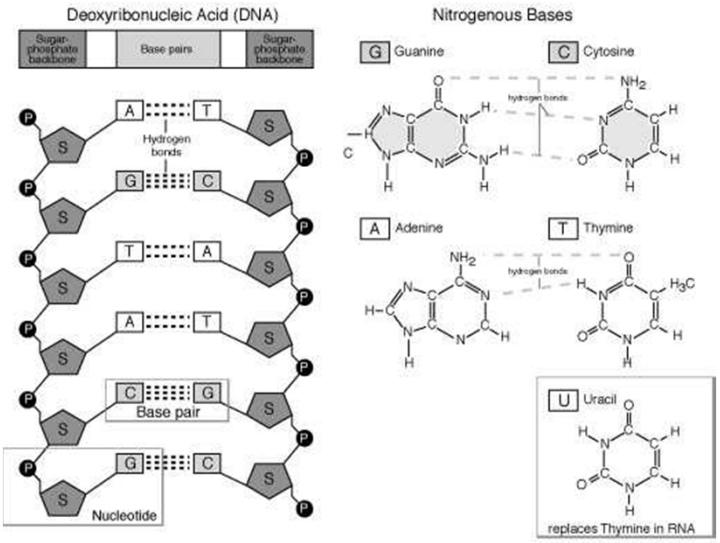
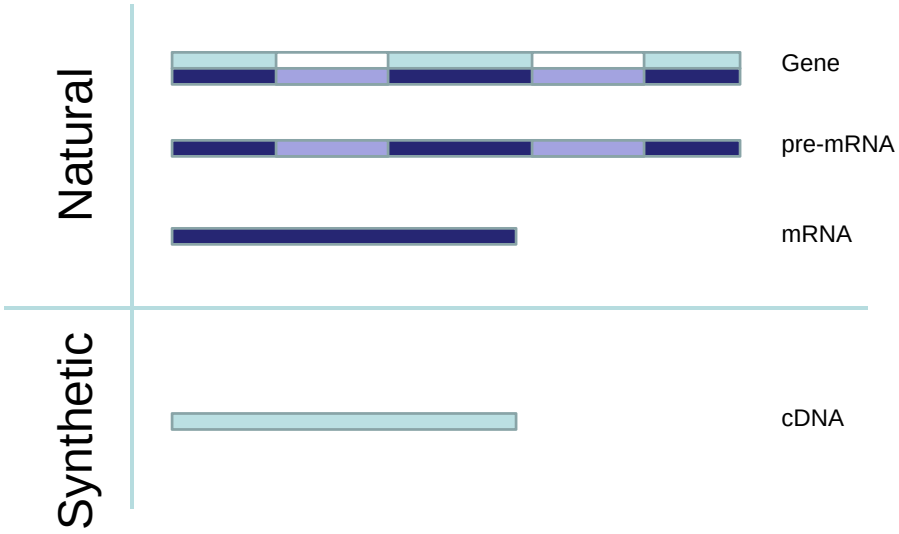
Nucleic Acids: Polymers of Nucleotides



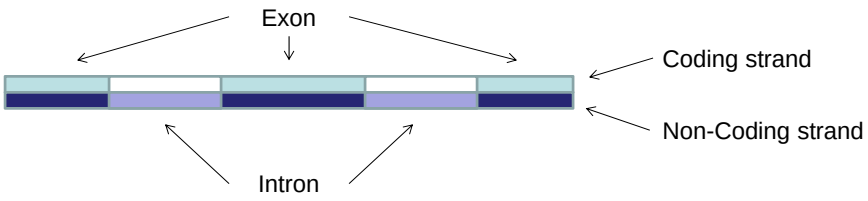
Structure of Nucleic Acids



Categories of Nucleic acids



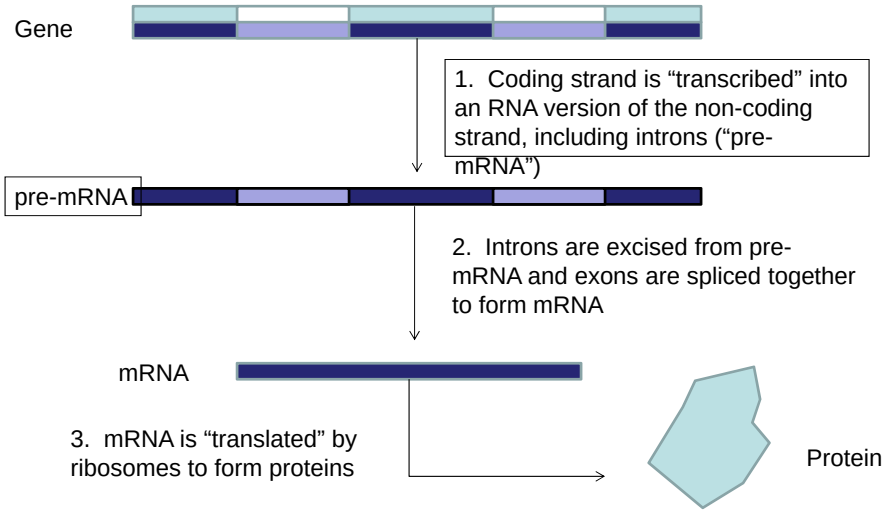
Gene Structure



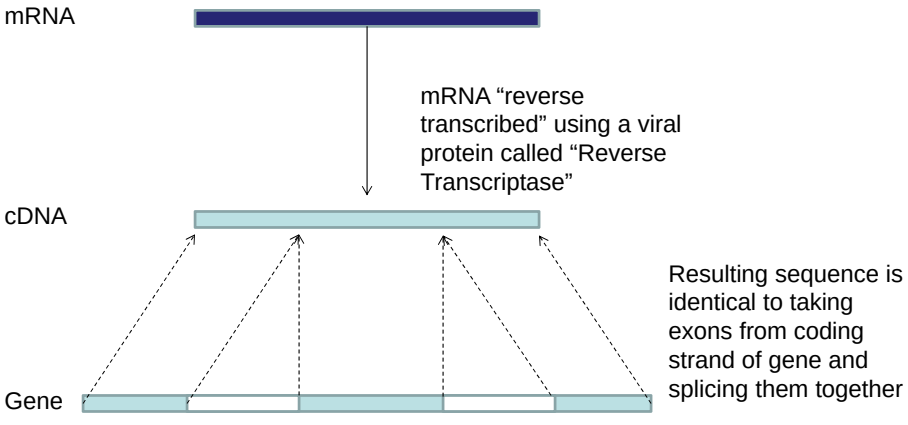
- Coding Strand: DNA Strand that serves as the template for (is “transcribed” into) pre-mRNA
- Non-Coding Strand: DNA strand that is not transcribed into pre-mRNA (DNA having the same sequence as pre-mRNA)
- Exon: Sequences that are translated to amino acids
- Introns: Sequences that are removed from pre-mRNA to generate mRNA

***** Many organisms do not contain introns**

From Genes to Proteins



Generation of cDNA

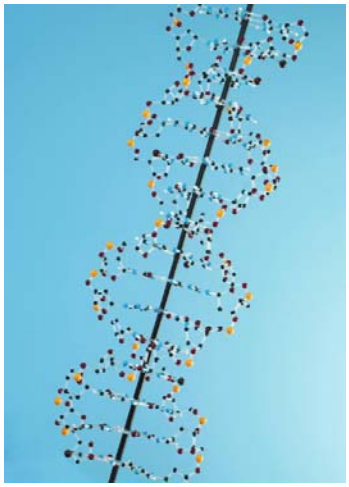


USPTO UTILITY GUIDELINES (2001)

"Congress intended `anything under the sun that is made by man' to be eligible for patenting. The Supreme Court interprets the statute to cover a `nonnaturally occurring manufacture or composition of matter-a product of human ingenuity.' Thus, the intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability. The genetic sequence data represented by strings of the letters A, T, C and G alone is raw, fundamental sequence data, i.e., nonfunctional descriptive information. **While descriptive sequence information alone is not patentable subject matter, a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting**, subject to satisfying the other criteria for patentability.

Categories of Claims

- cDNA
  - "An isolated nucleic acid comprising SEQ ID NO: 1"
- "Encoding a peptide"
  - "An isolated nucleic acid encoding a polypeptide comprising SEQ ID NO: 2"
- Fragment
  - "An isolated nucleic acid comprising at least 15 nucleotides of SEQ ID NO: 1"



Plaintiffs' Position: Nucleic Acid = Product of Nature

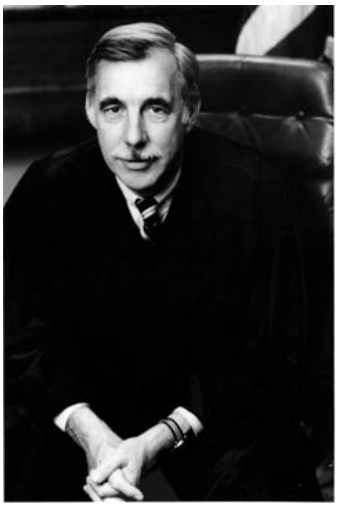
- Nucleic acids sequence occurs in nature
- Even if contiguous sequence changed or bonds broken, information content remains the same

Myriad's Position: New Chemical Compound

- Breaking covalent bonds necessary to isolation
- Therefore, new chemical entity

District Court: All Claims Rejected

- DNA = Information
- Information content of "isolated" nucleic acid same as natural nucleic acid
- NON-STATUTORY



CAFC: Judge Lourie: All Claims Allowable

- Isolation breaks covalent bonds
- Therefore, new chemical entity
- Evidences "Hand of Man"

CAFC: Judge Moore: All Claims Allowable, BUT . . .

- On a clean slate, would require substantial new utility
  - cDNA OK
  - "Genes" not okay
- BUT . . . trumped by settled expectations of patenting community

CAFC: Judge Gajarsa: cDNA is OK, Others are not

"Neither isolation of the naturally occurring material nor the resulting breaking of covalent bonds makes the claimed molecules patentable ….The functional portion of the composition — the nucleotide sequence — remains identical to that of the naturally occurring gene"

Oral hearings: Interesting Analogies

CAFC

- Baseball bat vs. branch
- Removing mineral from the earth
- Extracting kidney from body
- Picking a leaf off of a tree

SCOTUS

- Extracting gold
- Extracting salt from a chocolate chip cookie

SCOTUS Decision: Isolated "Genes" are Ineligible

"It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosome 17 and 13."

Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ____ (2013), slip op., at 11-12, 13.

Is that *REALLY* all that Myriad did?

- Does it matter that they've correlated the sequences with incidence of cancer?
- Does it matter that the sequence renders obvious methods of detecting variants?

SCOTUS Decision: Isolated "Genes" are Ineligible

"Myriad's [patent claims thus fall squarely within the law of nature exception]. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes "new . . . composition[s] of matter" that are patent eligible."

Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ____ (2013), slip op., at 11-12, 13.

Why not?

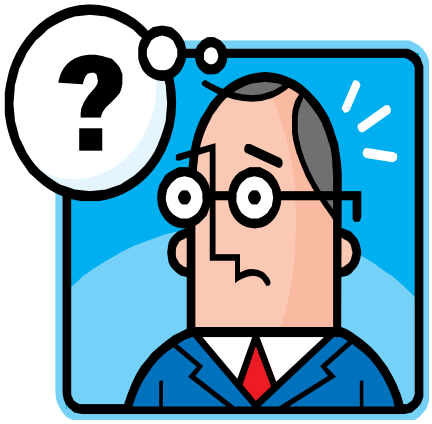
- Isn't a disembodied nucleic acid a "new" composition?
- What about an aqueous cell extract?
- What about a salt of the nucleic acid?

SCOTUS Decision: cDNA is Patent-eligible . . . Sometimes

"[T]he lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA."

Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ____ (2013), slip op., at 17.

Does this distinction make any sense?



Summary of *Myriad*

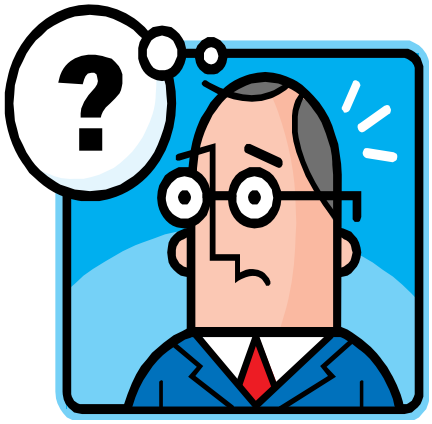
Non-statutory

- Isolated nucleic acid corresponding to naturally occurring sequence
  - Genes
  - Fragments of genes
  - mRNA
  - Fragments of mRNA
  - cDNA that does not span introns

Statutory

- cDNA
- Artificial variants of naturally occurring nucleic acids

Was there a narrower basis to reach the same result?



Utility of nucleic acids

- cDNA, mRNA, and non-intron containing genes
  - Probes
  - Expressing proteins in cells
  - Gene therapy
- Gene/mRNA fragments
  - Probes/Primers
  - Inhibiting expression of genes
  - Sequencing
- Genes containing introns
  - ???

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Thank You

Questions?

Bryan W. Jones, M.S., J.D.
D. Christopher Holly, Ph.D., J.D.

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