

Recent Changes in US Patent Law

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FISH & RICHARDSON

Today's Topics

- What is the AIA?
- Why is it important?
- Topics
 - First-Inventor-to-File (FITF)
 - Prior Art Redefined
 - Grace Period
 - Priority
 - Virtues of Common Ownership, and Joint Research Agreements
 - Lab Notebooks
- The US Supreme Court's *Myriad* Decision

What is the AIA?

- ❖ Leahy-Smith America Invents Act
- ❖ Signed into law on September 16, 2011
- ❖ Central patent application-related provisions went into effect on March 16, 2013

Why is it important?

- ❖ Biggest change in US patent law since 1952
- ❖ Changes U.S. patent system from “first-to-invent” (FTI) to “first-inventor-to-file” (FITF)
- ❖ FITF will harmonize U.S. with the rest of the world
 - But significant differences will continue to exist
- ❖ Important changes to what constitutes “prior art”
- ❖ Option for prioritized patent prosecution
- ❖ Changes to USPTO post-grant proceedings
- ❖ Changes to litigation

First Inventor To File

March 16, 2013

Broad changes to Definitions of Prior Art

- ❖ Redefines all prior art relative to the effective filing date **not the invention date**
- ❖ No “swearing behind” declarations
- ❖ Interference practice eliminated
- ❖ Obviousness (to POSITA) determined before the effective filing date of the claimed invention

The Good Old Days: First-to-Invent



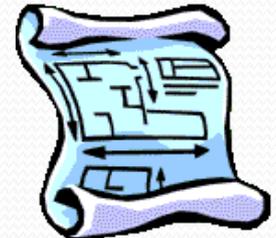
Amy invents
July 1, 2011



Bart invents
August 23, 2011



Bart files
September 1, 2011



Amy files
September 2, 2011

Amy wins

Post-AIA: First-Inventor-to-File



Amy invents
July 1, 2013



Bart invents
August 23, 2013



Bart files
September 1, 2013



Amy files
September 2, 2013

Bart wins

Prior Art Redefined

- ❖ Claimed invention is **not** novel if any of the following events occur prior to the effective filing date of the claimed invention:
 - patented, described in printed publication, in public use, on sale, or *otherwise available to public*
- ❖ Certain exceptions
- ❖ “effective filing date”: (i) the actual filing date of the patent or application, or (ii) the earlier filing date of a priority application, including foreign applications from which the patent claims priority.

Prior Art Redefined

Impact

- ❖ More categories of prior art
 - Public use and on sale activities outside the US now constitute prior art
- ❖ More prior art generally citable against an application
 - Prior art date needs only to beat the effective filing date rather than date of invention to be problematic

The Grace Period

One Year...

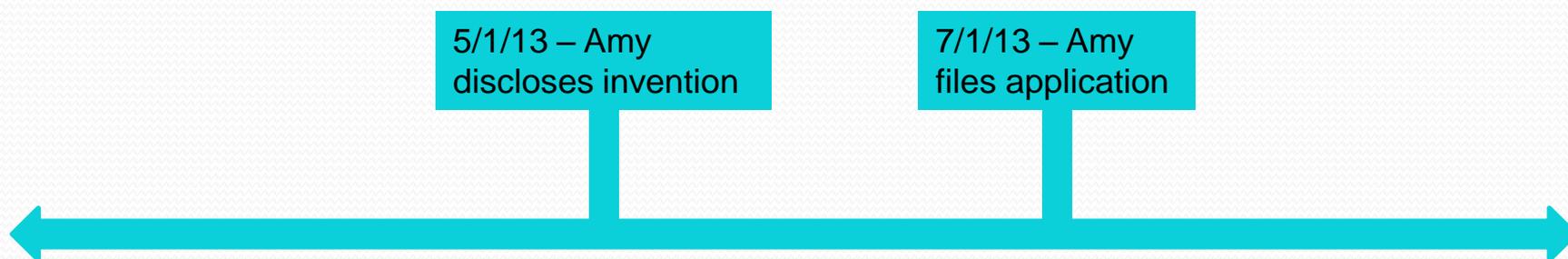
- ◆ A disclosure made **one year or less** before the effective filing date of a claimed invention shall not be prior art if--
 - (A) the disclosure was **made by the inventor or joint inventor** or by another who **obtained the subject matter disclosed from the inventor** or a joint inventor; or
 - (B) the subject matter disclosed had **previously been publicly disclosed by the inventor** or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

The Grace Period

What does this mean for you?

- ❖ An inventor's public disclosures will not preclude a patent, if they are made within one year before the filing of the patent application
 - AKA the “grace period”
 - An inventor's public articles and speeches are not prior art if made within one year of patent application
 - Unclear whether the grace period applies to public uses or sales
- ❖ But rights will be lost abroad! This is **ONLY FOR THE US.**

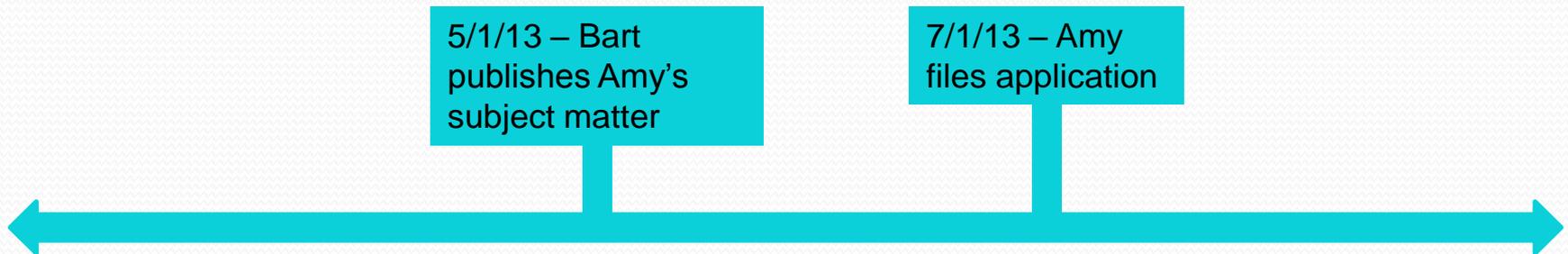
Example 1: Inventor's own disclosure



Amy gets the patent because Amy's publication was by Amy and within a year of filing

Amy: "That is my disclosure"

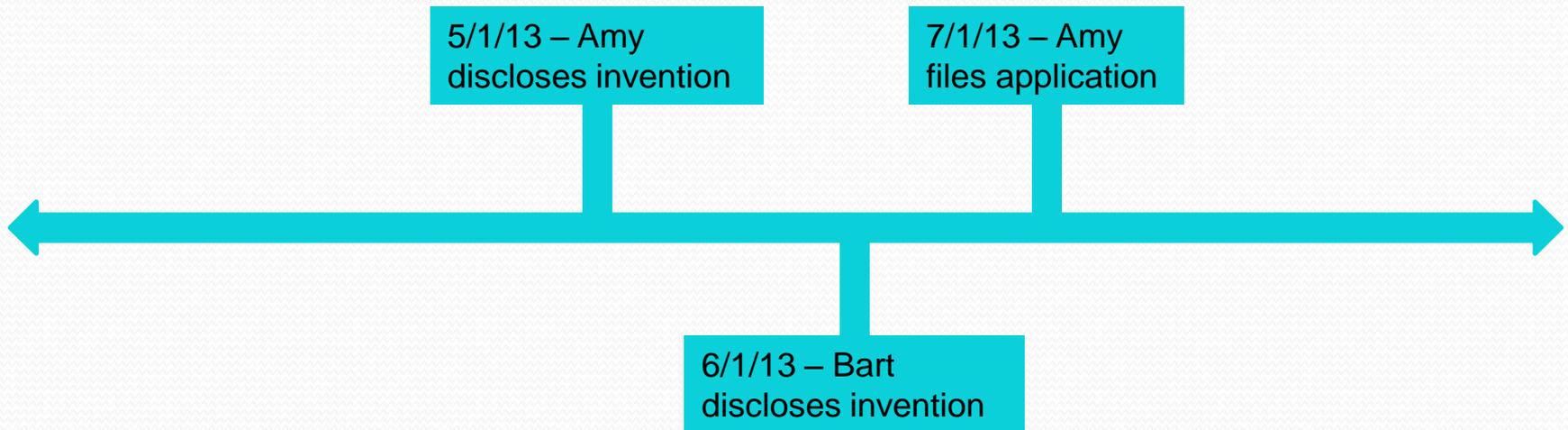
Example 2: Disclosure of Inventor's Work by Another



Amy gets the patent if Amy shows the subject matter disclosed by Bart was obtained from Amy

Amy: "That disclosure originated from me."

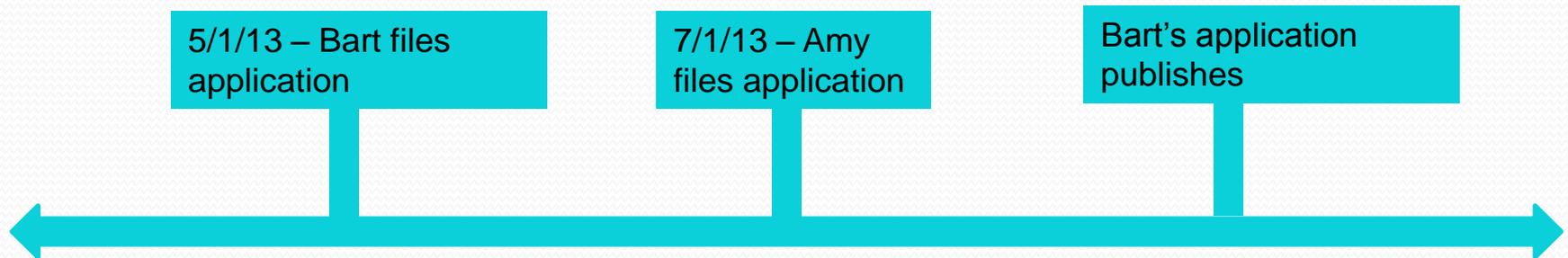
Example 3: Two Public Disclosures



Amy gets the patent if the subject matter of Bart's publication contains the same subject matter as in Amy's publication.

Amy: "I publicly disclosed the subject matter first"

Example 4: Derivation



Amy gets the patent if Amy shows the subject matter disclosed by Bart was obtained from Amy

Amy: “That disclosure originated from me.”

So, no, you can't get a patent on someone else's invention.

Priority Contests — Old Rules v. New Rules

❖ Old Rules: *Interferences*

- 102(g): *In determining priority under this subsection, there shall be considered not only the respective dates of **conception** and **reduction to practice** of the invention, but also the **reasonable diligence** of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other*
- Conception
- Reduction to practice
- Reasonable diligence

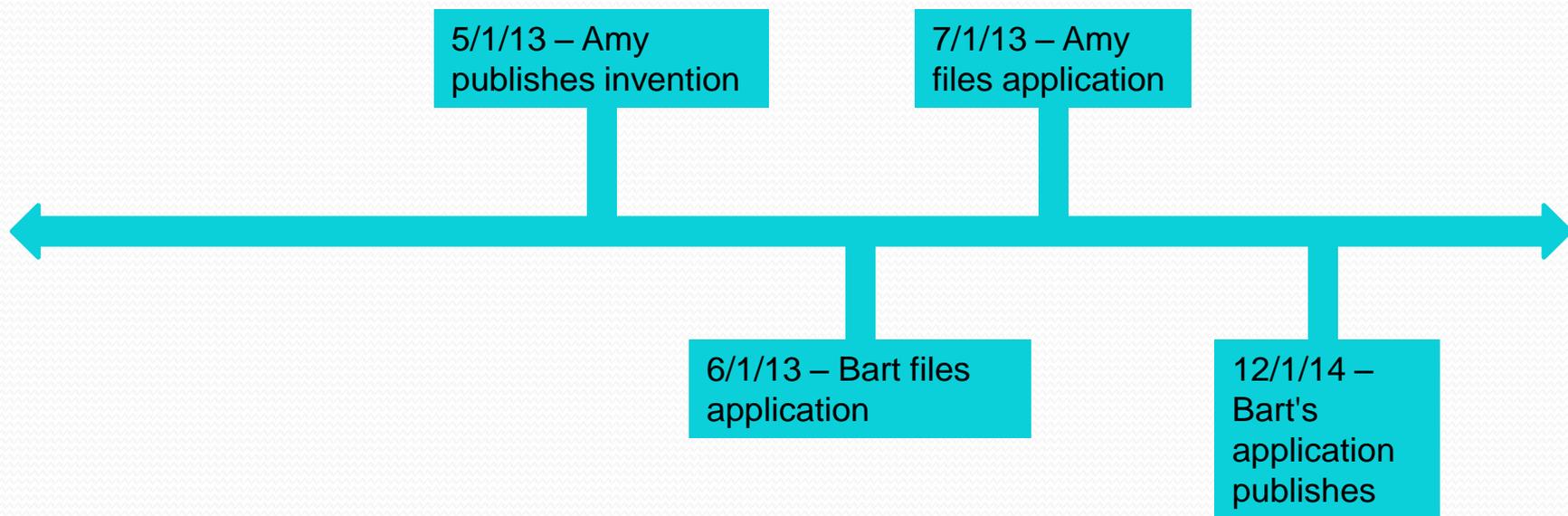
❖ New Rules:

- Filing date

Priority post AIA - the “First inventor to Publish”

- ❖ In certain situations, the inventor’s public disclosures can give the inventor priority over later filed patent applications...
- ❖ The public disclosure must fully support claimed invention to be entitled to priority

Example 5: Publication = Priority



Amy gets the patent if the subject matter of Bart's application is the same subject matter of Amy's publication

Amy: "I publicly disclosed the subject matter before Bart filed his patent application with that subject matter."

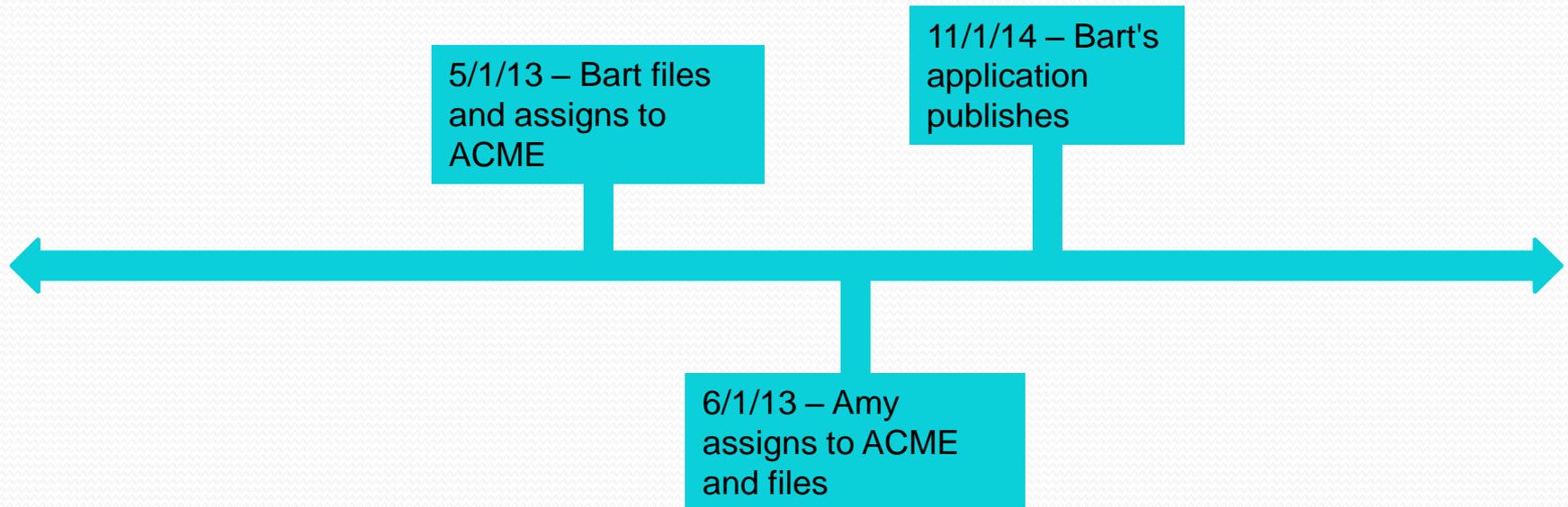
The Virtues of Common Ownership

❖ Commonly owned U.S. patents and applications will not be prior art in many cases

❖ This applies when:

- Amy's Application was effectively filed prior to Bart's Application, but did not publish/issue prior to the effective filing date of Bart's Application
- Amy's and Bart's Applications are owned by the same person or subject to an obligation of assignment to the same person or subject to a joint research agreement, and
- The common ownership existed "no later than the effective filing date of the claimed invention"

Example 6: Common Ownership



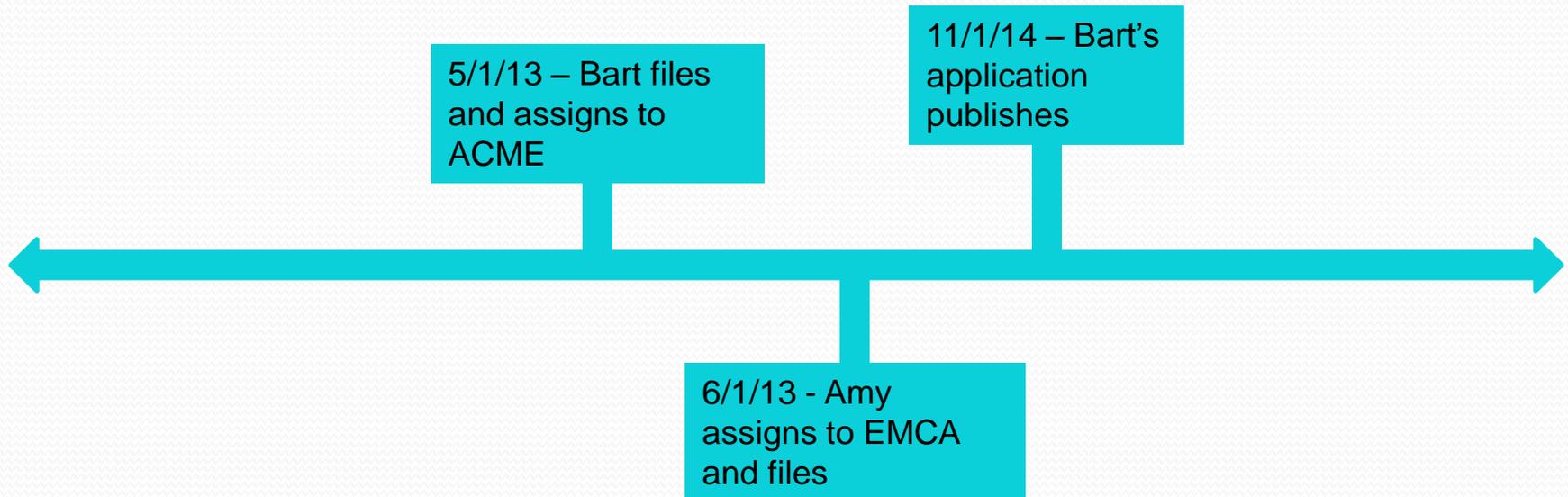
Amy avoids Bart as prior art since the subject matter of Amy and Bart were subject to an obligation to assign to the same company ACME before the effective filing date of the claimed invention

Amy: “We work for the same company and have assigned our rights to it before the effective filing date of my application.”

Joint Research Agreements

- ❖ The “common ownership” exception is applicable if:
 - claimed invention was made by/on behalf of at least one party to a joint research agreement in effect on/before the effective filing date of the claimed invention;
 - claimed invention was made as a result of activities within the scope of the joint research agreement; and
 - application discloses the parties to the joint research agreement

Example 7: Joint Research Agreement



Amy avoids Bart's filing as prior art if the subject matter of Bart and the claimed invention of Amy were made by or on behalf of a joint research agreement in effect before the effective filing date of the claimed invention.

Amy: "I was working with Bart, and we developed the subject matter together under a joint research agreement before I filed."

Laboratory Notebooks

- ❖ Recommendation: Keep Maintaining Laboratory Notebooks
- ❖ Notebooks somewhat less important under first-inventor-to-file rules – not used to establish date of invention
- ❖ HOWEVER, still important for:
 - ❖ Establishing rights in derivation proceedings
 - ❖ Establishing exceptions to prior art rules
 - ❖ Telling story of invention in litigation
 - ❖ Good science

Prioritized Patent Examination

- ▶ Pay additional fee for faster examination (about US\$5K for large entity)
- ▶ USPTO goal: final disposition on average 12 months from date of prioritized status
- ▶ Patent applications filed after Sept. 25, 2011
- ▶ Limit of 10,000 requests for prioritized exam each year

The US Supreme Court's *Myriad* Decision

- June 13, 2013, the end of a “rollercoaster” of litigation
- The claims at issue covered “isolated” genomic DNA and cDNA
- “[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 that **cDNA is patent eligible** because it is not naturally occurring.”
- “**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.”

The US Supreme Court's *Myriad* Decision

- The Court gave **no** deference to the USPTO policy of issuing such patents for three decades
- The Court stated the decision does **not** apply to:
 - other claims in Myriad's patents
 - method claims
 - *applications* of natural laws or products of nature
 - DNA in which the order of the nucleotides is altered

The US Supreme Court's *Myriad* Decision

- The decision raises many questions
- What impact will this decision have on other “naturally occurring” chemicals such as antibodies, hormones, and other proteins, therapeutic RNA, cells, microorganisms, and other biological molecules?
- Have the floodgates opened?
 - July 2, 2013 - Two public interest groups asked a federal appeals court to invalidate a patent on human embryonic stem cells held by the Wisconsin Alumni Research Foundation (WARF), because the claimed "cell culture falls within the 'product of nature' exception" of what can be patented

The US Supreme Court's *Myriad* Decision

- The USPTO has issued a statement to examiners:
 - “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.”
- However, claims “clearly limited to non-naturally-occurring nucleic acids, such as a 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**.”
- Claims to nucleic acids that are labeled or in vectors or cells that would not naturally include them should also still be patent eligible

The US Supreme Court's *Myriad* Decision

- But all is not lost for patent owners like Myriad
- The Supreme Court's decision left the plaintiffs (e.g., breast cancer patients) in the *Myriad* case without the result they probably expected, to be free of Myriad's patents
- In fact, Myriad can sue on other claims in those very same patents that were challenged

The US Supreme Court's *Myriad* Decision

- July 9, 2013 – Myriad Genetics sued Ambry Genetics Corp. for patent infringement of ten patents relating to genetic diagnostic testing for the BRCA 1 and BRCA 2 genes (some of the same patents at issue in the Supreme Court case)
- The asserted claims cover, e.g., cDNA, methods of screening and diagnosing, and primers

Patent Reform 2013

Thank you!

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For further information, see “Patent Reform”
at www.fr.com

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