

4/10/2019



**How New Supreme Court Rulings Impact Prior Art**

April 10, 2019

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& EBENSTEIN LLP**

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*Intellectual Property Law*

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**Disclaimer**

The following presentation reflects the personal opinions of its authors and does not necessarily represent the views of their respective clients, partners, employers or of the Association of University Technology Managers (AUTM). Additionally, the following content is presented solely for the purposes of discussion and illustration, and does not comprise, nor is not to be considered, as legal advice.

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<b>Agenda</b>	<ul style="list-style-type: none"><li>• About the panel</li></ul>
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### Amster Rothstein & Ebenstein LLP

**Charles R. Macedo**, Partner at Amster, Rothstein & Ebenstein LLP.



Mr. Macedo advises and litigates in all areas of intellectual property law, including patent, trademark and copyright law, with a special emphasis in complex litigation.

Mr. Macedo develops patent strategies intended to prevent infringement challenges from arising.

Mr. Macedo has been a long-time member of AUTM and given numerous webinars on various intellectual property topics.

J.D. 1989, Columbia Law School; B.S./M.S., Physics, 1986; former Law Clerk to Hon. Daniel M. Friedman at U.S. Court of Appeals for the Federal Circuit.

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### Amster Rothstein & Ebenstein LLP

**Dr. Brian Amos**, Associate at Amster, Rothstein & Ebenstein LLP.



Dr. Amos is a former research neuroscientist who represents academic and research institutions in the preparation and prosecution of patent applications worldwide, predominantly in the fields of biotechnology, medical therapeutics and pharmaceuticals. He works closely with scientists to identify and inventory new patentable technologies; protect discoveries through patents; and commercialize intellectual property through licensing and development arrangements with other business entities. Dr. Amos is a current member of AUTM.

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Agenda	
	<ul style="list-style-type: none"><li>• The AIA and its changes to the law of prior art</li></ul>

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<b>Agenda</b>	<ul style="list-style-type: none"><li>• The AIA and its changes to the law of prior art<ul style="list-style-type: none"><li>– Changing Premise from “First-to-invent” to “First-Inventor-to-file/Disclose” system</li></ul></li></ul>
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**Change In Priority System**

One of the most sweeping changes of the Act is to change the U.S. Patent Law from a “**first-to-invent**” priority system to a “**first-inventor-to-file**” priority system.  
(See Sec. 3. FIRST INVENTOR TO FILE.).

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**Change In Priority System**

One of the most sweeping changes of the Act is to change the U.S. Patent Law from a “**first-to-invent**” priority system to a “**first inventor-to-file**” priority system.  
(See Sec. 3. FIRST INVENTOR TO FILE.).

The stated purpose of this change is to “promote harmonization of the United States patent systems with those commonly used in nearly all other countries throughout the world”(See Sec. 3(p)).

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Pre-AIA "First-to-Invent" System

Under pre-AIA U.S. Patent Law, as to many categories of prior art, the determination whether a reference is prior art is based on whether the reference pre-dates the date of the patent applicant's "invention." (See, e.g., pre-AIA 35 U.S.C. § § 102(a) & (e)).

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**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**  
A person shall be entitled to a patent unless –  
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, **before the invention thereof by the applicant for patent**, or

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Under pre-AIA U.S. Patent Law, as to many categories of prior art, the determination whether a reference is prior art is based on whether the reference pre-dates the date of the patent applicant's "invention." (See, e.g., pre-AIA 35 U.S.C. § § 102(a) & (e)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**  
A person shall be entitled to a patent unless –  
\*\*\*  
(e) the invention was described in - (1) an application for patent, published \*\*\* by another filed in the United States **before the invention by the applicant for patent** \*\*\*\*

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Premise of "First-to-Invent" System

S	M	T	W	R	F	S
1	2  Conceive Invention	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

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Premise of "First-to-Invent" System

S	M	T	W	R	F	S
1	2  Conceive Invention	3 	4 	5 	6 	7
8	9 	10 	11 	12 	13  Make Invention	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

Working on making invention (between days 3-12)

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Premise of "First-to-Invent" System

S	M	T	W	R	F	S
1	2  Conceive Invention	3 	4 	5 	6 	7
8	9 	10 	11 	12 	13  Make Invention	14
15	16	17	18	19	20  File Patent Application	21
22	23	24	25	26	27	28

Working on making invention (between days 3-12)

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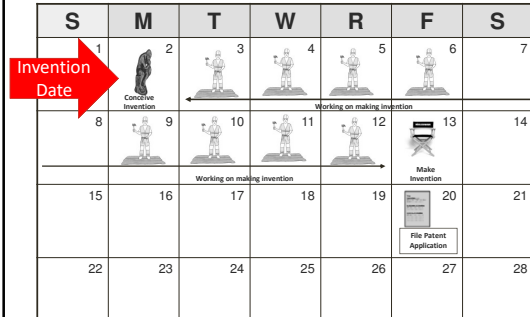
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Premise of "First-to-Invent" System




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New "First Inventor-to-File" System

Under the Act, the determination of whether a particular reference is prior art will instead be based on whether the reference pre-dates the "effective filing date of the claimed invention." (See AIA 35 U.S.C. § 102(a)(1) & (2)).

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New "First Inventor-to-File" System

**§ 102. Conditions for patentability; novelty**  
 (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—  
 (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or  
 \*\*\*

Under the Act, the determination of whether a particular reference is prior art will instead be based on whether the reference pre-dates the "effective filing date of the claimed invention." (See AIA 35 U.S.C. § 102(a)(1) & (2)).

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### New "First Inventor-to-File" System

**§ 102. Conditions for patentability; novelty**

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—  
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(2) the claimed invention was described in a patent issued \*\*\*, or in an application for patent published \*\*\*, in which the patent or application, as the case may be, names another inventor and **was effectively filed before the effective filing date of the claimed invention.**

Under the Act, the determination of whether a particular reference is prior art will instead be based on whether the reference pre-dates the **"effective filing date of the claimed invention."** (See AIA 35 U.S.C. § 102(a)(1) & (2)).

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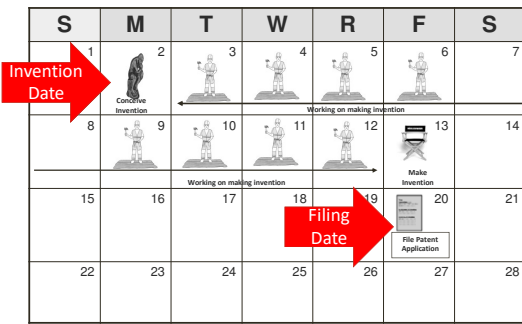
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### Change to "First Inventor-to-File" System




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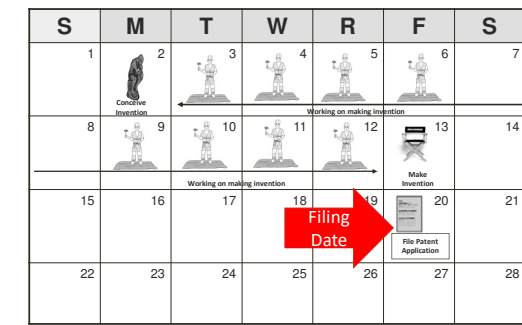
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### Change to "First Inventor-to-File" System




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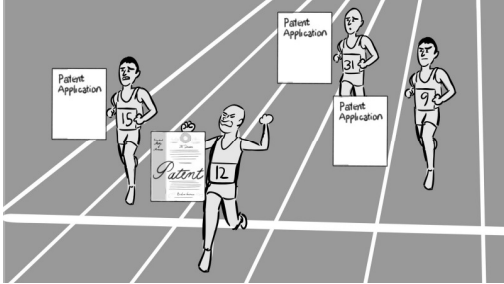
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### Premise of "First-to-File" System



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### Conversion from "First-to-Invent" to "First Inventor-to-File" System

Under **pre-AIA U.S. Patent Law**, as to many categories of prior art, the determination whether a reference is prior art is based on whether the reference pre-dates the date of the patent applicant's **"invention."** (See, e.g., pre-AIA 35 U.S.C. § § 102(a) & (e)).

Under **the Act**, the determination of whether a particular reference is prior art will instead be based on whether the reference pre-dates the **"effective filing date of the claimed invention."** (See AIA 35 U.S.C. § 102(a)(1) & (2)).

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### "First Inventor-to-file" New grace period provisions

The Act retains a limited one-year "grace period" under the "exceptions" provision for **"disclosures"** and **"public disclosures"** made one year or less before the effective filing date of the claimed invention "by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor." (AIA 35 U.S.C. § 102(b)(1)).

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**“First Inventor-to-file”**  
New grace period provisions

**§ 102. Conditions for patentability; novelty**  
(b) EXCEPTIONS.—  
(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or  
(B) the subject matter disclosed had, before such disclosure, 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.

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**“First Inventor-to-file”**  
New grace period provisions

Thus, AIA 102(b) retained a limited one-year grace period based on a prior public disclosure by an inventor

One year

Prior “public disclosure” by inventor or co-inventor

Effective filing date (earliest claimed priority date)

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**“First Inventor-to-file”**  
New grace period provisions

Thus, AIA 102(b) retained a limited one-year grace period based on a prior public disclosure by an inventor

One year

~~Prior “public disclosure” by inventor or co-inventor~~

Effective filing date (earliest claimed priority date)

Not prior art under AIA 102(b)

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**"First Inventor-to-file"**  
New grace period provisions

Thus, new 102(b) retained a limited one-year grace period based on a prior public disclosure by an inventor

One year

Prior "public disclosure" by inventor or co-inventor

Effective filing date (earliest claimed priority date)

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**"First Inventor-to-file"**  
New grace period provisions

Thus, AIA 102(b) retained a limited one-year grace period based on a prior public disclosure by an inventor

One year

Prior "public disclosure" by inventor or co-inventor

~~Effective filing date (earliest claimed priority date)~~

**102(b) exception does not apply, and prior public disclosure is prior art**

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**First Inventor To File**

Section 3 became effective on March 16, 2013 (18 months after enactment). This provision applies only to applications which have an earliest effective filing date after March 16, 2013. (See Sec. 3(n)).

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<b>Agenda</b>	<ul style="list-style-type: none"> <li>• The AIA and its changes to the law of prior art           <ul style="list-style-type: none"> <li>– Changing Premise from “First-to-invent” to “First-to-file/Disclose” system</li> <li>– “Otherwise available to the public” catch all</li> </ul> </li> </ul>
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<b>New definitions of prior art:</b>	
Types of Prior Art – Described in printed publication	
<p><b>§ 102. Conditions for patentability; novelty</b>          (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—          (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or <b>otherwise available to the public</b> before the effective filing date of the claimed invention; or          ***</p>	<p>Under <b>the Act</b>, prior art will include:</p> <ul style="list-style-type: none"> <li>*traditional categories of prior art; and</li> <li>* that which was <b>“otherwise available to the public”</b> before the critical date</li> </ul> <p>(AIA 35 U.S.C. § 102(a)(1)).</p>

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<b>Impact of “Otherwise Available to the Public”</b>	
<p><b>§ 102. Conditions for patentability; novelty</b>          (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—          (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or <b>otherwise available to the public</b> before the effective filing date of the claimed invention; or          ***</p>	<p>At the time, many thought “otherwise available to the public” removed “secret prior art”, such as secret sales, from being prior art because if it was secret it was not “available to the public”.</p>

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Impact of "Otherwise Available to the Public"

As early as 2005, patent reform bills in the House and Senate proposed language requiring that prior art be publicly available.

See H.R. 2795, 109th Cong. (2005) (proposing that new Section 102(a)(1) prohibit the issuance of a patent when "the claimed invention was patented, described in a printed publication, or otherwise publicly *known*" before the relevant date); S. 3818, 109th Cong. (2006) (same).

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Impact of "Otherwise Available to the Public"

The current statutory text first appeared in 2007. At that time, parallel patent reform bills were making their way through the House and the Senate.

Neither bill initially contained the "otherwise available to the public" catch-all provision; each provided only that "[a] patent for a claimed invention may not be obtained if \* \* \* the claimed invention was patented, described in a printed publication, in public use, or on sale."

H.R. 1908, 110th Cong. (2007); S. 1145, 110th Cong. (2007).

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Impact of "Otherwise Available to the Public"

The Senate Judiciary Committee amended its bill to add the "*otherwise available to the public*" language that Section 102(a)(1) now contains, and the accompanying committee report.

This Manager's Amendment also added the phrase "otherwise available to the public".

S. Rep. No. 259, 110th Cong., 2d Sess. 39 (2008).

The report elsewhere stated that the language was added to "emphasize the fact that [prior art] must be publicly available."

*Id.* at 9.

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<b>Agenda</b>	<ul style="list-style-type: none"><li>• <i>Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.</i>, 586 U.S. ____ (Jan. 22, 2019)</li></ul>
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*Helsinn* -- Question Presented

*Helsinn* question presented

"This case requires us to decide whether the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention 'on sale' within the meaning of § 102(a)."

(Slip op. at 1-2 (emphasis added)).

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*Helsinn's* Fact Pattern

Jan. 30, 2003

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Helsinn Files Provisional to which future applications claim priority

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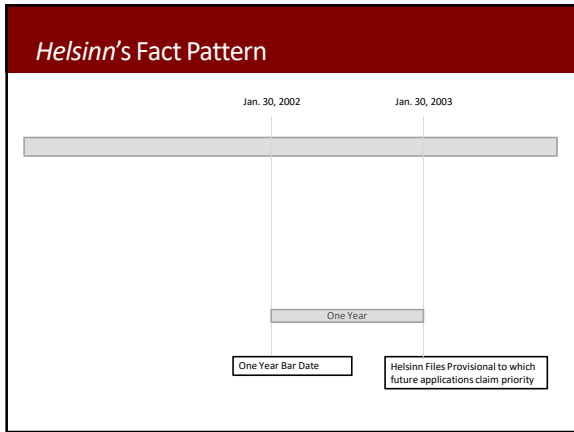
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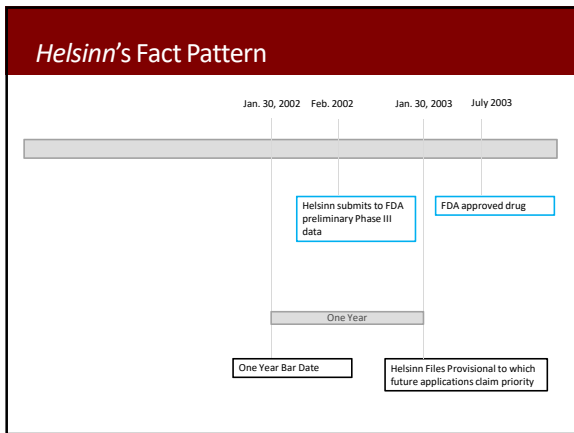
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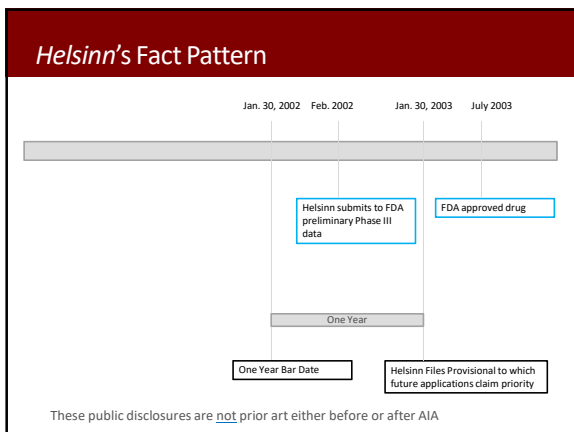
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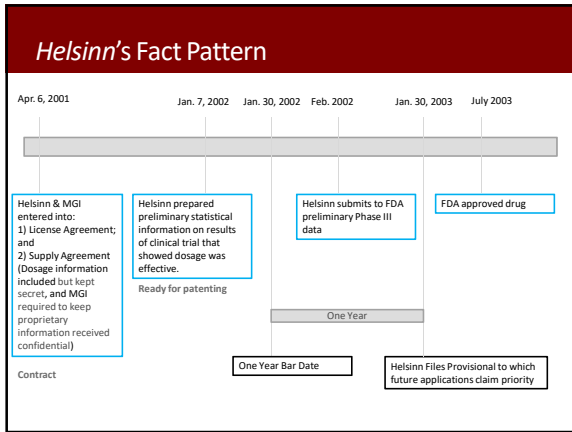
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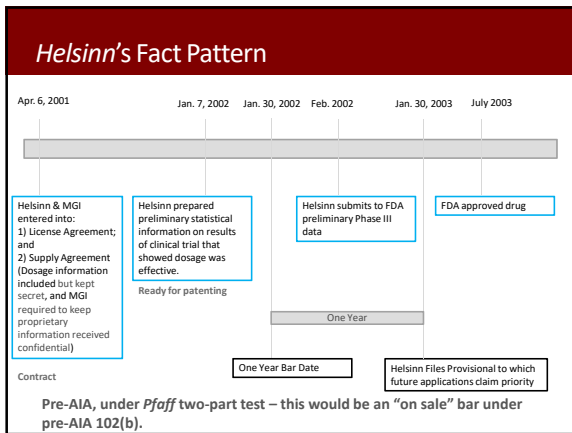
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### Helsinn Holding – Confidential Sales Can Be Prior Art

**Helsinn found**

"This case requires us to decide whether the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention 'on sale' within the meaning of § 102(a)."

"More than 20 years ago, this Court determined that an invention was 'on sale' within the meaning of an earlier version of § 102(a) when it was 'the subject of a commercial offer for sale' and 'ready for patenting.'" *Pfaff v. Wells Electronics, Inc.*, 525 U. S. 55, 67 (1998). **We did not further require that the sale make the details of the invention available to the public.** In light of this earlier construction, we determine that the reenactment of the phrase "on sale" in the AIA did not alter this meaning. Accordingly, **a commercial sale to a third party who is required to keep the invention confidential may place the invention "on sale" under the AIA.**

(Slip op. at 1-2 (emphasis added)).

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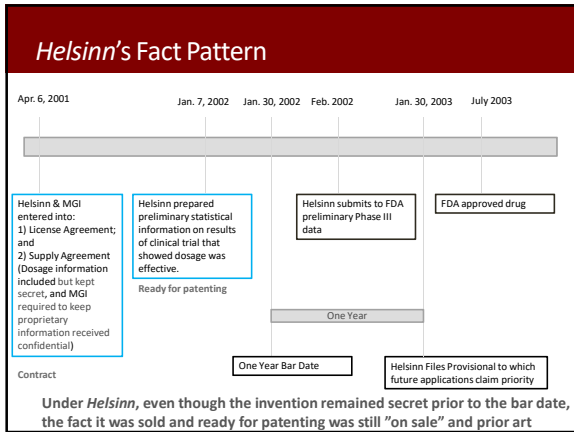
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### Impact of "Otherwise Available to the Public"

In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 586 U.S. \_\_\_\_ (Jan. 22, 2019), the U.S. Supreme Court decided the impact of "otherwise available to the public" qualifier for "on sale" prior art.

The unanimous court found

"The addition of the catchall phrase or "otherwise available to the public" is **not enough** of a change for the Court to conclude that Congress intended to alter the meaning of 'on sale.'"

(Slip op. at 8 (emphasis added)).

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### "On sale" under AIA post-*Helsinn*

- *Pfaff* Two-Part Test remains the law, "on sale" met when:
  - Claimed invention is subject of "commercial transaction"; and
  - Claimed invention is "ready for patenting"

Once both of these conditions are met, the claimed invention is "on sale" under the AIA.

An NDA keeping the invention confidential will not negate the sale from becoming prior art.

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New definitions of prior art:

Types of Prior Art -- On Sale

Under pre-AIA U.S. Patent Law, prior art includes:

- \* Prior sale *in the U.S.*
  - + more than 1 year before first U.S. application date

(See pre-AIA 35 U.S.C. § 102(b)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**

A person shall be entitled to a patent unless – \*\*\*

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale in this country, more than one year prior to the date of the application for patent in the United States, or*

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New definitions of prior art:

Types of Prior Art -- On Sale

**§ 102. Conditions for patentability; novelty**

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, *on sale*, or otherwise available to the public before the effective filing date of the claimed invention; or

\*\*\*

Under the Act, prior art includes:

- \* On sale *anywhere*
  - + before effective filing date

(See AIA 35 U.S.C. § 102(a)(1)).

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New definitions of prior art:

Types of Prior Art -- On Sale

**§ 102. Conditions for patentability; novelty**

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) the claim patented, de publication, *sale*, or othe public before the effective filing date of the claimed invention; or

\*\*\*

SO UNDER HELSINN AND THE AIA, EVEN A SECRET FOREIGN SALE IS PRIOR ART ONCE IT IS THE SUBJECT OF A COMMERCIAL OFFER FOR SALE AND READY FOR PATENTING.

Under the Act, prior art includes:

- \* On sale *anywhere*
  - + before effective filing date

(See AIA 35 U.S.C. § 102(a)(1)).

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Other pre-AIA exceptions

- Licenses by themselves are not sales

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Agenda

- How does *Helsinn* impact other kinds of prior art under the AIA?
  - Patented
  - Described in a printed publications
  - In public use
  - Otherwise available

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New definitions of prior art:

Types of Prior Art -- Issued patent

Under pre-AIA U.S. Patent Law, prior art includes:

- \* Patents anywhere
  - + before invention

(pre-AIA 35 U.S.C. § 102(a)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**  
A person shall be entitled to a patent unless –  
(a) the invention was known or used by others in this country, or **patented** or described in a printed publication **in this or a foreign country, before the invention thereof by the applicant for patent, or**

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**New definitions of prior art:**

Types of Prior Art -- Issued patent

Under **pre-AIA U.S. Patent Law**, prior art includes:

- \* Patents anywhere
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(pre-AIA 35 U.S.C. § 102 (b)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**

A person shall be entitled to a patent unless – \*\*\*

- (b) the invention was **patented** or described in a printed publication **in this or a foreign country** or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

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**New definitions of prior art:**

Types of Prior Art -- Issued patent

**§ 102. Conditions for patentability; novelty**

- (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
    - (1) the claimed invention was **patented**, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
- \*\*\*

Under **the Act**, prior art will include:

- \* Patents anywhere
  - + before effective filing date

(AIA 35 U.S.C. § 102(a)(1)).

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**New definitions of prior art:**

Types of Prior Art -- Issued patent

Under **pre-AIA U.S. Patent Law**, prior art includes:

- \* Patents anywhere
  - + **before invention**
  - + **more than 1 year before first U.S. application date**

(pre-AIA 35 U.S.C. § 102(a) & (b)).

Under **the Act**, prior art will include:

- \* Patents anywhere
  - + **before earliest effective filing date**

(AIA 35 U.S.C. § 102(a)(1)).

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New definitions of prior art:

Types of Prior Art -- Patent Applications

Under pre-AIA U.S. Patent Law, prior art includes:

\* Earlier filed U.S. and PCT patent applications (pre-AIA 35 U.S.C. § 102(e)).

Under the Act, prior art will include:

\* Earlier filed U.S. and PCT patent applications (AIA 35 U.S.C. § 102(a)(2)).

Horizontal lines for notes.

New definitions of prior art:

Types of Prior Art -- Patent Applications

§ 102. Conditions for patentability; novelty

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
(2) the claimed invention was described in a patent issued\*\*\*, or in an application for patent published\*\*\*, in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

Under the Act, an issued patent or published patent application is prior art as of its effective filing date. (See AIA 35 U.S.C. § 102(a)(1) & (2)).

Horizontal lines for notes.

Prior Art Status of Issued U.S. Patent

Image of a patent document with callouts for 'PRIOR ART AS OF: December 25, 2007 Issue Date', 'July 27, 2003 Filing Date', and 'January 27, 2005 Publication Date'.

Horizontal lines for notes.

Prior Art Status of Published U.S. Patent Application

United States Patent Application Publication  
Hajaj et al.

Pub. No. US 2005/0019542 A1  
Pub. Date: Jan. 27, 2005

**PRIOR ART AS OF:**  
January 27, 2005  
Publication Date  
(10) Pub. No.: US 2005/0019542 A1  
(43) Pub. Date: Jan. 27, 2005  
July 27, 2003  
Filing Date  
(21) Appl. No.: 10/625,071  
(22) Filed: Jul. 22, 2003

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Prior Art Status of Published PCT Patent Application

International Publication  
No. WO 2006/07412 A2

**PRIOR ART AS OF:**  
May 26, 2006  
Publication Date  
(43) International Publication Date  
26 May 2005 (26.05.2005)  
July 16, 2004  
PCT Filing Date  
(22) International Filing Date: 16 July 2004 (16.07.2004)  
To extent U.S. is designated

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Prior Art Status of Granted European Patent

EUROPEAN PATENT OFFICE  
EP 1 474 290 B1

**PRIOR ART AS OF:**  
March 3, 2008  
Publication And Grant Date  
(45) Date of publication and mention of the grant of the patent:  
26.03.2008 Bulletin 2008/13

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**New definitions of prior art:**

Types of Prior Art -- Described in printed publication

Under **pre-AIA U.S. Patent Law**, prior art includes:

- \* Printed Publications anywhere
- + before invention

(pre-AIA 35 U.S.C. § 102(a)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or **described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent**, or

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(pre-AIA 35 U.S.C. § 102 (b)).

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A person shall be entitled to a patent unless – \*\*\*

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- \*\*\*

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**Key considerations**

- Form of “publication”
- “Accessibility”
- Timing

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**Printed Publications can be**

**INDUSTRIAL PUBLICATIONS**

- Magazines
- Catalogs
- Brochures
- User manuals
- Product description handouts

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**INDUSTRIAL PUBLICATIONS**

- Magazines
- Catalogs
- Brochures
- User manuals
- Product description handouts

**ACADEMIC PUBLICATIONS**

- Electronic documents
- Doctorial dissertations
- Presentations at conferences
- Abstracts
- Journal publications

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Public Accessibility Is A Touchstone of “Printed Publications”

“[U]pon a satisfactory showing that it has been disseminated or otherwise made available to the extent that persons interested and of ordinary skill in the subject matter or art, exercising reasonable diligence can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.”

*In re Wyer*, 655 F.2d 221, 226 (CCPA 1981).

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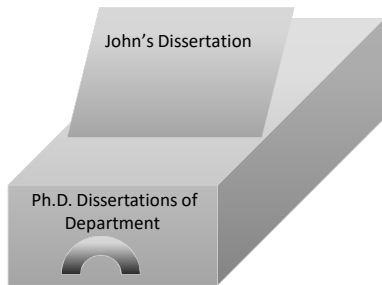
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Cataloging Impacts Accessibility



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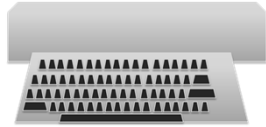
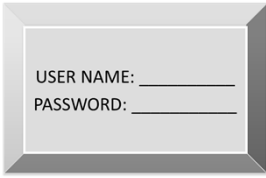
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Limitations on Access Impact Prior Art Status



Limiting Access And Placing Confidentiality Restrictions impact prior art status

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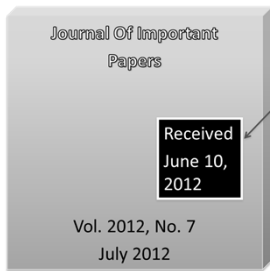
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Date Publication Received Is Prior Art Date



Prior art as of June 10, 2012, when received by Library

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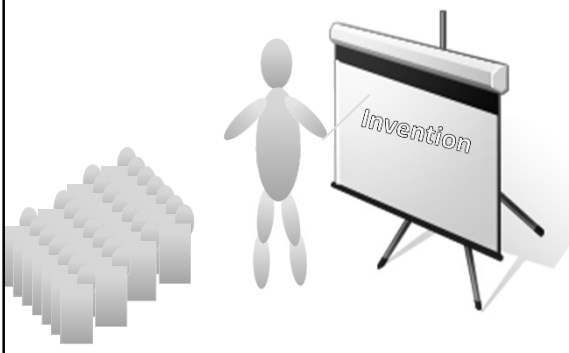
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Presentations when made, depending upon access restrictions



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**New definitions of prior art:**

Types of Prior Art -- Prior public use

Under **pre-AIA U.S. Patent Law**, prior art includes:

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  - + before invention

(pre-AIA 35 U.S.C. § 102(a)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**

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(pre-AIA 35 U.S.C. § § 102(b)).

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Types of Prior Art -- Prior public use

**§ 102. Conditions for patentability; novelty**

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(1) the claimed invention was patented, described in a printed publication, or **in public use**, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

\*\*\*

Under **the Act**, prior art will include:

- \* Prior public use **anywhere**
  - + before effective filing date

(See AIA 35 U.S.C. § 102(a)(1)).

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\* Prior public use **in the U.S.**  
+ **before invention**  
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(See pre-AIA 35 U.S.C. §§ 102(a) & (b)).

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(See AIA 35 U.S.C. § 102(a)(1)).

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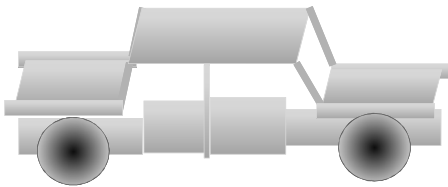
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**Public Demonstrations**



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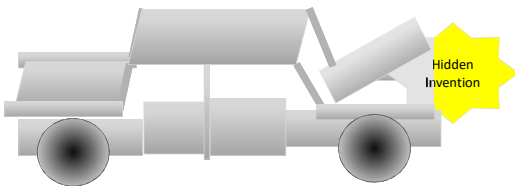
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**Public Demonstrations**

Even when the invention is hidden it could potentially be in public use.



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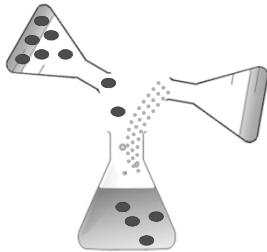
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### Laboratories



- Considerations
- Are laboratories locked?
  - Is access restricted?
  - Are NDA agreements executed and enforced?

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### New definitions of prior art:

Types of Prior Art

Under **pre-AIA U.S. Patent Law**, prior art includes:

- \* Prior Public Knowledge **in U.S.**
  - + before invention

(See pre-AIA 35 U.S.C. § 102(a)).

**35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.**  
 A person shall be entitled to a patent unless –  
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Types of Prior Art

**§ 102. Conditions for patentability; novelty**  
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 \*\*\*

Under **the Act**, prior art will include:

- \* Otherwise available **anywhere**
  - + before effective filing date

(See AIA 35 U.S.C. § 102(a)(1)).

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**New definitions of prior art:**

Types of Prior Art

Under <b>pre-AIA U.S. Patent Law</b> , prior art includes:	Under <b>the Act</b> , prior art will include:
* Patents <b>anywhere</b>	* Patents <b>anywhere</b>
* Printed Publications <b>anywhere</b>	* Printed Publications <b>anywhere</b>
* Prior Use <b>in the U.S.</b>	* Prior public use <b>anywhere</b>
* Prior Public Knowledge <b>in U.S.</b>	* Otherwise available <b>anywhere</b>
* Prior sale <b>in the U.S.</b> more than 1 year prior (pre-AIA 35 U.S.C. § 102(a) & (b)).	* On sale <b>anywhere</b> (AIA 35 U.S.C. § 102(a)(1)).

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**New definitions of prior art:**

Types of Prior Art

Under <b>pre-AIA U.S. Patent Law</b> , prior art includes:	Under <b>the Act</b> , prior art will include:
* Earlier filed U.S. and PCT patent applications (pre-AIA 35 U.S.C. § 102(e)).	* Earlier U.S. and PCT filed patent applications (AIA 35 U.S.C. § 102(a) (2)).

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**Prior Conception, Reduction to Practice**

- **NO MORE** 102(g) PRIOR ART

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<b>Agenda</b>	<ul style="list-style-type: none"><li>• What does this mean for University Technology Offices?</li></ul>
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### Example of Sale Bar

*Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*

The Supreme Court official synopsis confusingly discusses the “rights to” market, distribute, sell etc. in its summary. However, the license of those rights was not the trigger of the sale bar. The trigger was a supply & purchase agreement (clearly explained in CAFC decision). The agreement was publicly known.

*Enzo Biochem v. Gen-Probe, Inc.*, 424 F. 3d 1276, 1282-86 (Fed. Cir. 2005).

Provision of **agreement executed more than one year prior to filing date of patent in suit, which required patentee to supply its customer with “active ingredients” of polynucleotide probes** for detecting *Neisseria gonorrhoeae* bacteria, **constituted commercial offer to sell** invention of patent.

Both are a sale bar (offer to sell)

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### Sale Bar - The License Exception

*In re Kollar*, 286 F.3d 1326, 1330-31 (Fed. Cir. 2002) (citing *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1217 (Fed. Cir. 1998)).

“We have held that **merely granting a license to an invention, without more, does not trigger the on-sale bar** of §102(b).

A license of **rights in an** invention - the most common scenario in a tech transfer office situation - is not a problem *per se*. Distinguish between sale of **rights in** an invention (e.g. a license to the invention which is not a bar *per se*) with sale/offers for sale **of invention** itself (which incurs the sale bar)

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### Example of Use Bar

Critical Question:

Whether the use (i) **accessible to the public** or was it (ii) **commercially exploited**?

*Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005).

"The parties do not dispute that Invitrogen used the claimed process before the critical date, *in its own laboratories*, to produce competent cells. *Invitrogen did not sell the claimed process or any products made with it. The record also shows that Invitrogen kept its use of the claimed process confidential. The process was known only within the company.* Stratagene does not dispute that the claimed process was maintained as a secret within Invitrogen until some time after the critical date."

**Not** a public use. Invitrogen kept process under wraps AND did not sell any product made with the process. No public use bar.

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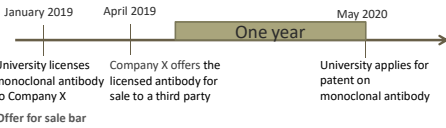
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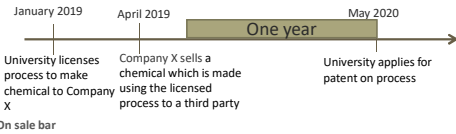
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### Likely On Sale Bar

**Example 1:**



**Example 2:**



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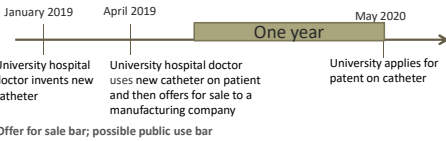
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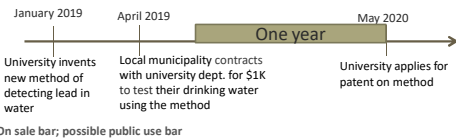
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### Likely On Sale Bar

**Example 3:**



**Example 4:**



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### Likely Public Use Bar

**Example 1:**



University hospital doctor invents new blood pressure monitoring device. University licenses device to Company X  
Company X attends health fair and demonstrates device on an attendee  
University applies for patent on device  
Public use bar

**Example 2:**



University PI invents new DNA sequencing method  
PI and her post-docs use the new DNA sequencing method in their university lab. They do not publish method or results yet.  
University applies for patent on sequencing method  
No public use bar

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### Tips to reduce chance of sale/use bar

- **Licensing exception** - review license terms to make sure it is a license of rights in an invention and does not amount to a sale offer
- A **third party (e.g. licensee)** who sells, offers to sell or publicly/commercially exploits your method or product can bar your institution's later patent application for same
- If your **patent is not yet filed**, make clear to **licensee** they **should not**: (1) **perform** process, (2) **offer to perform** process **for \$**, or (3) **offer product for sale** without prior communication with your office

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### Tips to reduce chance of sale/use bar

- **Be aware of other potential traps** - e.g. any university departments that sell services to the public/businesses; visiting scientist who returns to home institution and "publicly" uses method learned at your institution
- **Experimental testing of method/product is permitted and does not trigger bar**. Best practice is to memorialize the testing. Consider confidentiality agreements if one might consider testing an otherwise public use

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Questions?

Thank you for your participation.

For more information please contact us at:  
cmacedo@arelaw.com  
bamos@arelaw.com

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