



Overview of Intellectual Property Law: Considerations for Life Science Companies and Universities

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Agenda

- Overview of new patent laws – the America Invents Act
- Important things to remember for life science companies/universities

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The America Invents Act

- Signed by President Obama on September 16, 2011
- Touted as a bill to promote job growth
- Moves toward international harmonization
- Increases fees and Patent Office staff and services

Fees

- Increase in all fees by $\sim 15\%$
- Micro entity defined
- Penalty for paper filing





First Inventor to File

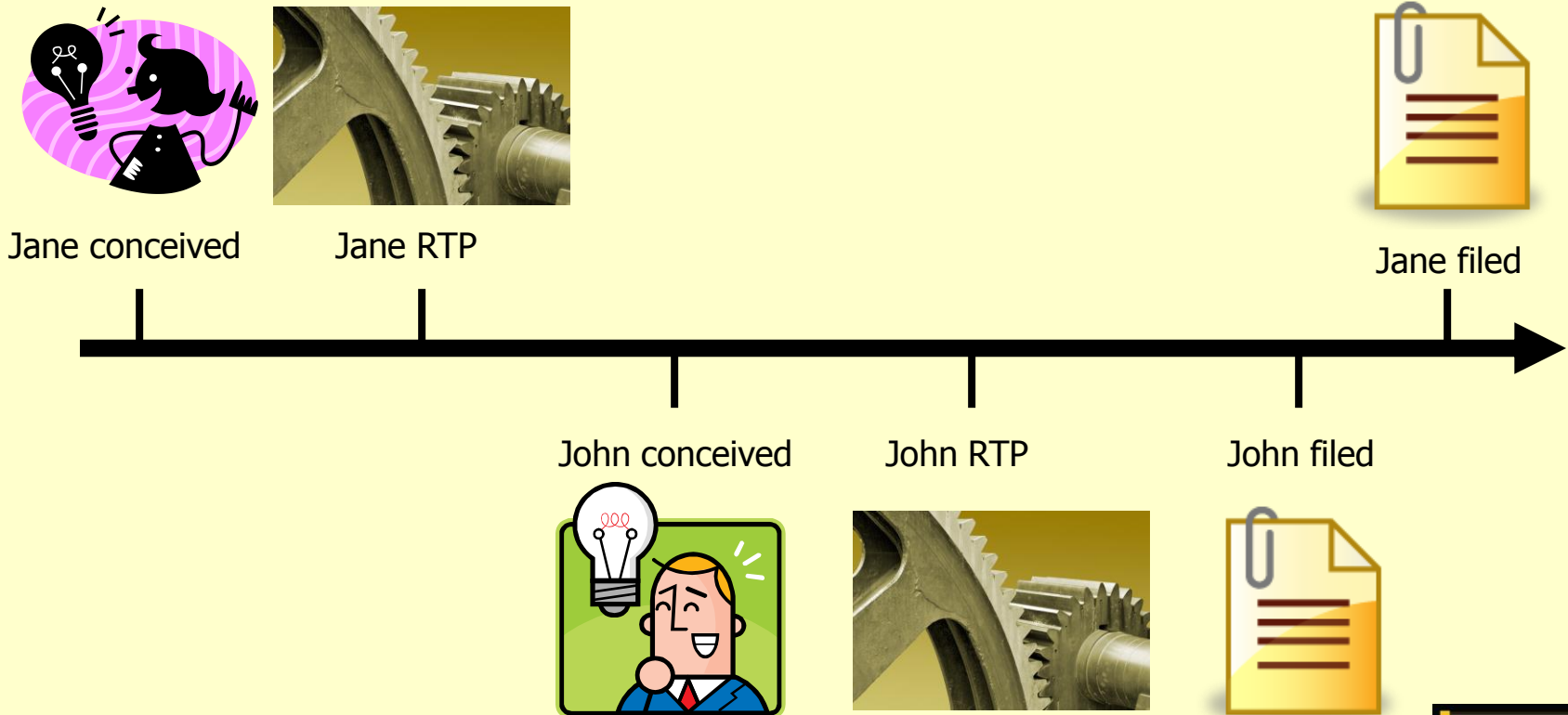
- Not the same as “first to file” system in the European Patent Office
 - There is a grace-period in the U.S.
- Inventor must be an individual who invents or discovers and must be named
- Inventor not necessarily the first true inventor
 - Race to the patent office



First Inventor to File

- Derivation Proceeding created
 - Modified interference-type proceeding (interferences eliminated for applications filed on or after March 16, 2013)
 - Challenger must show proof of prior conception and that first filer derived from him

First Inventor to File - Example



- John wins as long as he didn't derive from Jane
- Under old system, Jane wins if no statutory bar



Prior Art

- On sale, public use, published, patented, or otherwise available to the public
- Abolishes the distinction between foreign and domestic prior art
 - Applies to activity anywhere in the world, not just in the U.S.
- Published U.S./PCT patent applications/patents are prior art as of their earliest effective filing date
 - Effective filing dates can include foreign priority documents



Prior Art Exceptions

- Activity by inventor less than one year before filing (grace period)
 - Keep in mind this only applies to U.S. filings – absolute novelty required elsewhere
 - Intervening disclosures by a third party that were previously disclosed by the inventor
 - Absolute bar if activity more than one year before effective filing date
- Information or public disclosure derived from the inventor

Prior Art - Example



Jane filed



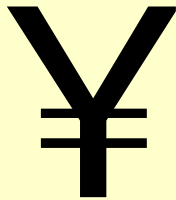
Jane published in U.S.

John filed



- Jane's application is prior art to John (assuming no exceptions)
- Under old system, John could potentially antedate Jane

Prior Art - Example



Jane sold in Japan



John filed



- Jane's sale is prior art to John (assuming no exceptions)
- Under old system, not prior art because not in the U.S.

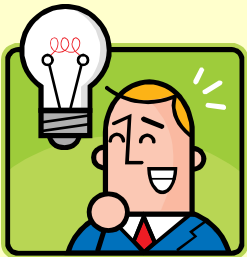
Prior Art - Example



Jane publicly used in China

> 1 year

John conceived



John filed



- Jane's use is prior art to John, no exceptions possible
- Under old system, not prior art because not in the U.S.

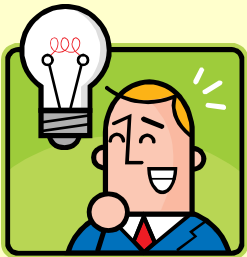
Prior Art - Example



Jane publicly used in the U.S.

< 1 year

John conceived

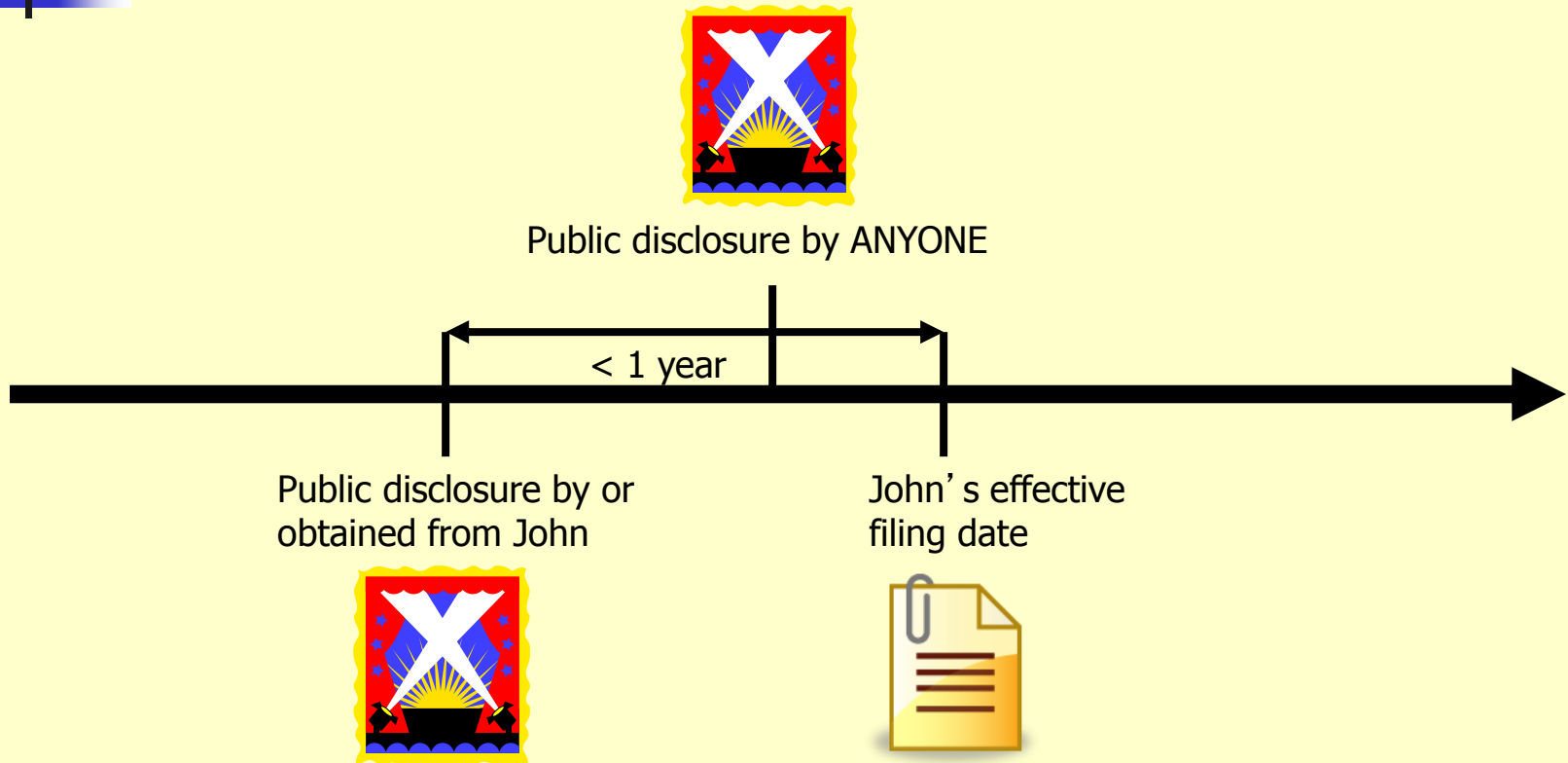


John filed



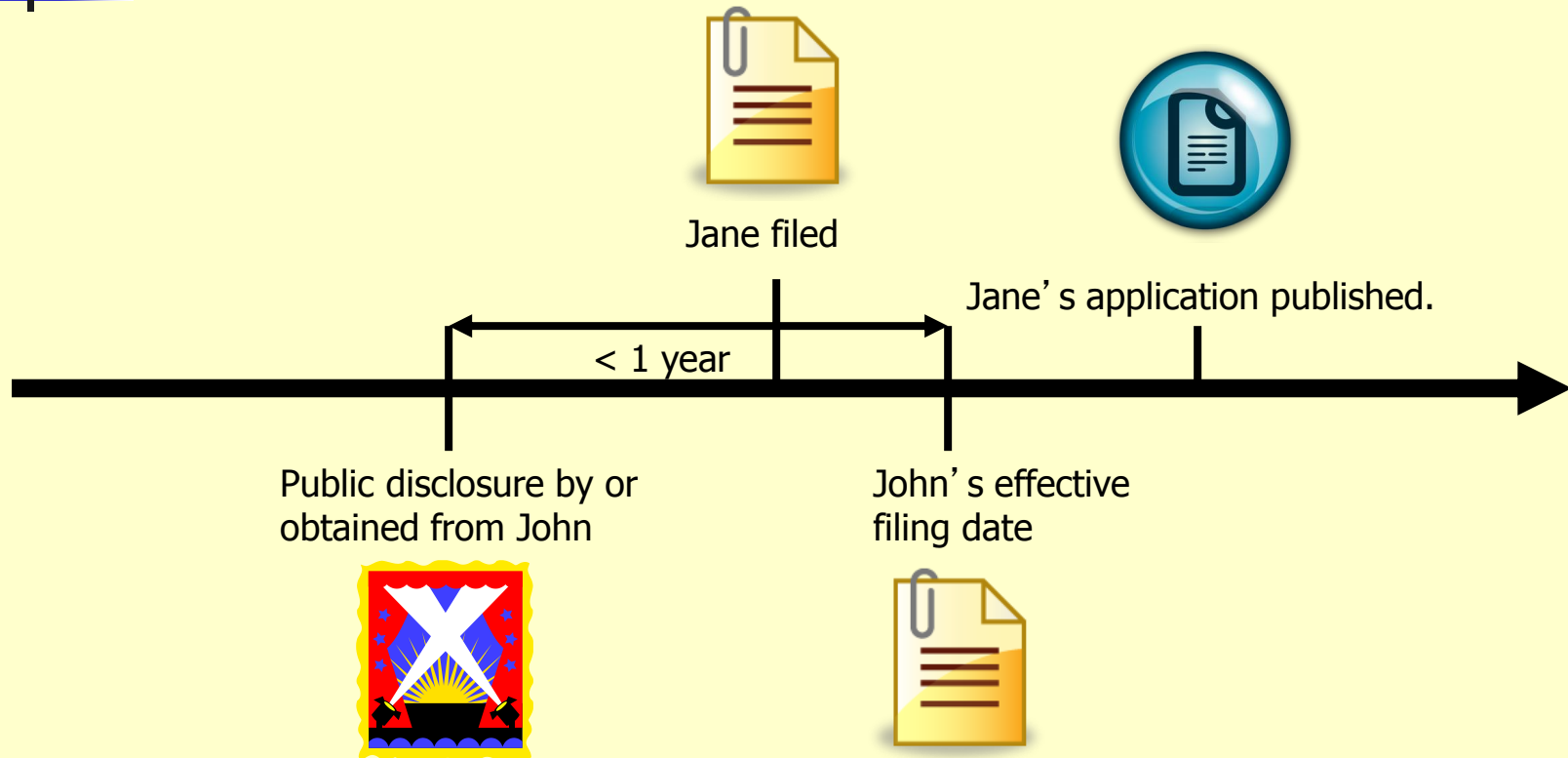
- Jane's use is prior art to John (may be an exception)
- Under old system, John could antedate Jane's use

Grace Period - Example



- Grace period applies, second disclosure is not prior art

Additional Example



- Jane's application is not prior art due to John's disclosure and John antedates Jane's filing using same disclosure



Prioritized Examination

- Fee - \$4,000 for large entity
- Limitations on the number of claims
- No prior art search required
- Limited number of applications each year
- Shorter time to respond to Office Actions
- USPTO goal – final disposition in 12 months



Things to Remember



File applications as soon as possible

- Race to the patent office for competitive areas of research
- Avoid “cover page provisionals”
 - Need to enable the invention
 - examples, examples, examples



Prioritized Examination

- Investment opportunities
- Valuation of a business
- Licensing

Be mindful of what you do before filing

- Recall that public disclosure can negatively impact filing in foreign countries
 - Publish manuscript, paper or thesis – keep in mind some journals have early electronic publishing
 - Disclose invention in a presentation
 - Discuss with anyone without a confidentiality agreement
 - Offer for sale or have any commercial activity
 - Submit a non-confidential grant application
- Remember grace period only in U.S.
- Derivative proceedings likely costly
 - Be careful with disclosures



Duty of disclosure after filing

- Everyone associated with the prosecution of a patent application (inventor(s), agents, attorneys, etc.) must disclose any prior art known to them that is material to patentability.
- Failure to disclose is possibly inequitable conduct, which can invalidate the patent



Who is an Inventor?

- An inventor is a person who conceives an invention claimed in a patent application or patent, not someone who only reduces an invention to practice
- A person is not an inventor simply because she is the boss or worked on aspects of the research
- Collaborations – does that make one an inventor?
- Authorship ≠ Inventorship



Lab Notebooks

- Still important
- Good practice for inventors to keep records of any private disclosure, even with collaborators
- May be useful to show derivation of inventor's work by another
- May show contribution to invention if an inventorship dispute develops



Assignments

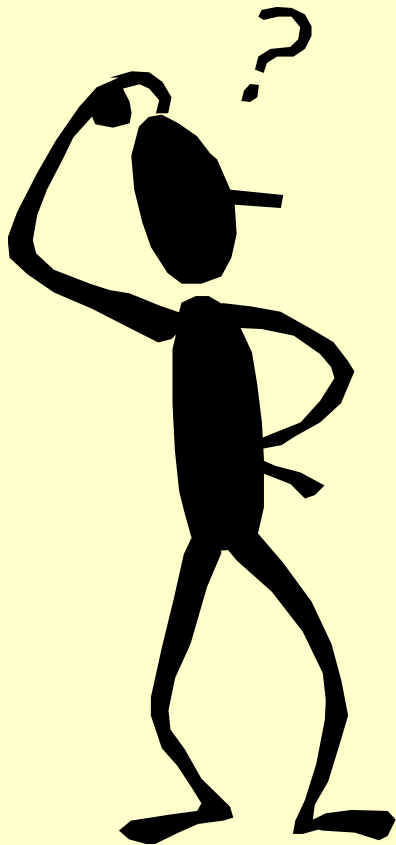
- Language in Assignment agreements and employment contracts with researchers and scientists is important
- Patent rights initially vest in the inventor
- “agree to assign” vs “do hereby assign”

Is it patentable subject matter?



- DNA? cDNA? Therapeutic methods?
- Case law changing regularly, so increasingly important to draft patent applications with this in mind

Questions?



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