PATENT SEMINAR

AMERICA INVENTS ACT

February 20, 2013

Opening remarks

Dr. Patrick O'Shea, Vice President and Chief Research Officer

Panel Members

Felicia Metz, JD, Sr. IP Manager, Office of Technology Commercialization

Anne Bowden, JD, University Counsel

Mary Anthony Merchant, JD, Ph.D., Ballard Spahr, LLP

Moderator

Dr. Gayatri Varma, Executive Director, Office of Technology Commercialization

OVERVIEW

- Opening remarks by Dr. O'Shea
- Panel discussion
  - Types of intellectual property (IP)
  - University IP policy
  - What is patentable?
  - Current patent law
  - America Invents Act

Types of Intellectual Property: **Patents**

- Utility
  - process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof
  - New, useful, non-obvious
- Plant
  - asexually reproduced, distinct and new variety of plant
- Design
  - new, original, and ornamental design for an article of manufacture

Types of Intellectual Property: **Copyright**

- Original works of authorship fixed in any tangible medium of expression
  - (1) literary works;
  - (2) musical works, including any accompanying words;
  - (3) dramatic works, including any accompanying music;
  - (4) pantomimes and choreographic works;
  - (5) pictorial, graphic, and sculptural works;
  - (6) motion pictures and other audiovisual works;
  - (7) sound recordings; and
  - (8) architectural works.
- Does not protect underlying ideas or functionality (scope of patents)
- Software code protected as a literary work

Types of Intellectual Property: **Trademark**

- Brand name/logo intended to identify source of goods

Types of Intellectual Property cont.

- trade secrets
- service marks
- mask works
- plant varieties
- data

University IP Policy

- Who owns inventions created by University of Maryland employees?
  - Federal law provides some of the answers
  - University IP policy provides some answers
  - Contracts provide the remaining answers

University IP Policy cont.

- Bayh-Dole Act
  - Universities elect to retain title to inventions made from government-funded research
  - Universities are encouraged to collaborate with commercial entities to promote the use of university research
  - Universities are encouraged to license inventions to small business firms-500 employees or less
  - Universities must share licensing income with faculty inventors and use royalty income to further research activities

University IP Policy cont.

- University owns inventions that University employees create:
  - Using Federal $$$ (Bayh-Dole Act);
  - Under a sponsored research agreement
  - Using significant public resources without permission & an agreement
  - Under a written agreement that gives UM ownership

University IP Policy cont.

- Faculty and student ownership of inventions:
  - If the IP Policy does not give the University ownership of inventions, then the faculty or student inventors own it.
  - The IP Policy states expressly that students own inventions they make as part of their academic or research obligations.

University IP Policy cont.

University owns © in works created by:

- Non-faculty employees (students and staff) as part of their job (work for hire)
- Faculty as a required deliverable under a sponsored research agreement
- Staff or faculty with the use of significant U. resources

Faculty & students own ©

- In works for which the university does not own ©
- For anything created by students as part of their academic and research activities, even when University resources are used

Who is an inventor?

- One who contributes to the conception of the invention
  - Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention. An idea is sufficiently definite and permanent when only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation
  - Contributions of joint inventors do not have to be equal

Patentable Subject Matter §101

To be patentable, the invention must be

- Patentable /Useful (§ 101)
- Novel (§ 102)
- Non-obvious (§ 103)
- Fully disclosed (§ 112)

WHAT CAN BE PATENTED???

35 U.S.C. §101 What is Patentable?

35 U.S.C. § 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."

Exceptions to What is Patentable

- Laws of nature
- Natural phenomena
- Abstract ideas

"Research into such matters may be costly and time-consuming; monetary incentive may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts'"

Breyer, J. , *Labcorp v. Metabolite*, 2006.

Prometheus Claim 1

1. 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 $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Processes & Correlations in Claim 1

1. 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 $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Natural Law Question:

Do the patent claims add *enough* elements
to the Correlations (Law of Nature)
to allow the Processes (in the claims)
to qualify as Patent-eligible Processes
that *apply* natural laws?

Prometheus OTHER ELEMENTS

A process that focuses on the use of a natural law must also contain other elements or a combination of elements, "additional features", or "an inventive concept" sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.

2 things that are NOT sufficient are

- 1) limiting the use of the law of nature, abstract idea or natural phenomena to a particular technological environment or
- 2) adding steps that are "**purely conventional or obvious**", well understood, routine, or conventional activity already engaged in by the scientific community

Myriad CAFC-SC(GVR)-CAFC

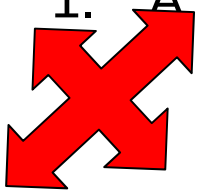
COMPOSITIONS

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.

METHODS

1. A method for detecting a germline alteration in a BRCA1 gene



analyzing a sequence of a BRCA1 gene/RNA
analyzing a sequence of BRCA1 cDNA made from mRNA from human sample

2. A method of testing compounds using cells with BRCA DNA

First to File System & 1st to Invent

BOTH SYSTEMS Exist On or After March 16, 2013

FIRST TO FILE -KEY to Patentability-

EFFECTIVE FILING DATE

- First to File (With Exceptions)
- Determination of Prior Art
- Eliminates Geographic Limitations

FIRST TO INVENT-KEY to Patentability-

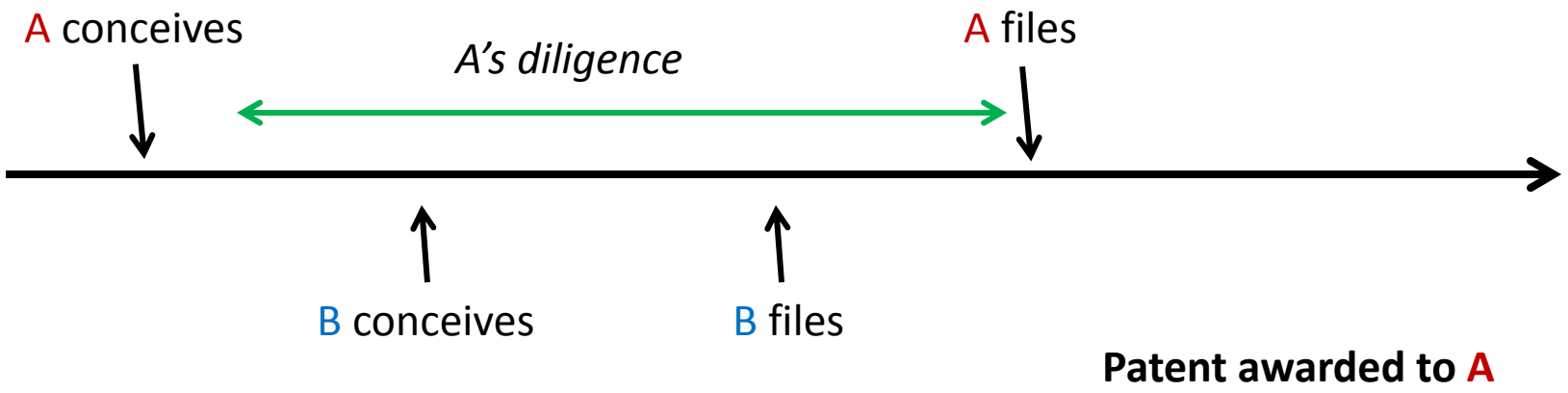
INVENTION DATE

1st to Invent - in relation to the Inv Date

	Pre AIA				AIA
	102(a)		102(b)	102(c)	102(a)(1)
WHAT	1. Known 2. Used	1. Patented 2. Described in a printed publication	1. Patented 2. Described in a printed publication 3. In use 4. On sale	1. Patented 2. Caused to be Patented 3. Subject of an inventor's certificate	1. Patented 2. Described in a printed publication 3. In public use 4. On sale 5. Otherwise available to the public
By whom?	Others		Anyone	Applicant Legal Assigns	Anyone
Where?	In this country	Anywhere	Anywhere	Anywhere but US	Anywhere
When?	Before the invention	More than 1 year prior to the earliest filing date	More than 1 year prior to the earliest filing date	Before the effective filing date	Before the effective filing date

First-to-Invent

Inventor who conceives first and is diligent to reduce invention to practice entitled to patent even if another files first



1st to File System

A person shall be entitled to a patent unless –

(1) The invention was available to the public before the effective filing date of the person's application;

OR

(2) A US patent application disclosing the invention was filed by another before the effective filing date of the person's application.

New §102 Grace Period and Exceptions

Before Effective Filing Date	"Disclosures"	Patents/Applications
102(a) Prior art Entitled to a Patent UNLESS	102(a)(1) Printed publication, public use, on sale, available to public	102(a)(2) 1st filed U.S. patent application by another
102(b) Exceptions NOT Prior Art	102(b)(1) ≤ 1 year (A) Any disclosure coming directly or indirectly from the Inventor (B) Disclosure by others after Inventor's public disclosure	102(b)(2) (A) 1st pat/app derived invention from Inventor (B) 1st pat/app filed after public disclosure by Inventor (C) Common assignee/ Research Plan-for Inventor and 1st pat/app

AIA: First-Inventor-to-File

Same invention independently conceived by separate inventors

Patent awarded to A

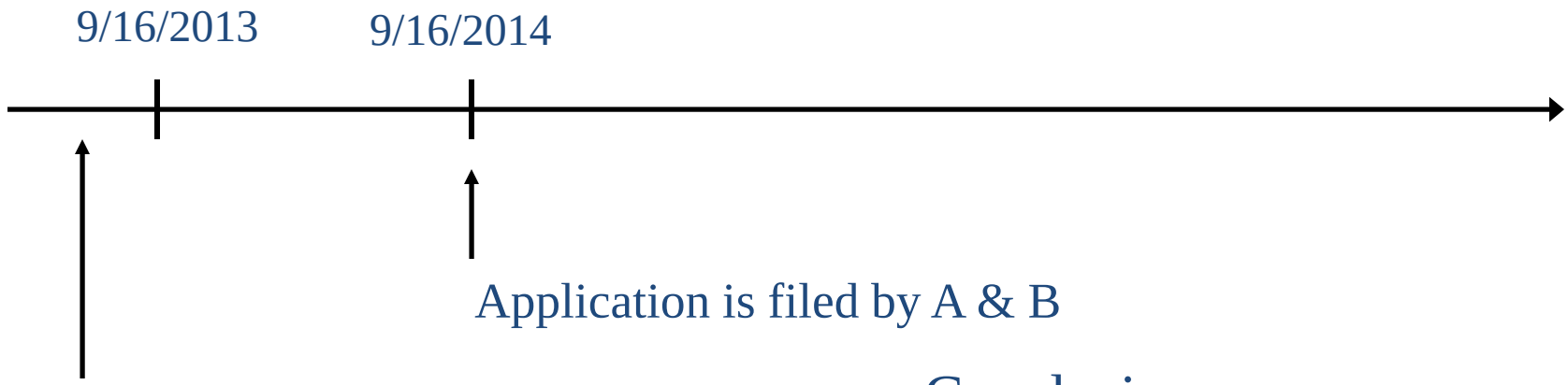
AIA: First-Inventor-to-File

Same invention independently conceived by separate inventors

Patent awarded to B

AIA FTF Disclosure Scenarios

- A & B are inventors for patent application, more than a year before the filing, A & B publish a paper describing the invention



Conclusion:
Disclosure is art under 102(a)(1)
No patent for A&B

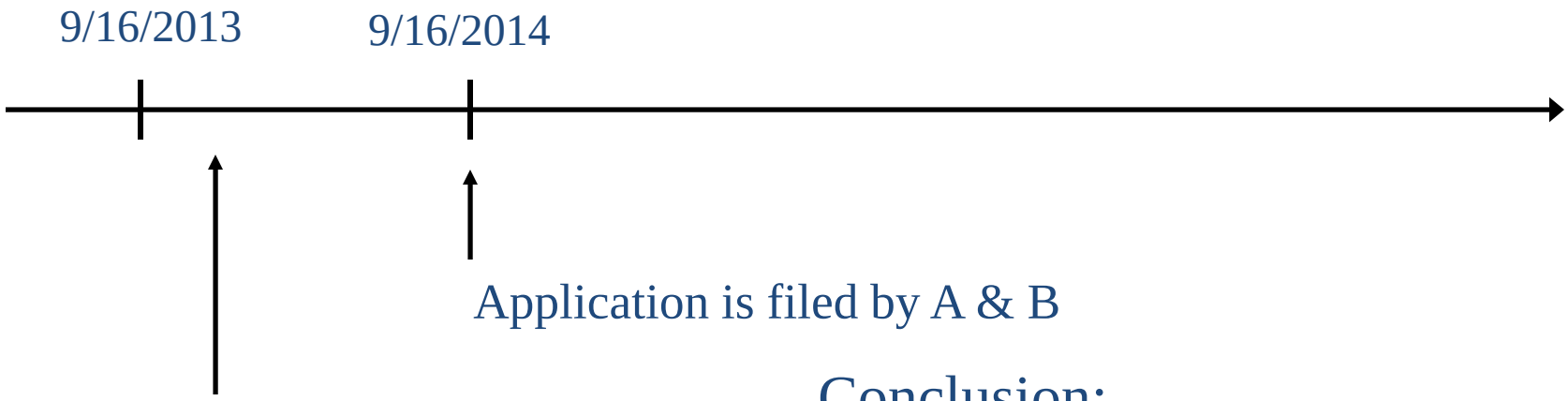
AIA FTF Disclosure Scenarios

- A & B are inventors for patent application, less than a year before the filing, A & B publish a paper describing the invention

Conclusion:
Disclosure is not art under 102(b)(1)(A)

AIA FTF Disclosure Scenarios

- A & B are inventors for patent application, less than a year before the filing, A is an author on a paper describing the invention

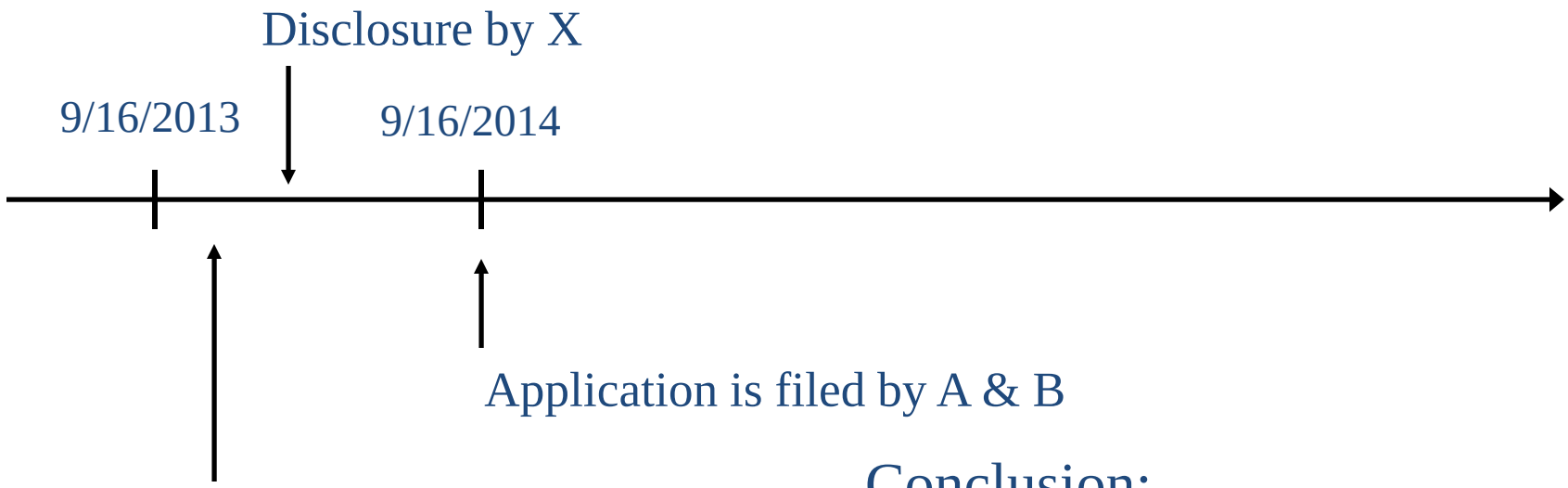


Conclusion:
Disclosure is not art under 102(b)(1)(A) because A is a joint inventor.

AIA FTF Disclosure Scenarios

1st to file/ 1st to disclose

- A & B are inventors for patent application, less than a year before the filing, X publishes a paper describing the invention, but before X's disclosure, A&B publicly disclose their invention

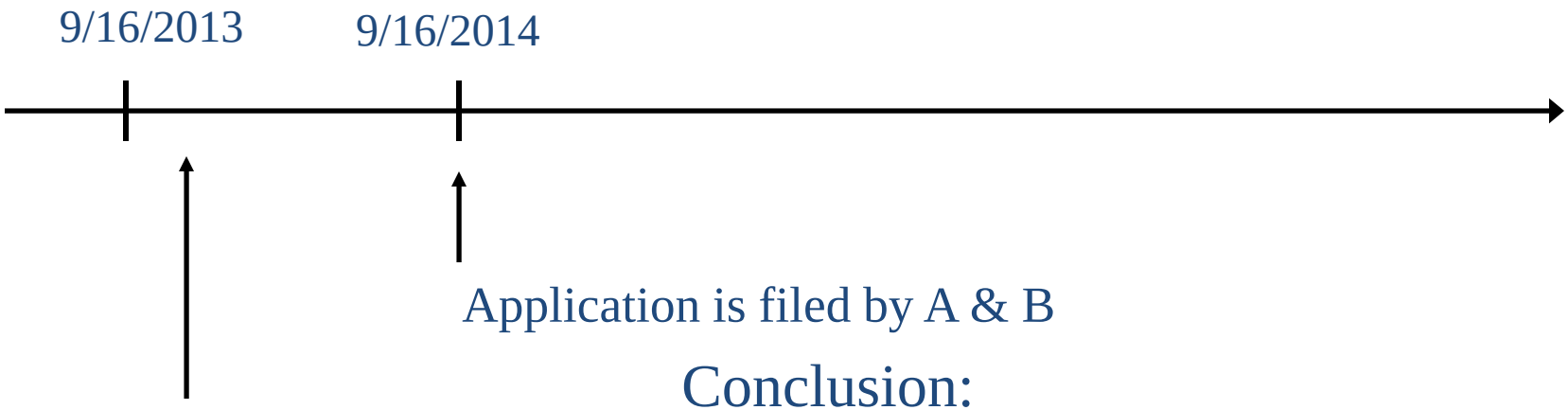


Conclusion:
Intervening disclosure by X is not art under 102(b)(1)(B)

AIA FTF Disclosure Scenarios

Derived from Inventors

- A & B are inventors for patent application, less than a year before the filing, Y publishes a paper describing the invention

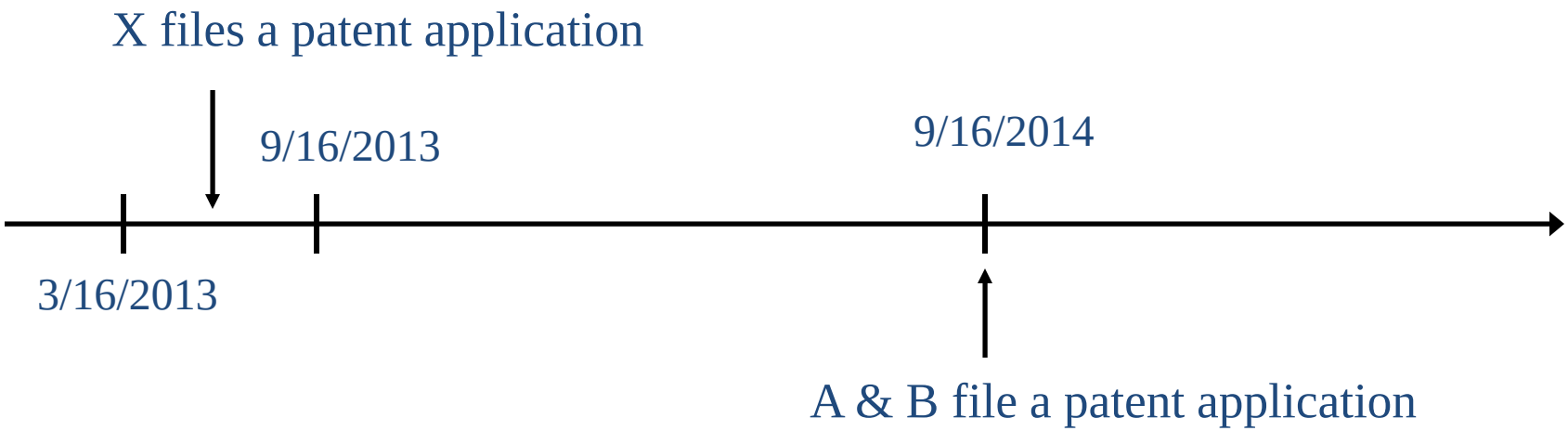


Conclusion:

Y Disclosure is prior art to Application by A&B **UNLESS** Y obtained information directly or indirectly from A or B (102(b)(1)(A))

1st to File Scenarios

X files an application, A & B file a patent application

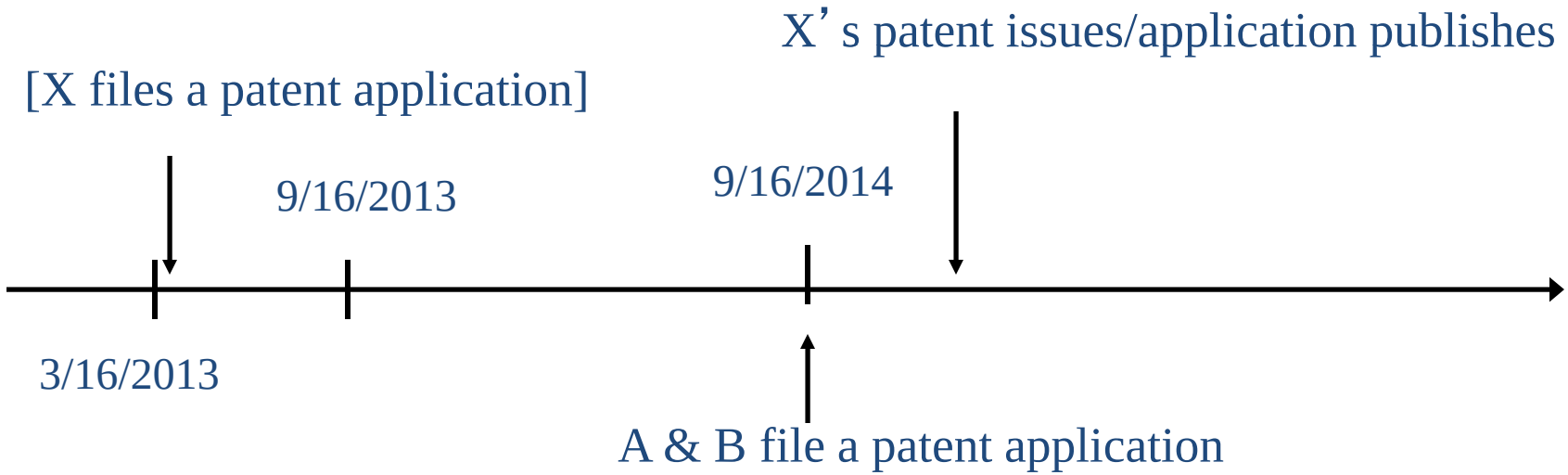


Conclusion:
X gets a patent, A&B get bupkis
102(a)(2)

1st to File Scenarios Reality

A&B file a patent application, later- X's patent issues or application publishes

X independently arrived at same subject matter.



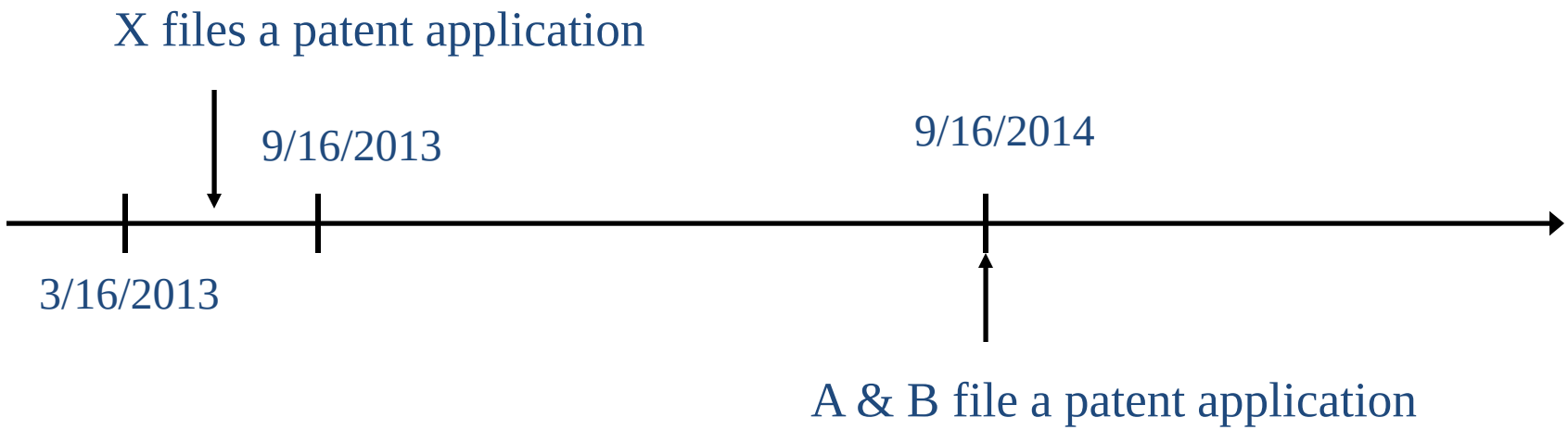
Conclusion:

X gets a patent, A&B get whatever is not taught by X's patent/application

1st to File Scenarios

1st to File

X files a patent application, A & B file a patent application, but X derived the invention from A&B

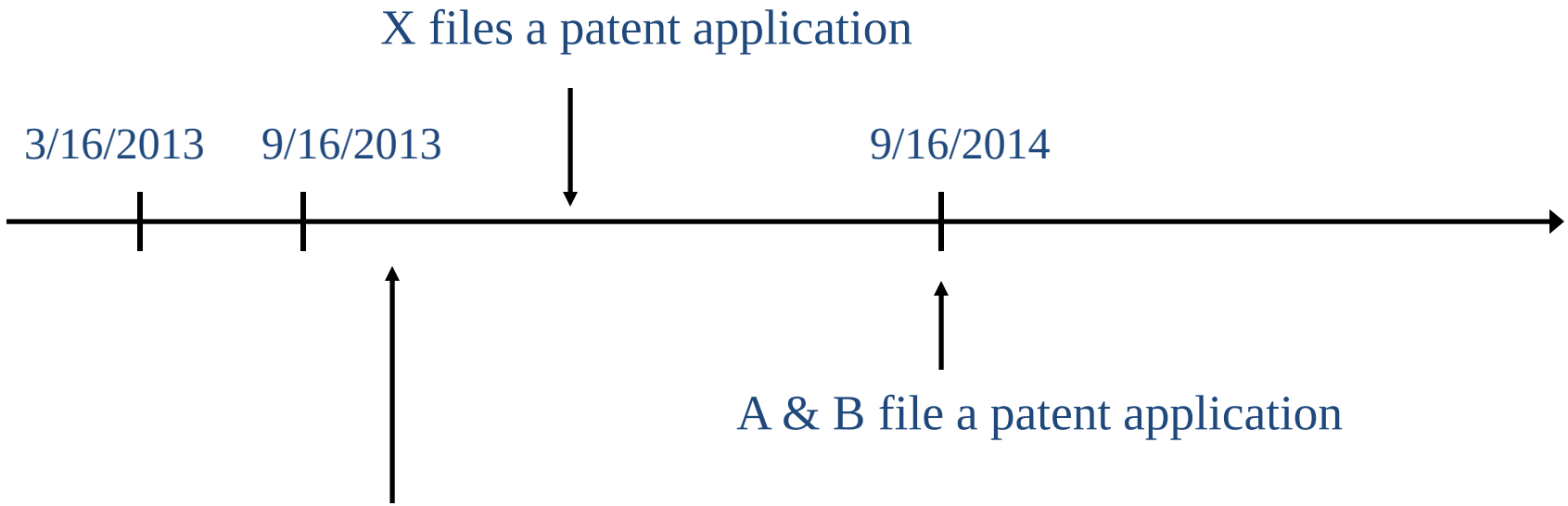


Conclusion:

A&B get a patent if X loses the derivation proceeding 102(b)(2)(A)

1st to File Scenarios 1st to Disclose

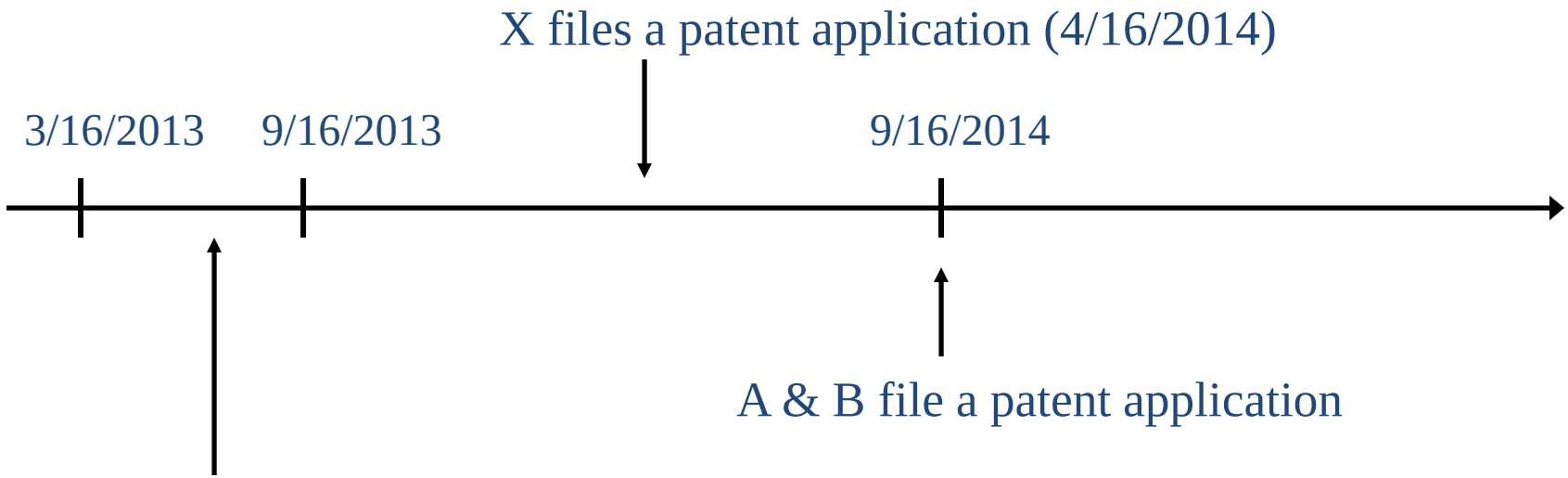
- A & B file a patent application, less than a year before the filing, A publishes, and X files an application after the publication



Conclusion:
A&B get a patent, X gets nada
102(b)(2)(B)

1st to File Scenarios 1st Disclosure

- A & B file a patent application, more than a year before the filing, A publishes, and X files an application after the publication

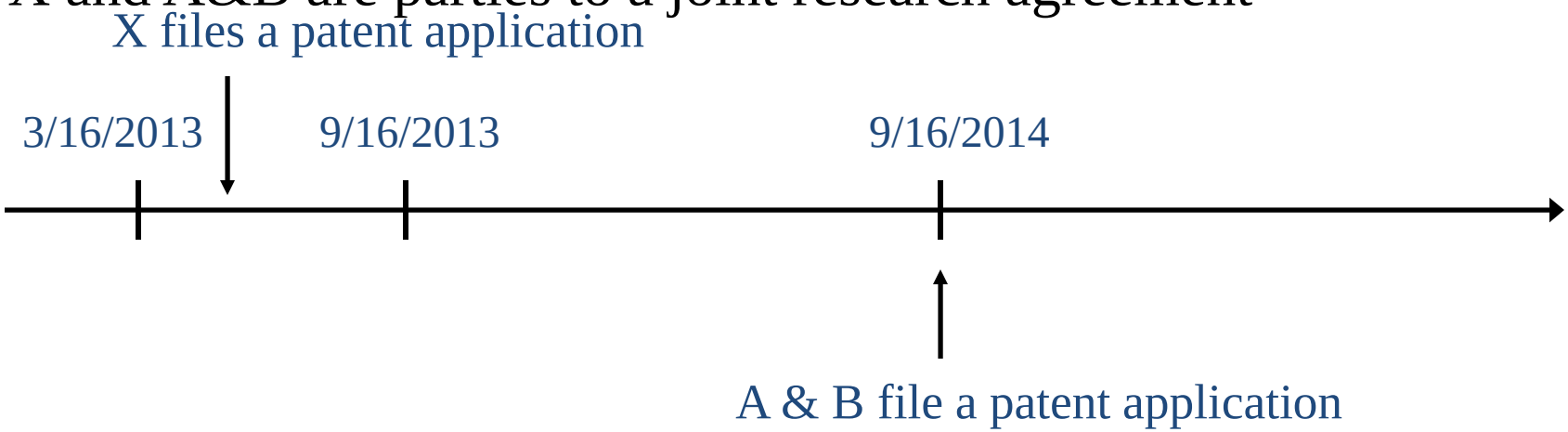


Conclusion:
No one gets a patent
if A's disclosure anticipates the inventions
102(a)(1)

1st to File Common Assignee

X files a patent application, A & B file a patent application,

X and A&B are parties to a joint research agreement



Conclusion:
A&B get a patent, X gets patent 102(b)(2)(C)

AIA: Research Agreements

- Another exception to prior art (intended to promote research collaboration):
  - **Common ownership under a joint research agreement**
  - **Joint research agreement** means a written contract, grant, or cooperative agreement entered into by 2 or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—

Subject matter disclosed and a claimed invention shall be **deemed to have been owned by the same person** or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a **joint research agreement that was in effect on or before the effective filing date of the claimed invention**;

(2) the claimed invention was made as a result of activities undertaken **within the scope of the joint research agreement**; and

(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

Actions/Challenges to Patents and Applications

9/16/2012

1. Supplemental Examination- any patent - before/on/after 9/16/2012
2. Pre-Issuance Submissions- any application - before/on/after 9/16/2012
3. *Inter-Partes* Review- any patent - before/on/after 9/16/2012

   Transition period- higher standard- reasonable likelihood to prevail
4. Transitional Post Grant Review for validity of Business Method Patents

3/16/2013

1. Derivation Proceedings (Interference Proceedings)
2. Post-Grant Review

Inventor responsibilities

- Keep good records
  - Lab notebooks
  - Emails
- Disclose timely to OTC
- Assist in patent process and update OTC on public disclosures
- Formalize research/collaboration agreements

Questions?

www.techtransfer.umd.edu