

The “*Bowman*” and “*Myriad*” Supreme Court Decisions

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Roadmap

Bowman v. Monsanto Co., 569 U. S. 1 ____ (2013)

- *Monsanto* patents
- Bowman's actions
- Summary of Court Proceedings
- Outcome

Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 2 ____ (2013)

- *Myriad's* Patents
- Summary Court Proceedings
- Supreme Court II Decision
- What has happened since
- Outcome and Ramifications for Patent Eligibility

■ ***Monsanto's patents:***

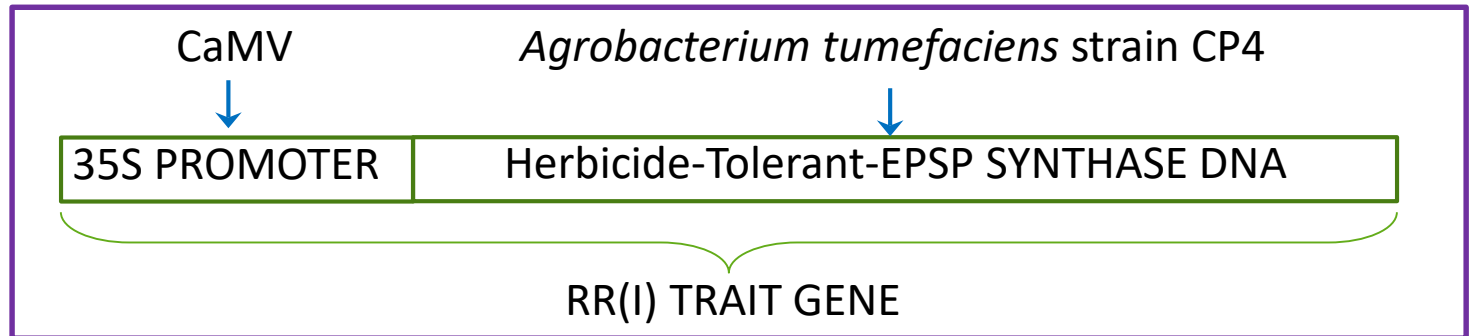
- US5,352,605 (67 claims)
 - chimeric genes comprising CaMV promoters (35S and 19S)
 - genetically transformed plant cells comprising the chimeric gene
- RE39,247 (149 claims)
 - DNA encoding the EPSPS enzyme (confers tolerance to glyphosate)
 - Glyphosate-tolerant plant cells, plants
 - Seed of glyphosate-tolerant plant
 - Transgenic soybean plant with gene encoding EPSPS enzyme
 - Methods for producing transgenic plants
 - Methods for selectively controlling weeds

BOWMAN v. MONSANTO

Intellectual Property at Issue

The Technology

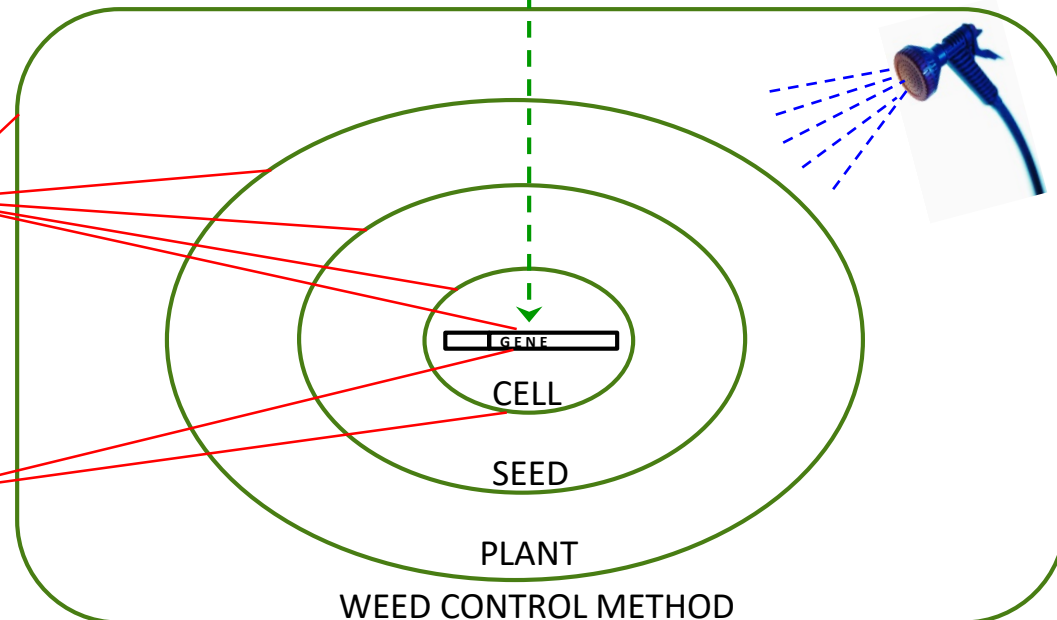
Roundup Ready® (I) Glyphosate Tolerance Trait



The Monsanto Patents

'247E Patent
(based on EPSPS*)

'605 Patent
(based on P-35S)



*-Expires in 2014

BOWMAN v. MONSANTO

Soybean Seed Industry

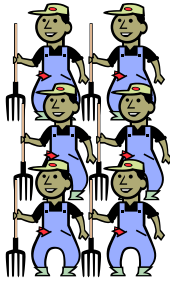
BASF

The Chemical Company

MONSANTO



**VARIOUS FARMERS
SIGN AGREEMENTS,
BUY RR SOY SEED,
GROW, PRODUCE
GRAIN, & SELL GRAIN
TO DEALERS**



<1996 – Soy Industry: Seed vs Grain ; Certified Seed vs Saved Seed
1996 – Monsanto’s RR Soybean Market Launch:

Soy Seed Sales under Grower Agreements to Farmers

□ Grower Agreement Post-Sale Restrictions:

- Plant the Seed for One Crop in One Season
- No Supplying the Seed to 3rd Party for Planting
- No Saving any New Seed for Planting
- No Supplying New Seed to 3rd Party for Planting
- Can Use/Supply New Seed as Grain Only

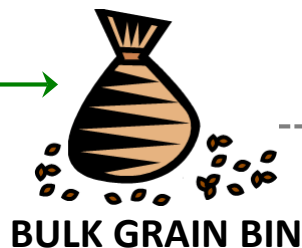
1998 – RR Soy market share has risen to ~50%



SOY GRAIN MARKET / PRODUCTS



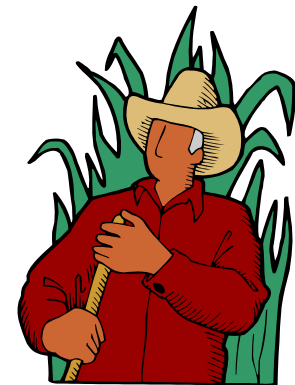
**GRAIN DEALER
& “SEED” RETAILER**



BULK GRAIN BIN

= ~50% RR SOY

“SEED” BIN



FARMER BOWMAN

1999 – Farmer Bowman begins farming RR Soy

BOWMAN v. MONSANTO



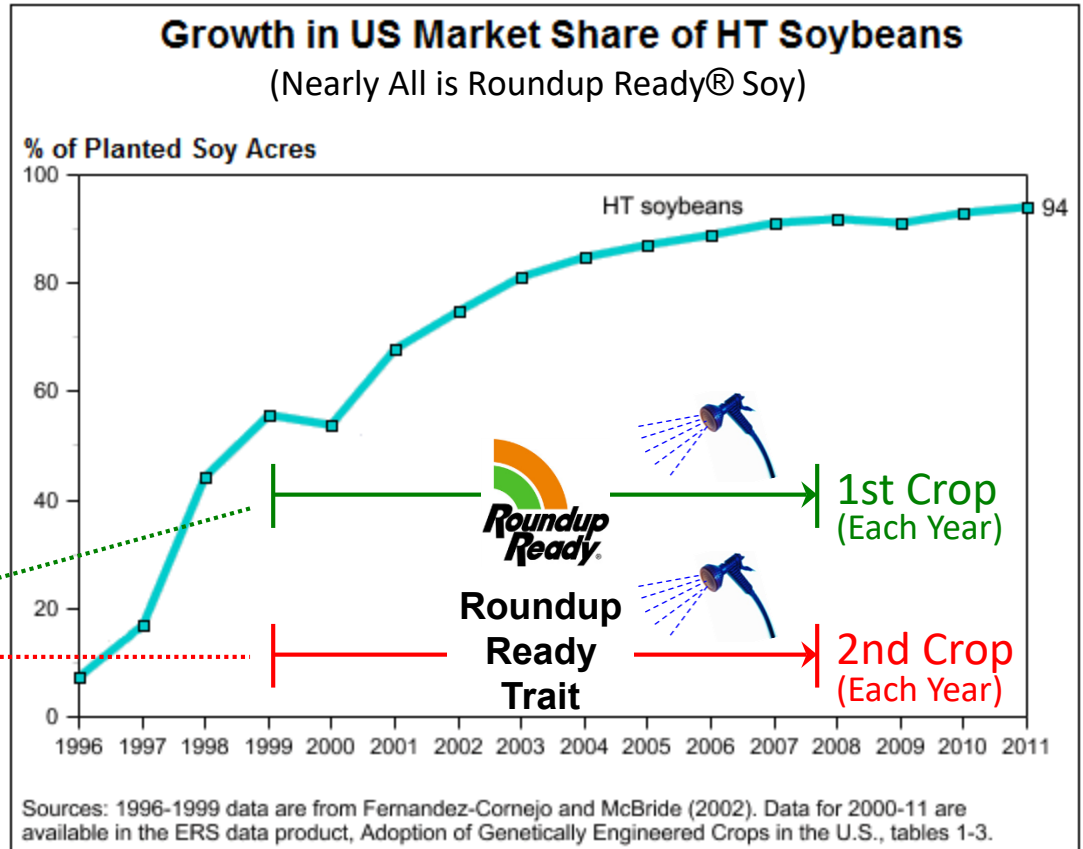
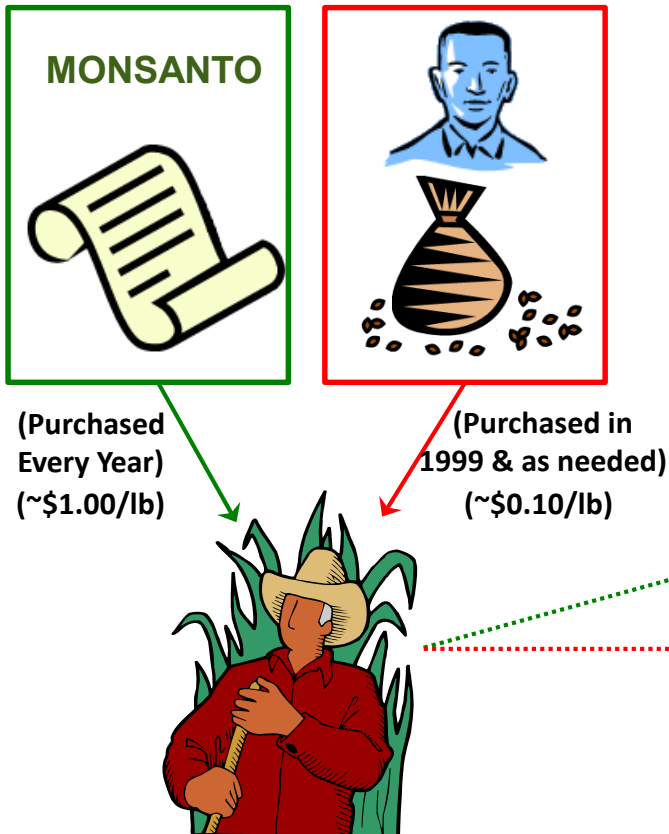
Bowman's RR Soybean Business Practices

Farmer Bowman's Two Soy Crops Each Year:

"First Crop" – Early Planted (~May 15)

"Second Crop" – Late Planted (~July 1)

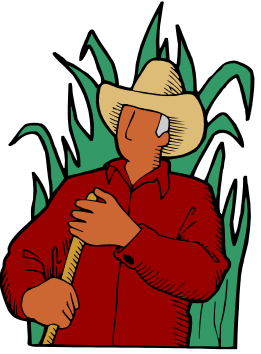
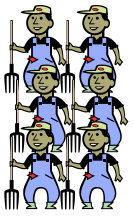
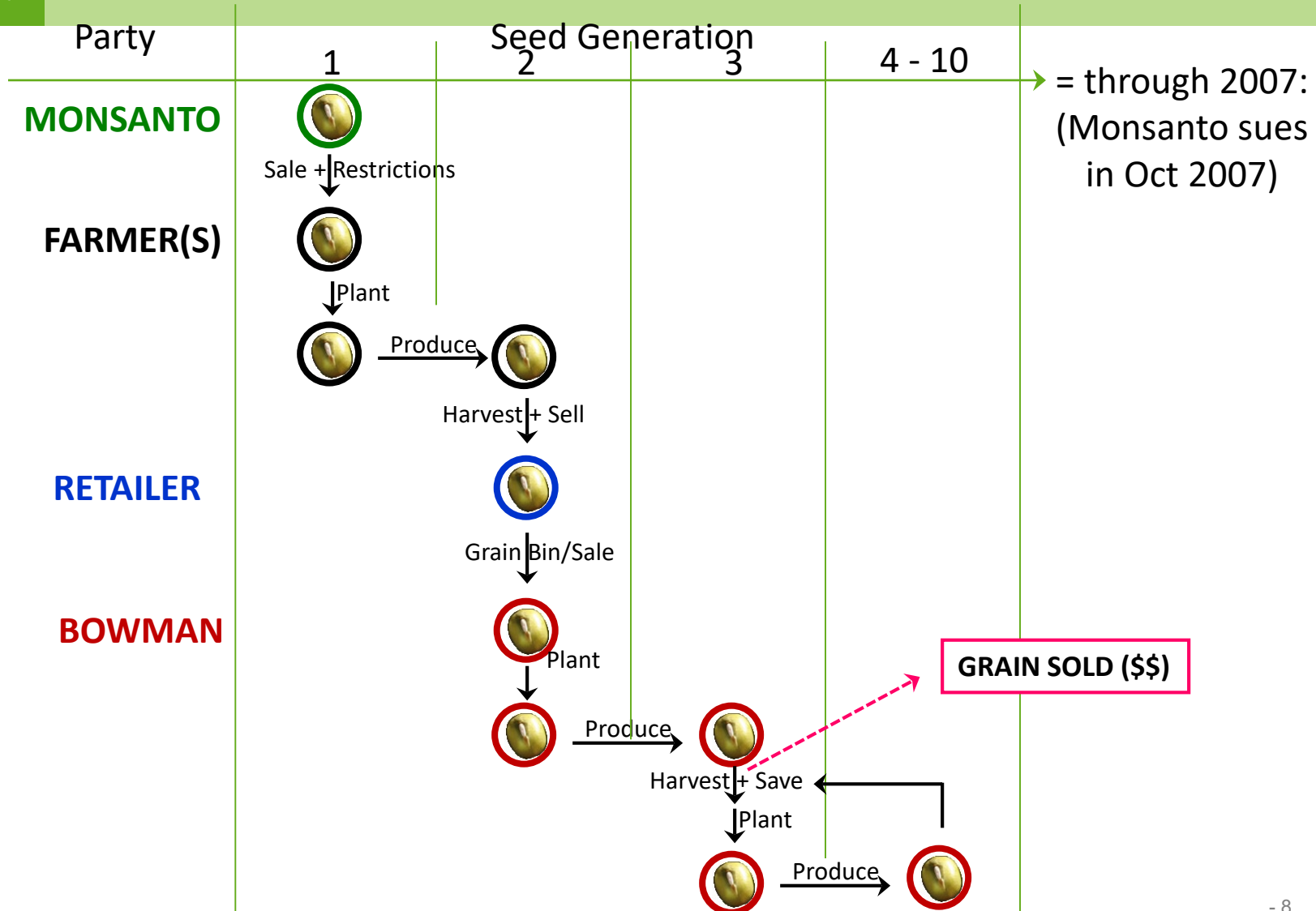
PARALLEL SEED PURCHASES



BOWMAN v. MONSANTO



Steps to Bowman's RR Soybean Success



BOWMAN v. MONSANTO

Legal Doctrine Involved

The Big Issue = “Patent Exhaustion” Doctrine

What is It?

The Legal Principle that there is Depletion of Patent Rights in a Patented Product that the Patent Owner Sells



How does it Normally Apply to Typical Products Sold ‘Over-the-Counter’?

This Legal Principle means:

- In the Sale, the Ownership of the Article Transfers from the Seller to the Buyer
- The Ownership of the IP Stays with the Patent Owner, but
- the Patent Owner/Seller cannot Enforce the Patent to Restrict the Buyer’s Use of the Product, but
- the Buyer cannot make Duplicates of the Product



How does it Apply to Seeds?

Specifically, does this Legal Principle deplete Patent Owners’ rights in a “Self-Replicating” Product they Sell, such that the Patent Owners cannot Enforce the Patent to prevent or stop the Buyer from Replicating It?



BOWMAN v. MONSANTO

Court Proceedings



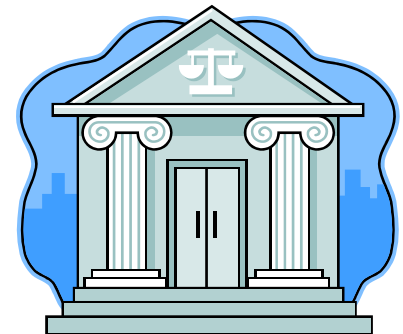
2009 – The Federal Trial Court says Monsanto Wins:

1. New Seed is a New Thing that Monsanto didn't Sell
2. The Monsanto Patents Do Apply to the New Seed
3. Farmer Bowman's Use of the Seed to Plant and Grow New Soybeans Infringes

2009 – Farmer Bowman Appeals the Trial Court's Decision:

- I Bought the Commodity Soy [Bin-Run Seed] Fair and Square
- Monsanto Allows Sales of Commodity Soy
- Everyone Involved in the Sale Understood that the Soy is 'Self-Replicating'
- Everyone Involved in the Sale Understood that the Commodity Soy was for Planting***
- It Should Not Make any Difference that the Soy is 'Self-Replicating'
- I Own that Soy Outright and Can do Whatever I Want with It

2011 – The Federal Appeals Court says Monsanto Wins:
The Trial Court was Correct



*** Misleading Statement: Grain Elevators do Not have "Seed Bins" and Cannot Legally Sell Grain as "Seed"

BOWMAN v. MONSANTO

Court Proceedings Timeline

- 20Dec2011 – **Farmer Bowman Appeals to the US Supreme Court** [*no right to be heard*]
- 27Feb2012 – **Monsanto Submits Arguments Why the Supreme Court Should Decline**
- 02Apr2012 – **The Supreme Court asks the US Federal Government’s Attorney for their View**
- 24Aug2012 – **The Government’s Attorney Recommends the Court Decline**
- 04Sep2012 – **Farmer Bowman Submits Criticisms of the Government Attorney’s Reasons**
- 05Oct2012 – The Supreme Court Agrees to Hear Farmer Bowman’s Appeal**
- 03Dec2012 – **Bowman files Brief on the Merits**
- 16Jan2013 – **Monsanto files Response Brief**
- 10Dec-23Jan – **Multiple Amicus Briefs filed**
- 11Feb2013 – **Bowman files Reply Brief**
- 19Feb2013 – **Oral Argument Held - Highlights:**
 - The Court understood the issues: a Few sentences into Bowman’s argument, Justice Roberts asked why anyone would invest in developing improved crops if sale of the first seed exhausted all patent rights in replicated copies of that seed.
- 13May2013 – Supreme Court Decision**

BOWMAN v. MONSANTO

The Two Sides Illustrated by Analogy

Farmer Bowman:

- Purchasing Seeds is just like Purchasing Any other Thing.
- When you Buy a Stick of Gum, you Own it and can Use it however You Want:
 You can Chew it, Bury it in the Ground, Shred it into little Pieces, etc.
- No one has the Right to Sue me later, telling me I Didn't have the Right to Use my Gum.
- I Bought the Seeds, so I Own those Seeds, and can Use them however I Want.
- Since I Owned the Seeds, I had the Right to Plant them in the Ground, which is All I did.
- That Means my Planting my Seeds is Not an Infringement of the Patents.



Monsanto:

- Purchasing Patent-Protected Seeds is like Purchasing a Book.
- When you Buy a Book, you can Read it, Bury it in the Ground, Shred it into little Pieces, etc.
- But if you Make and Sell Copies of the Book, you Infringe the Copyright on the Book.
- So, if you Buy Patent-Protected Seeds, you can Eat them, Feed them to Animals, or Process them, but if you Replicate and Sell them, you Infringe the Patent [i.e. if without a License].
- Farmer Bowman had No License for the Replicated Seeds, so he Infringed the Patents.

BOWMAN v. MONSANTO

Summary of the Supreme Court's Decision - 1

I. Patent Exhaustion Applies the Same to Seeds as to Other Articles

- Exhaustion of Claims to the Article Occurs Only upon Sale of that Article, and only in Regard to that Article, Not to Replicated Copies

II. Patent Exhaustion for Crop Seed Sales does Not Apply to the Right to Replicate Seeds / Make Copies

- Rights to Methods for Replicating Seeds are Not Exhausted

III. Self-Replication Inherent to Seeds does Not Provide Bowman an Excuse

- Seeds' Inherent Replication Ability does not Convert Bowman's Activity from the Forbidden "Making" of Copies into a Permitted "Use" of Seed

“...we think that blame-the-bean defense tough to credit.”

IV. Bowman's Only Right to Replicate Seeds was Obtained *via* a Limited Grant in His Monsanto Sales Agreement

- Bowman had No Right to Replicate Seed, except to Grow One Crop from the Seed he Bought from Monsanto

BOWMAN v. MONSANTO

Summary of the Supreme Court's Decision - 2

Outcomes for the Parties

Because the Court Held that there is no Patent Exhaustion in Regard to Replicated Copies of the Patented Invention:

- **Monsanto can Enforce their Patents to Stop Bowman from Producing Seed/Grain from RR Grain he Buys from his local Grain Elevator**
- **Bowman is an Infringer of Monsanto's Patents and his asserted Defense of Patent Exhaustion does not Protect him**

Implications

The Court's Opinion Indicates that Post-Sale Restrictions are Still Valid re. Reproduction/Duplication, i.e. so as to Permit a License Agreement to Forbid a Licensee from Reproducing the Patented Invention.

Roadmap

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Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 2 ____ (2013)

- *Myriad's* Patents
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- What has happened since
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Myriad's Patent: Product Claims

- Product claims directed to isolated DNA, cDNA, and fragments for BRCA1 and BRCA2 (mutations in the BRCA genes correlate with increased risk of breast / ovarian cancer):
 - An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having an amino acid sequence set forth in SEQ ID NO: 2.

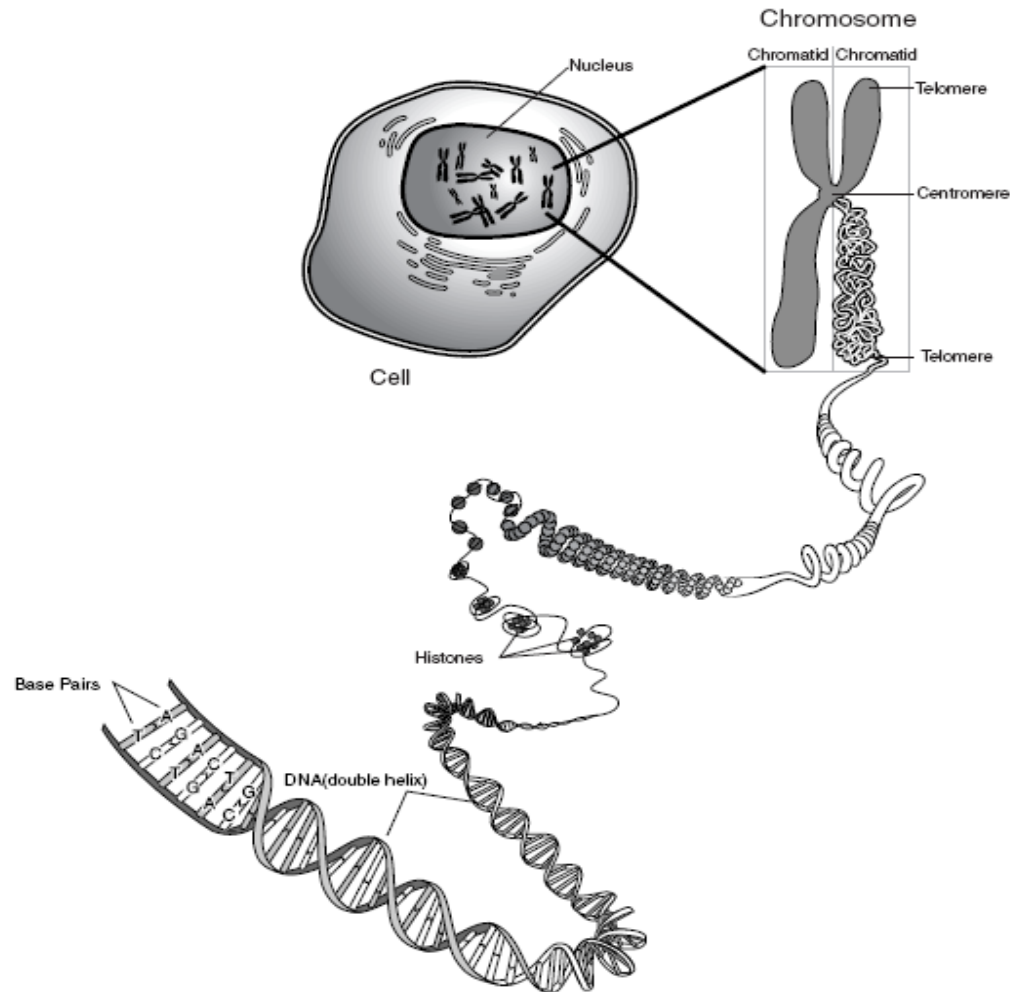
Myriad's Patent: 2 Types of Methods

- Method claims directed to “analyzing” and “comparing” the isolated genes with those of a patient:
 - Drawn to a method for screening a tumor sample, which comprises ***comparing*** a first BRCA1 sequence from a tumor sample with a second BRCA1 sequence from a nontumor sample, wherein the difference in sequence indicates an alteration in the BRCA1 gene in the tumor sample.

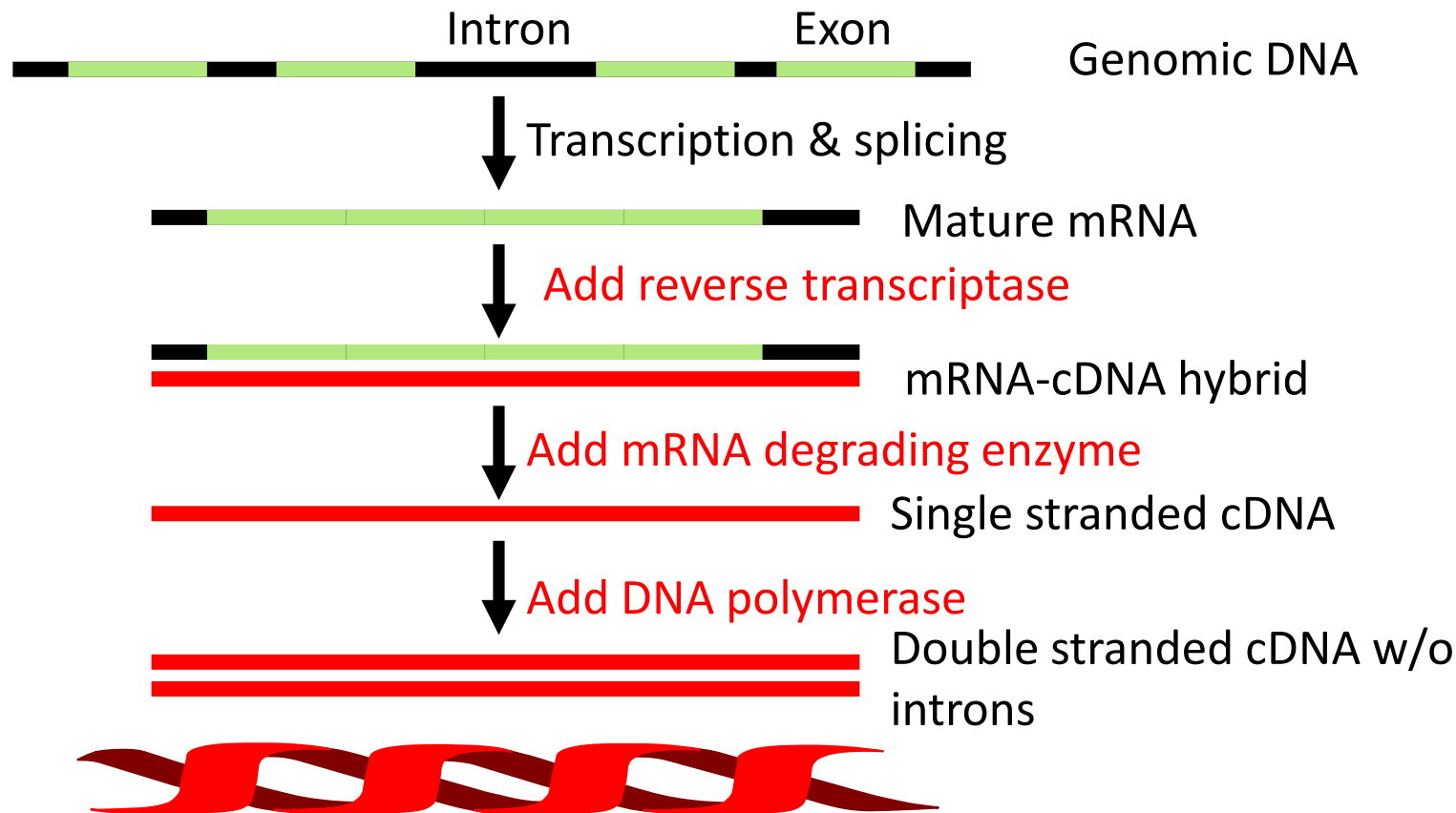
Myriad's Patent: 2 Types of Methods

- Method claim directed to screening cancer therapeutics:
 - Drawn to a method for screening potential cancer therapeutics which comprises
 - 1) **growing** host cells transformed with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic,
 - 2) **determining** the growth rate of the host cells with or without the potential therapeutic, and
 - 3) comparing the growth rate of the host cells.

Myriad's Patent



Isolated genomic DNA & cDNA



Patent Eligible Subject Matter: Defined by Statute

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 therefor, subject to the conditions and requirements of this title.”
- Construed broadly, but excludes laws of nature, physical phenomena, or abstract ideas.
- Threshold enquiry before determining whether claims patentable under §§ 102, 103, and 112.

The District Court Southern District of New York, March 2010

- Plaintiffs have standing under DJ action to challenge Myriad's patents
- Product Claims not patent eligible under § 101
 - isolated DNA falls under “product of nature” exception because isolated BRCA DNA not “markedly different” from naturally existing BRCA1/2 (relying on *Chakrabarty*) → encoded information is the same in both.
- Method Claims not patent eligible under § 101
 - claims directed to “analyzing” and “comparing” invalid under “machine-or-transformation” test (*Bilski*) – mental processes independent of physical transformations.
 - claim directed to “comparing” cell growth rates → “arguably recites certain transformative steps” but transformative steps are “nothing more than preparatory, data gathering steps to obtain growth rate information”

Federal Circuit I – score board

- **Reversed** District Court (2-1) – claims to “isolated” DNA are patent eligible
- **Reversed** District Court (3-0) – complementary DNA (cDNA) patent eligible
- **Reversed** District Court (3-0) – method claim to screening cancer therapeutics through changes in cell growth rate are patent eligible
- **Affirmed** District Court (3-0) – method claims “comparing” and “analyzing” are not patent eligible
- **Affirmed** District Court (3-0) – one plaintiff has standing

Federal Circuit I – isolated DNA (Lourie)

- Supreme Court decisions in *Chakrabarty* and *Funk Brothers* set out framework for deciding patent eligibility of isolated DNA
- Distinction “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”
- Challenged claims patent eligible “because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature”

Myriad Slip Op. at 39-41 (emphasis added)

Federal Circuit I – isolated DNA

3 Judges – 3 approaches

■ Turns on the interpretation of “**markedly different**”

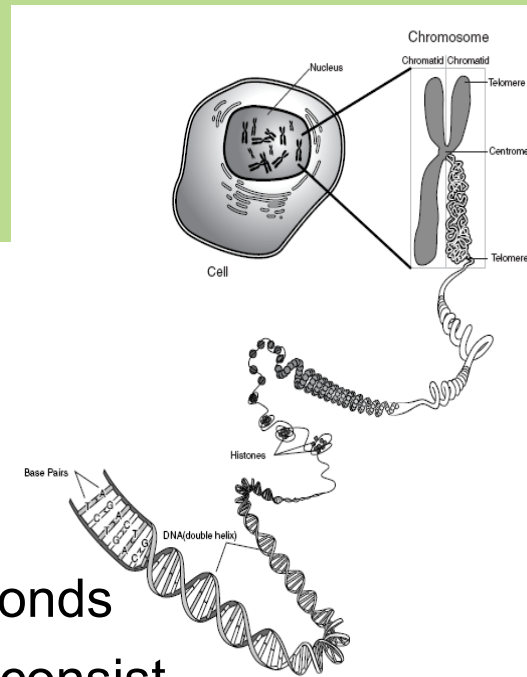
→ **Structure** (Lourie)

- isolated DNA “markedly different”
- “Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule”

→ **Structure & Function/Utility** (Moore)

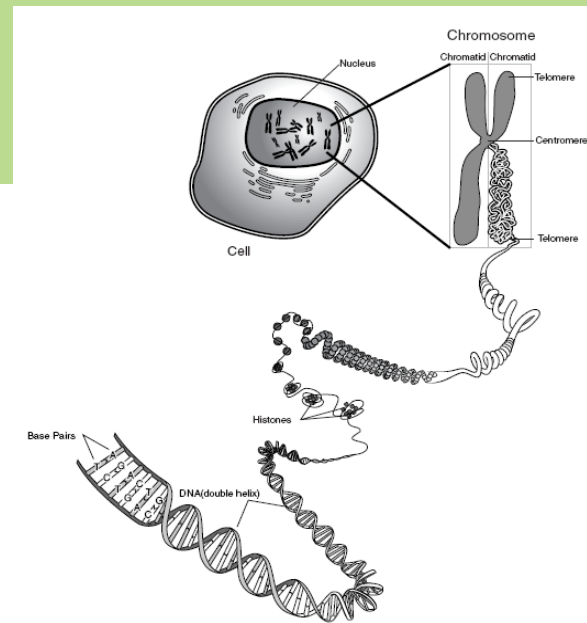
- Structure imparting New Utility
- “markedly different . . . with the potential for significant utility”

→ Structural differences not controlling – focused on **similarities** rather than marked differences (Bryson)



Briefs – DOJ's “Magic Microscope”

- cDNA patent eligible but isolated and unmodified genomic DNA not, because sequence exists in humans based on evolution not made by man
- DOJ did not defend PTO's longstanding position that isolated DNA is patent eligible
- DOJ's “magic microscope” (oral argument) could focus on the claimed BRCA sequences as they exist in the human body but could not *in vivo* focus on cDNA → therefore only cDNA is patent eligible.



Supreme Court I & Federal Circuit II

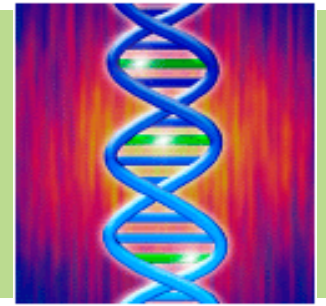
■ Supreme Court I

- Granted Certiorari
- Deciding *Mayo v. Prometheus* case
- Remanded to Federal Circuit
 - to reevaluate in view of the *Mayo* decision

■ Federal Circuit II

- Same outcome as Federal Circuit I, but includes arguments addressing *Mayo*

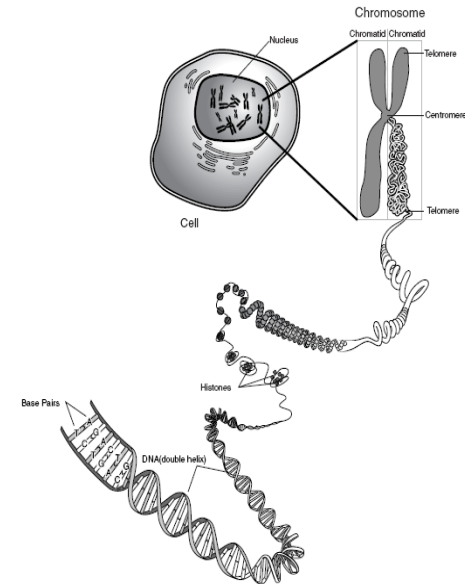
Supreme Court II



■ **Question:** Are human genes patent eligible?

■ **Claims at issue:**

- isolated naturally occurring DNA sequences
- cDNA sequences



Supreme Court II - Holding

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

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

Isolated DNA: Rationale for Patent Ineligibility

- Isolating is not inventive ("Separating [a] gene from its surrounding genetic material is not an act of invention.")
- Same nucleotide sequence/ same information content as in nature. ("Myriad did not create anything.")
- Followed *Mayo*: claim must convey inventive concept independent of newly discovered natural phenomenon.
- Claims "not expressed in terms of chemical composition" and do not rely "on the chemical changes that result from [] isolation . . ."
- Claims "concerned primarily with the information contained in the genetic sequence"

cDNA: Rationale for Patent Eligibility

- Non-naturally occurring
- “lab technician unquestionably creates something new when cDNA is made“

- Caveat: Exons-only molecule
 - cDNA without intron removal: not eligible under § 101?
 - what if cDNA is a primer or probe and not used for information content?
 - Bacterial cDNA, naturally without introns: presumably not eligible, especially if utility pertains to information content

Supreme Court II

The Court explicitly stated that it did not consider:

- patent eligibility of other types of inventions
 - “new *applications* of knowledge about the BRCA1 and BRAC2 genes”
 - “innovative methods of manipulating genes”
 - “the patentability of DNA in which the order of the naturally occurring nucleotides has been altered”
 - “scientific alteration of the genetic code”

USPTO Guidance

- “[N]aturally occurring nucleic acids are not patent eligible merely because they have been isolated.”
- “Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101.” (emphasis added)
- “Claims clearly limited to non-naturally-occurring nucleic acids, such as cDNA or a nucleic acid in which the order of the naturally-occurring nucleotides has been altered (*e.g.*, a man-made variant sequence), remain eligible.” (emphasis added)
- http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf

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What Has Happened Since *Myriad*: Further Lawsuits

- **2 companies announced they would start testing for the BRCA1 and BRCA2 genes**
- ***Myriad Genetics, Inc. v. Ambry Genetics Corp.* on July 9**
 - alleging infringement of 10 different patents including the patents challenged in the original lawsuit; only asserting claims that were left valid by the Supreme Court decision. Myriad writes:
 - As of the morning of June 13, 2013, Plaintiffs collectively had 24 patents containing 520 claims concerning two genes (BRCA1 and BRCA2), and methods of use and synthetic compositions of matter related thereto. On June 13, the Supreme Court of the United States ruled that five patent claims covering isolated naturally occurring DNA were not patent-eligible, thereby reducing the overall patent estate to 24 patents and 515 patent claims. This case involves none of those five rejected claims.
- ***Myriad Genetics, Inc. v. Gene by Gene Ltd.* on July 10**
 - Similar complaint – slightly different claims asserted.

Ramifications: Patent Eligibility

■ Affected Subject Matter

- All isolated DNAs that retain native (unaltered) sequence, not just human genes, particularly if utility pertains to information content

■ Unaffected Subject Matter

- cDNA (introns removed)
- Synthetic DNA with non-native (altered) sequences
- Other synthetic molecules, *e.g.*, a semi-synthetic antibiotic
- Did not consider: New applications of knowledge; innovative methods

■ Potentially Affected Subject Matter???

Ramifications: Patent Eligibility

■ Biotech Applications

- Typically first claim to “an isolated polynucleotide”
 - delete “isolated”?
 - use other terms – “recombinant” or “synthetic”
 - only cDNA
 - sequences with at least one change from naturally occurring

■ Rely on Other Types of Claims

- constructs, expression cassettes, vectors, transformed host cells, transformed plants/seeds, compositions, kits, etc.
- Methods – must not forget to comply with *Mayo v. Prometheus*

Suggested Strategies

■ Existing Applications with Pending Claims:

- review claims for any *Myriad* or *Mayo* issues
- review specification for potential support for new language/claims
- amend claims
- add other types of claims (if supported)
 - directed to product or method
 - be creative

■ Prosecution: Potential Arguments

- USPTO guidelines and Court decision narrow and relates only to “isolated nucleic acid” and should not apply to anything else
- When applicable, point to what the Court decision stated was not addressed

Suggested Strategies

■ Issued Patents:

- should already have claims other than just DNA claims
- If family member still pending, new claims can be pursued
- if want to enforce, only assert claims other than those to naturally occurring DNA
- could request a reissue to delete those claims, narrow original claims, and/or add claims (but . . .)

■ New applications:

- Focus on distinguishing characteristics of compositions (new utilities, minimum modifications compared to naturally occurring)
- Focus on chemical composition rather than information encoded by sequence
- Rely on other types of claims – ensure fully supported

Questions?

Thank You

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