



The Role of the Patent Examiner

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Agenda

- What is Patentable? (35 USC 101)
- Patent Prosecution
- America Invents Act

Constitution

Article I, Section 8:

“The Congress shall have power...to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their writings and discoveries.”

What is patentable??

35 USC § 101 - Inventions Patentable:

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.

Courts have interpreted the categories to *exclude*:

- "Laws of nature, natural phenomena, and abstract ideas"

Judicial Exceptions

- The basic tools of scientific and technological work are not patentable, even when claimed as a process, machine, manufacture or composition of matter.
- The “judicial exceptions” to eligibility are typically identified as:
 - abstract ideas (e.g., mental processes)
 - laws of nature (e.g., naturally occurring correlations)
 - natural phenomena (e.g., wind)

Natural Principle

- A natural principle is the handiwork of nature and occurs without the hand of man.
 - Includes a correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood, because the correlation exists in principle apart from any human action.
- Examples:
 - the relationship between blood glucose levels and diabetes is a natural principle.
 - Diagnosing a condition based on a naturally occurring correlation of levels of a substance produced in the body when a condition is present.
 - Identifying a disease using a naturally occurring relationship between the presence of a substance in the body and incidence of disease.

Patent Eligible – now what?

- Examiner considers whether a claim is new and nonobvious
- Applicants are entitled to a patent unless at least one of the patentability requirements is not met
- Entitlement is refuted by prior art rejections
- A prior art rejection under 35 USC 102 asserts that the claims lack “novelty” and are therefore unpatentable
- A prior art rejection under 35 USC 103 asserts the differences between subject matter sought to be patented and prior art are such that the subject matter as a whole *would have been obvious* at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains

Example Claim

1. A method for detecting a nucleic acid, wherein said method comprises:
 - (a) isolating nucleic acid from a nucleic acid containing sample, wherein an agent that impedes cell lysis was added to the sample; and
 - (b) detecting the presence or absence of the nucleic acid.
2. A composition comprising mutant DNA and normal DNA, wherein the percentage of free mutant DNA in the total free DNA of the composition is selected from the group consisting of: about 5-10% free mutant DNA, about 10-13% free mutant DNA, ...

Claim Interpretation

Is the careful consideration of

each and every word

in a claim to determine what the claim covers.

Each application is considered on its own.

Claim Interpretation: MPEP § 2111

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. en banc: 2005) (the "BRI" test);

Words of a claim must be given their "Plain Meaning" unless such meaning is inconsistent with the specification.

- "Plain Meaning" refers to ordinary and customary meaning given to the term by those of ordinary skill in the art.
- Applicant may be own lexicographer.

Guidance for Claim Interpretation

Consideration of the Specification:

- background description
- explicit definitions
- general description
- preferred embodiments
- working examples
- prophetic examples

Things to consider outside of the specification:

- prior art and technical disclosures
- declarations and experimental evidence
- technical and English language dictionaries

Examination Process

- Restriction between Claim 1 and Claim 2
- Examiner Performs a search for prior art
 - Applicants submit relevant prior art
 - Patent databases
 - STN & Dialog
- Office Action – rejection of claim 1, withdrawal of claim 2
- Options for applicants
 - Interview – in person or on the phone
 - Persuade the examiner the art does not read on the claims
 - Amend the claims around the prior art

Flowchart of Patent Examination and Appeal System

(I) Patent Examination

Classification determines
TC/AU for examination



Patent Examination



Application undergoes
Pre-Exam

First Office Action on the Merits
(FOAM)

Applicant(s) Response

Final Office Action

Applicant(s) Response

Advisory Action

Applicant(s) Appeal



Notice of Allowance



Applicant(s) pay issue fee



USPTO grants Patent

Example Claim

1. A method for detecting a nucleic acid, wherein said method comprises:

(a) isolating nucleic acid from a non-cellular fraction of a nucleic acid containing sample, wherein said sample comprises an agent that impedes cell lysis, if cells are present, and wherein said agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor ~~was added to the sample~~; and

(b) detecting the presence or absence of the free nucleic acid.

Examiner's Role

- Issue Valid Patents
 - Make appropriate objections
 - Make only reasonable rejections
 - Help the applicant identify allowable subject matter
- Act as an advocate for the Public
 - Ensure development of a clear and complete record
 - Patent prosecution before the Office should not be viewed as adversarial. Instead it should be understood to be a cooperative investigation between the Examiner and the Applicant, which ensures an Applicant receives a patent only for that which they are entitled to in accordance with the Patent laws.

The Office Action

Legal record

- For published Image File Wrapper (IFW) applications, publicly available document from www.uspto.gov
- Sets forth the legal basis for any objections, rejections and indications of allowable subject matter
- Relied upon in any Court proceedings for a resulting patent
- Aids the public and the Courts with the underlying rationale behind patentability determinations
- Must be consistent with the policies of the Office
 - Set forth in the Manual of Patent Examining Procedures (MPEP)
 - Published Guidelines (Interim or Final) used between MPEP updates

Legal Basis: 35 USC 112

- 35 U.S.C. §112
 - Specification requirements
 - Written Description
 - Enablement
 - Best Mode
 - Claim requirements
 - Content
 - Particularly point out (not vague)
 - Distinctly claim (not indefinite)
 - Format
 - Independent
 - Dependent
 - Multiple Dependent

35 U.S.C. § 112: Supplementary Examination Guidelines

- Purpose: Assist the Examining Corps in evaluating claims for compliance with §112, ¶2, and other patentability requirements related to enhancing the quality of patents.
- Goal: Ensure that the scope of any patent rights granted is clear and supported by the invention disclosed to the public.
 - Section 112 is a valuable tool for examiners to accomplish this goal.

Definiteness Test

- “The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted).” MPEP § 2173.02.
- “The primary purpose of the definiteness requirement for claim language is to ensure that the scope of the claims is clear so that the public is informed of the boundaries of what constitutes infringement of the patent.” (the metes and bounds of the claim).

America Invents Act Implementation

Group 2 Rulemaking (Effective September 16, 2012)

Patent Related

- Inventor's oath / declaration
- Preissuance submission
- Supplemental examination
- Citation of patent owner claim scope statements

Administrative Trials

- Inter partes review
- Post grant review
- Covered business method review

America Invents Act

First Inventor to File Final Rules and Guidelines

Effective March 16, 2013



Critical Date for Claimed Invention

- Pre-AIA: date of invention
- AIA: effective filing date

35 U.S.C. 100(i)(1): New Definition for Effective Filing Date

Effective filing date of a claimed invention under examination is the earlier of:

- the actual filing date of the patent or application containing a claim to the invention;

or

- the filing date of the earliest application for which the patent or application is entitled to a right of **foreign priority or domestic benefit** as to such claimed invention

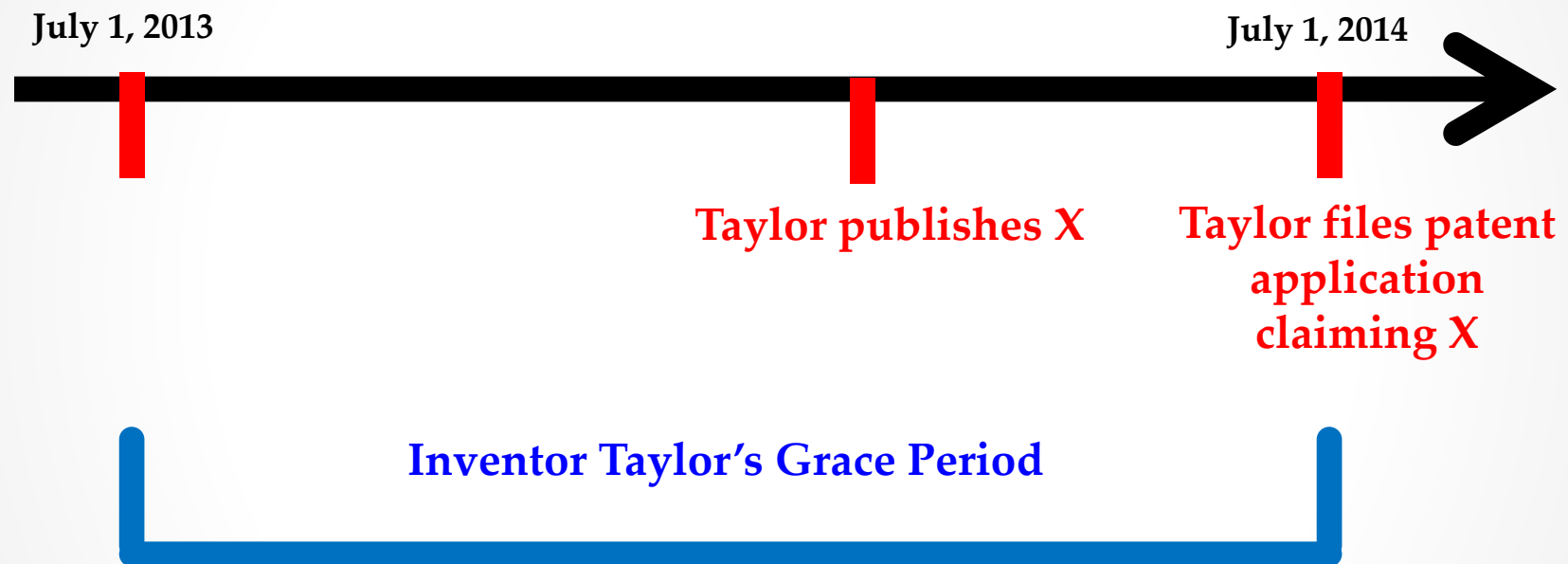
AIA Statutory Framework

Prior Art 35 U.S.C. 102(a) (Basis for Rejection)	Exceptions 35 U.S.C. 102(b) (Not Basis for Rejection)	
102(a)(1) Disclosure with Prior Public Availability Date	102(b)(1)	(A) Grace Period Disclosure by Inventor or Obtained from Inventor
		(B) Grace Period Intervening Disclosure by Third Party
102(a)(2) U.S. Patent, U.S. Patent Application, and PCT Application with Prior Filing Date	102(b)(2)	(A) Disclosure Obtained from Inventor
		(B) Intervening Disclosure by Third Party
		(C) Commonly Owned Disclosure

35 U.S.C. 102(a)(1): Prior Public Disclosures as Prior Art

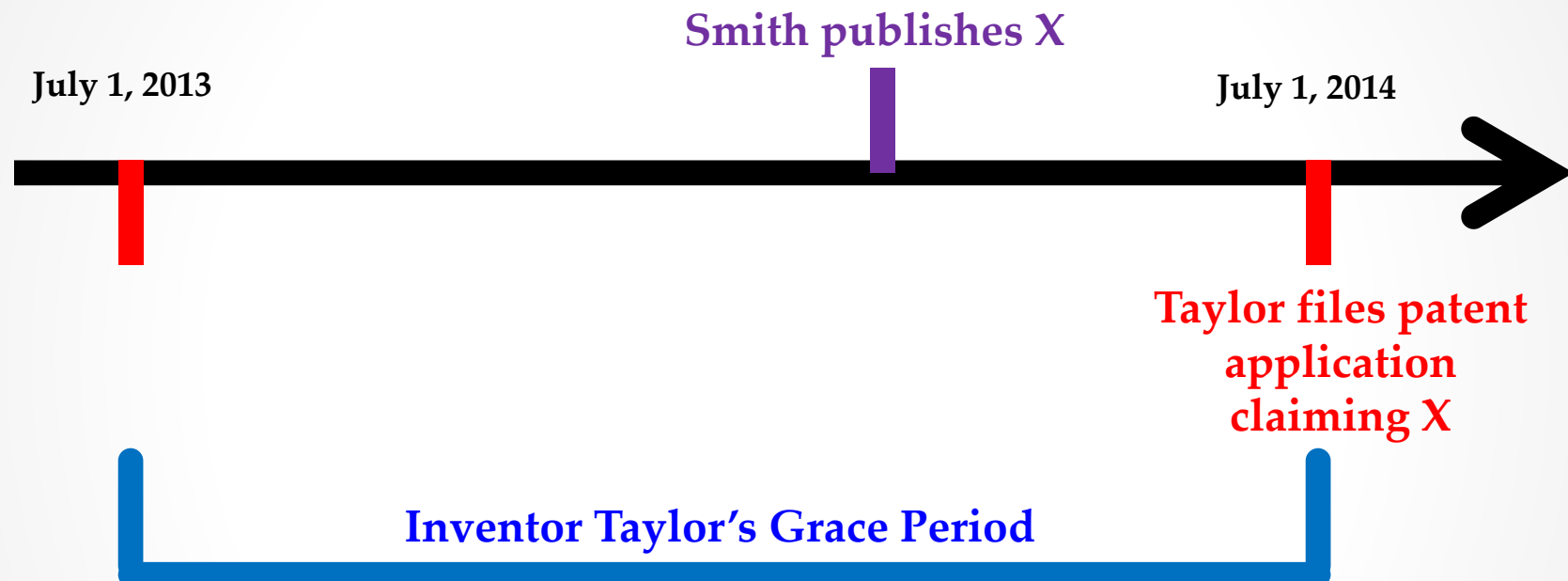
- 35 U.S.C. 102(a)(1) precludes a patent if a claimed invention was, before the effective filing date of the claimed invention:
 - patented;
 - described in a printed publication;
 - **in public use**;
 - **on sale**; or
 - **otherwise available to the public**

Example 1: Exception in 102(b)(1)(A)



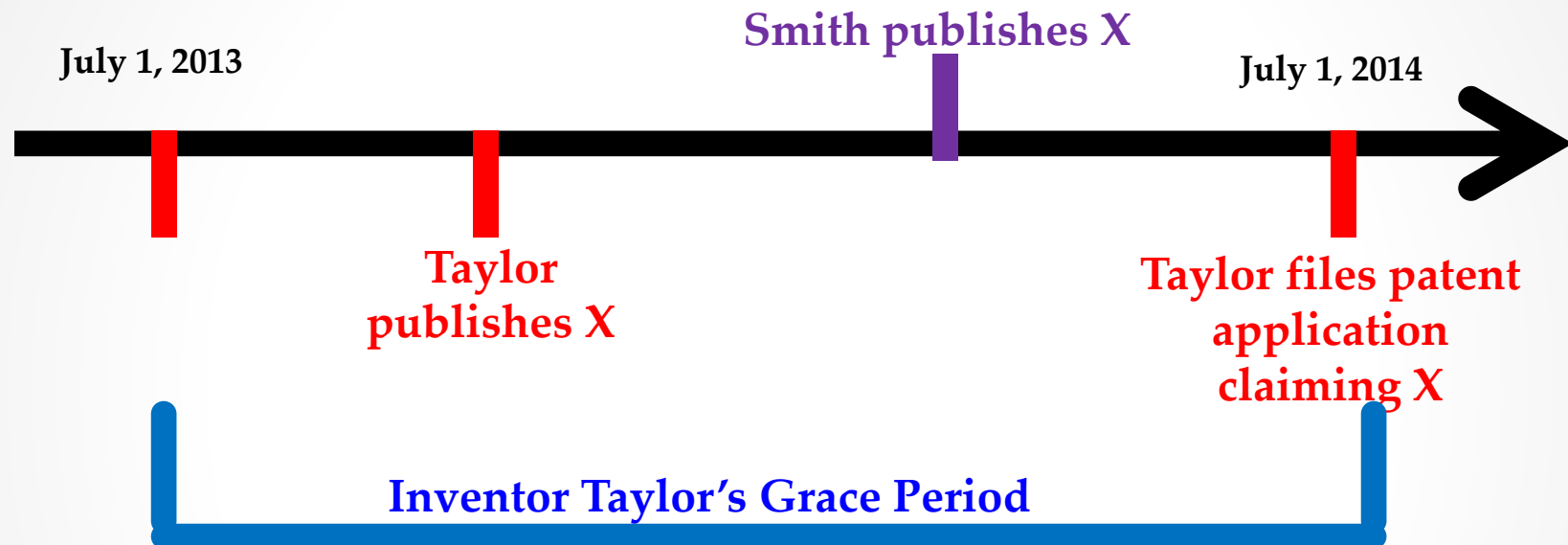
- Taylor's publication is not available as prior art against Taylor's application because of the exception under 102(b)(1)(A) for a grace period disclosure by an inventor.

Example 2: Exception in 102(b)(1)(A)



- Smith's publication would be prior art to Taylor under 102(a)(1) if it does not fall within any exception in 102(b)(1).
- However, if Smith obtained subject matter X from Taylor, then it falls into the 102(b)(1)(A) exception as a grace period disclosure obtained from the inventor, and is not prior art to Taylor.

Example 3: Exception in 102(b)(1)(B)

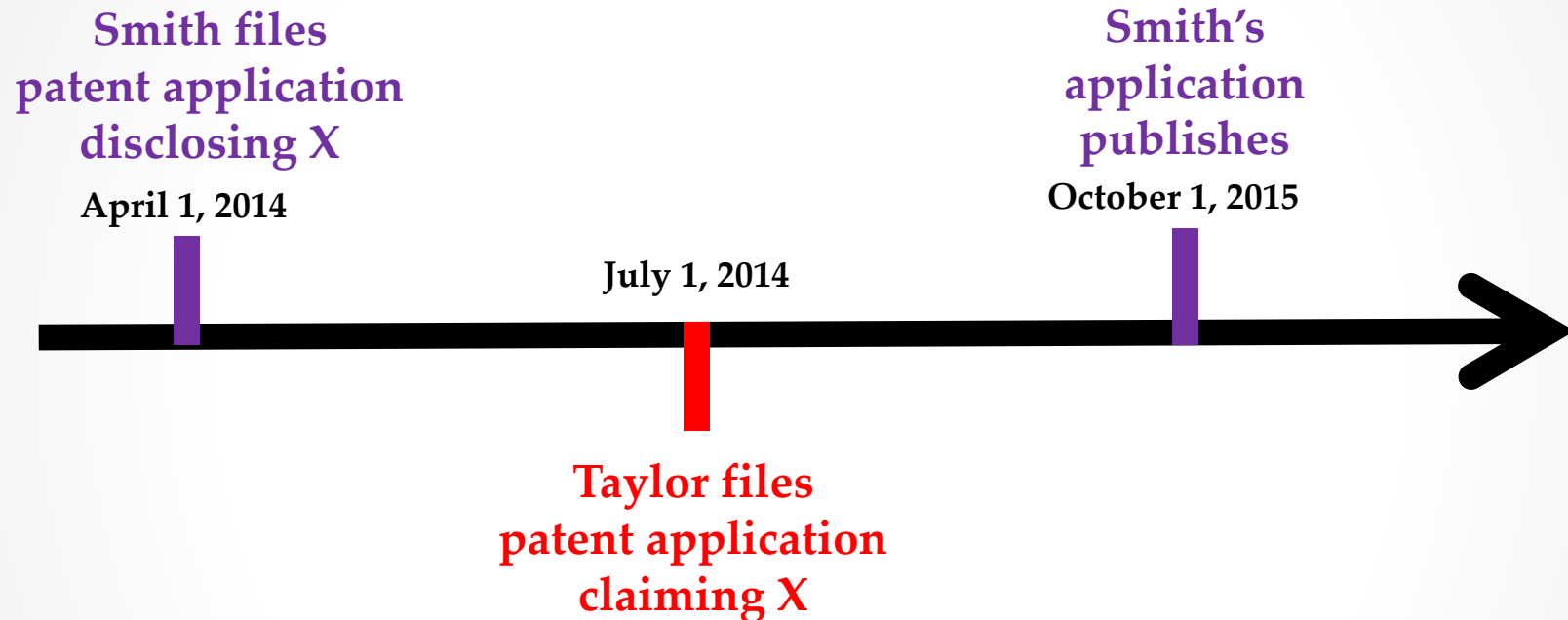


- Smith's publication is not prior art because of the exception under 102(b)(1)(B) for a grace period intervening disclosure by a third party.
- Taylor's publication is not prior art because of the exception under 102(b)(1)(A) for a grace period disclosure by the inventor.
- If Taylor's disclosure had been before the grace period, it would be prior art against his own application. However, it would still render Smith inapplicable as prior art.

AIA Statutory Framework

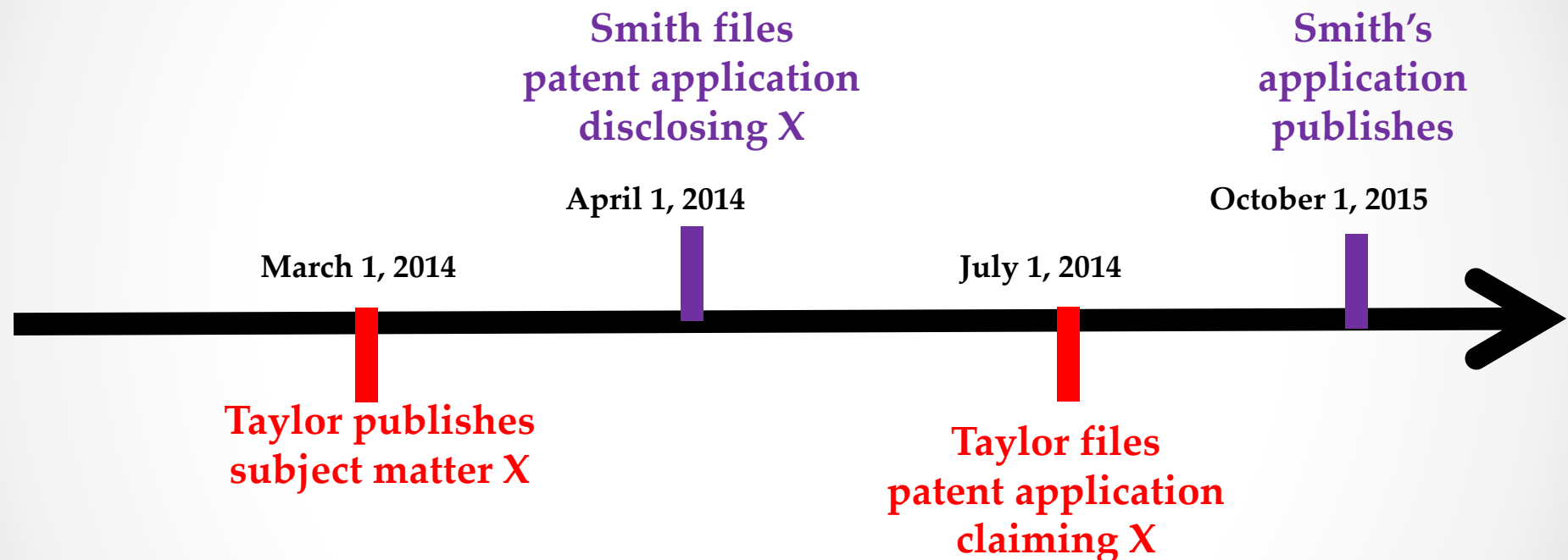
Prior Art 35 U.S.C. 102(a) (Basis for Rejection)	Exceptions 35 U.S.C. 102(b) (Not Basis for Rejection)	
102(a)(1) Disclosure with Prior Public Availability Date	102(b)(1)	(A) Grace Period Disclosure by Inventor or Obtained from Inventor
		(B) Grace Period Intervening Disclosure by Third Party
102(a)(2) U.S. Patent, U.S. Patent Application, and PCT Application with Prior Filing Date	102(b)(2)	(A) Disclosure Obtained from Inventor
		(B) Intervening Disclosure by Third Party
		(C) Commonly Owned Disclosure

Example 4: Exception in 102(b)(2)(A)



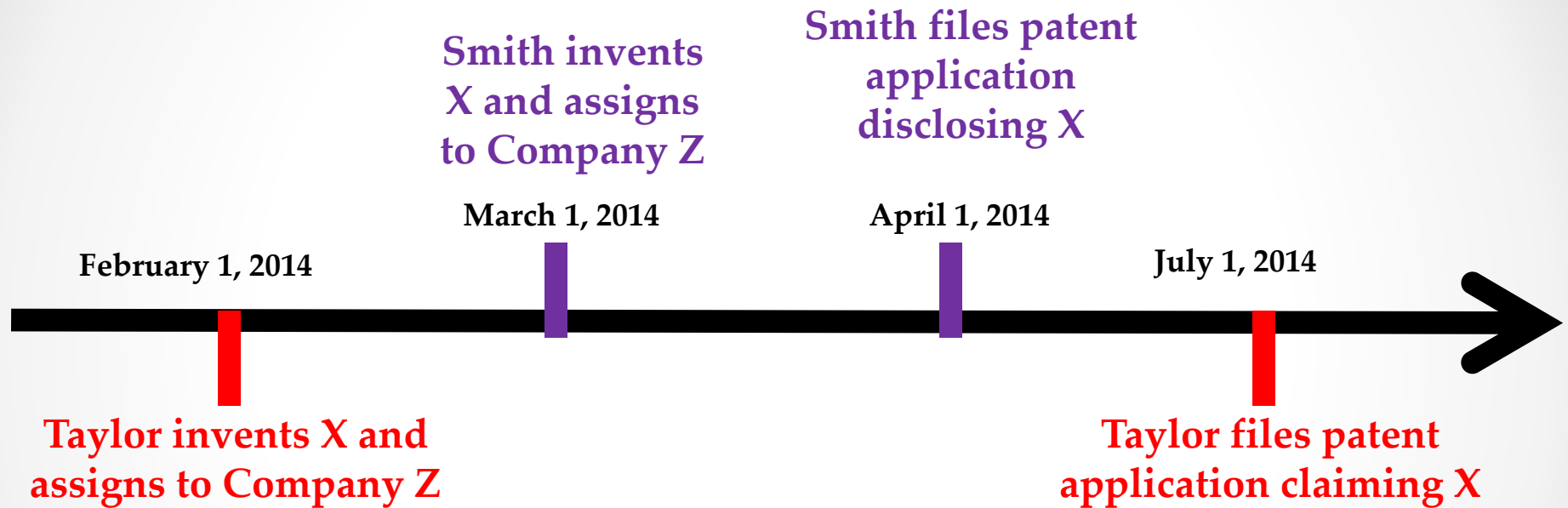
- Smith's patent application publication is not prior art if Smith obtained X from Inventor Taylor because of the exception under 102(b)(2)(A) for a disclosure obtained from the inventor

Example 5: Exception in 102(b)(2)(B)



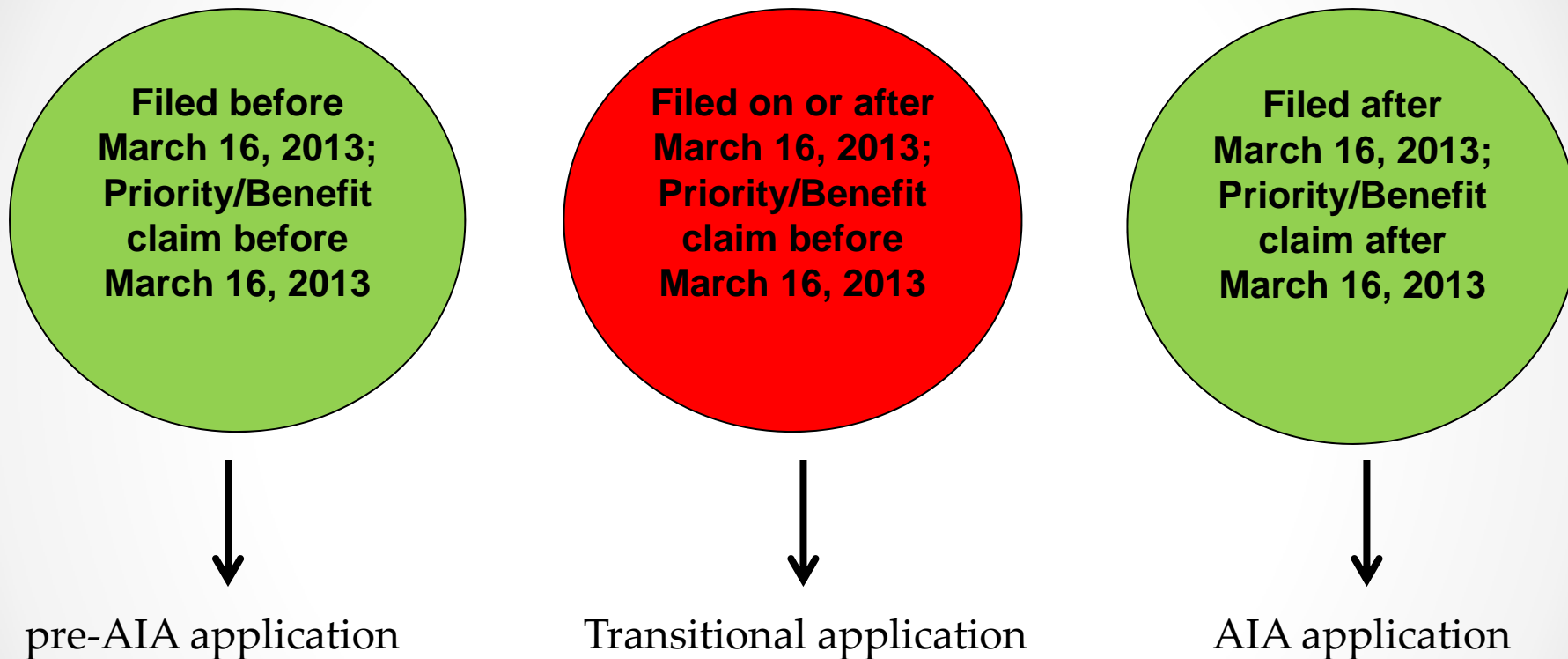
- Smith's patent application publication is not prior art against Taylor's application because of the exception under 102(b)(2)(B) for an intervening disclosure by a third party.

Example 6: Exception in 102(b)(2)(C)



- Smith's patent application publication is not prior art because of the exception under 102(b)(2)(C) for a commonly owned disclosure.
- There is no requirement that Smith's and Taylor's subject matter be the same in order for the common ownership exception to apply.

Applicability of AIA



Rule 1.55(j), 1.78(a)(6), or 1.78(c)(6): Statements in Transitional Applications

- Nonprovisional applications that are:
 - filed on or after March 16, 2013;
 - and
 - claim foreign priority or domestic benefit of an application filed before March 16, 2013,are called **transitional applications**
- If a transitional application has ever included a claim to an invention having an effective filing date on or after March 16, 2013, applicant must provide a statement to that effect

FITF Examiner Training

- Three-part overview training (March-April 2013)
 - Introductory Video: background for overview training
 - Live Training: >20 training sessions
 - Follow-up Video: statutory review and illustrations
- Comprehensive training (June-July 2013)
- Just-in-time training as needed (March-July 2013)

Resources

- Statutory Framework Chart:
http://www.uspto.gov/aia_implementation/FITF_card.pdf
- FAQs:
http://www.uspto.gov/aia_implementation/faqs_first_inventor.jsp
- Examiner Introductory Video: http://helix-1.uspto.gov/asxgen/AIA_Close_Cpt.wmv
- Examiner Overview Training Slides: (available on AIA micro-site soon)
- Examiner Follow-up Video: (available on AIA micro-site soon)



Thank You

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