AIA and Novelty, Part 1: The AIA Framework

Michael S. Sinha, MD, JD, MPH
Adjunct Faculty, Northeastern University School of Law
Visiting Scholar, NUSL Center for Health Policy and Law
Research Fellow, Harvard-MIT Center for Regulatory Science
Affiliated Researcher, Program On Regulation, Therapeutics, And Law (PORTAL)
Teaching Faculty, Harvard Medical School Center for Bioethics
Lecturer, Department of Health Sciences, California State University, East Bay

Syllabus

• Updated syllabus will be available online
  • SUBJECT TO CHANGE! Always consult the online syllabus!


Grading

Inventiveness: 5 points
Format: 5 points
Drawings: 5 points
Claims: 10 points
Quality: 5 points
TOTAL: 30 points

Metrics tracked:
• Number of pages
• Word count
• # of claims
• # of drawings
• Formatting (Y/N)
• Classifications
• Fields
• References

Novelty

Three Main Issues Under Novelty

• Prior Art: what is a “reference”?

• Timing Issues: What is in, and out, of the “prior art”?

• Identity Standard: How similar does a prior art reference have to be to anticipate (destroy novelty, invalidate) a patent?
The “Critical Date” for Novelty

The Filing Date (AIA)

Prior Art

LESS

Prior Art

Earlier Invention: Earlier “Critical Date”

Novelty

Pre-AIA §102

• §102(a): before invention, public use or knowledge in US, or patent or “printed publication” anywhere
• §102(b): 1 yr before US filing, public use or “on sale” in US, or patent or “printed publication” anywhere
• §102(c): before invention, US patent application leading to issued US patent or published application
• §102(g)(1): interference ⇒ made by another US patent applicant in WTO country, and not ASC
• §102(g)(2): no interference ⇒ made in US by another, and not abandoned/suppressed/concealed

AIA §102

• Critical Date = “effective filing date”
• Art Under AIA §102(a)(1): patent, printed publication, public use, matter on sale, or matter otherwise publicly available
• Art Under AIA §102(a)(2): US patent or published application
• effective date = “effective filing date”
• exclusions: derivation, pre-filing inventor-connected disclosure, common ownership (New §102(b)(2))
• Grace Period Under AIA §102(b)(1)
• year preceding effective filing date
• disclosure made by inventor, made by “derivant,” or preceded by inventor-connected public disclosure

Effective filing date on or after March 16, 2013: AIA applies

Novelty: § 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

• Generally corresponds to the categories of prior art in pre-AIA §102(a) and §102(b)
Effective Filing Date: § 100(i)(1)

- Actual filing date of the patent or published application containing the claimed invention; or
- Filing date of the earliest application for which the patent or application is entitled
  - International filings under §119 or §365
  - Earlier domestic filings under §120 (continuation) or §121 (divisional)

In Public Use or On Sale

- Eliminated pre-AIA geographic limitation; use or sale may occur anywhere in the world

Otherwise Available to the Public

- Introduced by the AIA; no corresponding language in pre-AIA §102
- Catch-all to account for other means of making an invention publicly available

First-to-File and Prior Art

- What's old in these five categories of prior art?
  - Answer: as we’ll see shortly, much is old
  - e.g., old “printed publication” cases still apply, though the addition of “otherwise available to the public” category might make some cases easier

§ 102(b)(1): Inventor Disclosure

§ 102(b)(1)(A)

- A disclosure made one year or less before the effective filing date of the claimed invention shall not be prior art under §102(a)(1) if:
  - the disclosure was made by:
    - the inventor or joint inventor; or
    - another who obtained the subject matter directly or indirectly from the inventor or joint inventor

§ 102(b)(1): Intervening Disclosure

§ 102(b)(1)(B)

- A disclosure made one year or less before the effective filing date of the claimed invention shall not be prior art under §102(a)(1) if:
  - the subject matter disclosed was, before such disclosure, publicly disclosed by:
    - the inventor or joint inventor; or
    - another who obtained the subject matter directly or indirectly from the inventor or joint inventor
**One Year or Less**

- AIA grace period measured from the filing date of the earliest US or foreign patent application to which a benefit/priority claim is made

**Subject Matter**

- The subject matter in the prior disclosure must be the same as that later publicly disclosed for the exception to apply
- Mere insubstantial changes or trivial/obvious variations in subject matter are not covered
- Mode of disclosure by inventor need not be the same as the mode of disclosure for the intervening grace period
- No requirement for verbatim disclosures

---

**Example 1**

- A’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(A) as a grace period inventor disclosure

**Example 2**

- A’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(A) as a grace period inventor disclosure
- B’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(B) as a grace period intervening disclosure

**Example 3**

- A’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(A) as a grace period inventor disclosure
- B’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(B) as grace period intervening disclosure as to subject matter X only. B’s publication is prior art as to subject matter Y
Novelty: § 102(a)(2)

- Precludes a patent if a claimed invention was described in a:
  - US Patent
  - US Patent Application Publication
  - WIPO Publication of PCT Application designating the US ("WIPO Published Application")
  - … that names another inventor and was effectively filed before the effective filing date of the claimed invention
- Generally corresponds to the categories of prior art in pre-AIA § 102(e)

WIPO Published Applications

- Eliminated pre-AIA requirement that WIPO publications are treated as prior art only if:
  - (i) filed on or after November 29, 2000;
  - AND
  - (ii) published in English

Names Another Inventor

- Requirement to name another inventor is satisfied if there is any difference in inventive entity between
  - (i) prior art US patent, US patent application publication, or WIPO published application
  - AND
  - (ii) application under examination

Effectively Filed: § 102(d)

- Effective prior art date of subject matter in US patents and published applications under AIA § 102(a)(2) is:
  - Actual filing date of the US patent or published application
  - OR
  - Date to which the US patent or published application is entitled to claim a right of priority or benefit under § 119, § 120, § 121, or § 365 which describes the subject matter

Non-Inventor Disclosure

§ 102(b)(2)(A)

- A disclosure in an application or patent shall not be prior art under § 102(a)(2) if:
  - The disclosure was made by another who obtained the subject matter directly or indirectly from the inventor or joint inventor

Intervening Disclosures

§ 102(b)(2)(B)

- A disclosure in an application or patent shall not be prior art under § 102(a)(2) if:
  - The subject matter disclosed was, before such subject matter was effectively filed, publicly disclosed by:
    - the inventor or joint inventor; or
    - Another who obtained the subject matter directly or indirectly from the inventor or joint inventor
**Commonly Owned Disclosure**

§ 102(b)(2)(C)

- A disclosure in an application or patent shall not be prior art under § 102(a)(2) if:
  - The subject matter and the claimed invention were **commonly owned or subject to an obligation of assignment** to the same person not later than the effective filing date of the claimed invention
  - Resembles pre-AIA § 103(c), but now disqualifies art for both novelty and nonobviousness (pre-AIA: just obviousness)

**Commonly Owned or Subject to Assignment**

- Applicant can establish common ownership or obligation of assignment by making a clear and conspicuous statement
- Corroborating evidence is not required

---

**Example 4**

- B’s patent application is prior art under 102(a)(2) but knocked out by the exception in 102(b)(2)(A) as a non-inventor disclosure if non-inventor B obtained X from inventor A

---

**Example 5**

- A’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(A) if made within the grace period
- B’s patent application is prior art under 102(a)(2) but knocked out by the exception in 102(b)(2)(B) as an intervening disclosure

---

**Example 6**

- A’s publication is prior art under 102(a)(1) but knocked out by the exception in 102(b)(1)(A) if made within the grace period
- B’s patent application is prior art under 102(a)(2) but knocked out by the exception in 102(b)(2)(B) as an intervening disclosure for subject matter X. B’s patent application is prior art as to subject matter Y
• B’s patent application is prior art under 102(a)(2) but knocked out by the exception in 102(b)(2)(C) as a commonly owned disclosure

In re Klopfenstein (Fed. Cir. 2004)

Background
• Oct.-Nov. 1998: 14-slide poster presentation made twice—for 2.5 days and <1 day, respectively
• Oct. 30, 2000: US patent application filed
• Both parties agreed that poster presentation “disclosed every limitation of the [claimed] invention”

Factors to Weigh for Non-Distributed, Non-Indexed Work
• Duration of display
• Expertise of “target audience”
• “[R]easonable expectations” regarding copying
• “[S]implicity or ease” of copying

Reasonable Accessibility
• 50 copies of “trade catalogue.” Jockmus (2d Cir. 1928)
• “[U]ncatalogued and unshelved” “master’s thesis.” Bayer (CCPA 1978)
• Cataloged doctoral dissertation in “Freiburg University library.” Hall (Fed. Cir. 1986)
• “Undergraduate theses” indexed alphabetically by author. Cronyn (Fed. Cir. 1989)
• 33 letters relating to naval research. Aluminum (N.D. Ill. 1990)
• “[S]lide presentation” on “poster boards” at “Cereal Chemists” meeting and at Agriculture Experiment Station. Klopfenstein (Fed. Cir. 2004)

Public Accessibility
• “A reference is publicly accessible ‘upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it...’”
  • Kyocera v. ITC (Fed. Cir. 2008)
• Need to travel does NOT defeat public accessibility requirement
  • In re Lister (Fed. Cir. 2009)
• Inability to find without precise direction is not publicly accessible
  • EFF v. Pers. Audio (PTAB 2014)
Egbert v. Lippmann (1881)

**Background**
- 1855: Samuel Barnes (SB) invented kind of corset springs & gave a set to his “intimate friend,” Frances Lee Egbert (FL)
- 1858: SB gave new set to FL
- ca. 1860: SB married FL
- 1863: SB & FL showed to Joseph Sturgis
- 1866: SB filed patent application

J. Woods’ opinion for the Court
- “[T]o constitute the public use of an invention it is **not necessary that more than one** of the patented articles should be publicly used.”
- “[W]hether the use of an invention is public or private does not necessarily depend upon the number of persons to whom its use is known.”
- “[I]f its inventor sells a machine of which his invention forms a part, and allows it to be used **without restriction** …, the use is a public one.”

J. Miller’s dissenting opinion
- “A private use with consent, which could lead to no copy or reproduction of the machine, which taught the nature of the invention to no one but the party to whom consent was given, which left the public at large ignorant as of this as it was before the author’s discovery, was no abandonment to the public, and did not defeat his claim for a patent.”

Moleculon Research v. CBS

**Background**
- 1957-62: Nichols made “paper models” of cube puzzle, showing to “close friends” and “explain[ing] … to at least one.”
- 1968: Nichols made “wood” version “usually kept at home but on occasion brought into his office.”
- Jan. 1969: Nichols “explained” to Moleculon president, who indicated interest in commercializing
- Mar. 1969: Nichols assigned rights to Moleculon
- Mar. 3, 1970: Nichols filed patent application
**Moleculon Research**  
(Fed. Cir. 1986)

**J. Baldwin’s opinion for the Court**

- Not “Public Use”: District court did not err in finding, “[b]ased on the personal relationships and surrounding circumstances,” that:
  - Nichols’ use was “private,” and
  - “Nichols at all times retained control over the puzzle’s use and the distribution of information concerning it.”
- Not “On Sale”: “[A]ssignment or sale of the rights in the invention and potential patent rights is not a sale of ‘the invention’ within … § 102(b).”

---

**Metallizing Engineering v. Kenyon Bearing & Auto Parts**

**Metallizing Engineering**  
(2d Cir. 1946)

**Background**

- The invention was an improved method for conditioning metal surfaces so that the surfaces were better prepared for the process of “metallizing,” which involves applying a metal spray to restore the worn metal surfaces
- District court held that the patent was valid and infringed

---

**Pfaff v. Wells Electronics (1998)**

**Background**

- Nov. 1980: TI asked Pfaff to design “chip socket.”
- Pre-Mar. 17, 1981: “Pfaff showed a sketch” to TI.
- Apr. 8, 1981: TI gave “written confirmation of … oral purchase order for 30,100” sockets.
- Summer, 1981: Pfaff “reduced … to practice.”
- Apr. 19, 1982: Pfaff filed application.

J. Stevens’ opinion for the Court

• Ability to experiment, even publicly, without triggering statutory bar
• Meaning of “Invention” in §102(b)
  • Reduction to Practice NOT Required
  • Complete Concept is Required

Helsinn Healthcare v. Teva Pharmaceuticals

Background

• Palonosetron is an antiemetic used to treat nausea and vomiting associated with chemotherapy
  • Serotonin 5-HT3 receptor antagonist
  • In the same class as ondansetron (Zofran)
• The patent at issue is on a particular dose, not on the compound itself (original patent on the drug was issued April 13, 1993, 10 years before the patent at issue here was filed)
• Such “secondary patents” are often used to extend market exclusivity of pharmaceuticals well beyond the product’s original patent expiration date

Helsinn Healthcare v. Teva Pharmaceuticals

Procedural History

• District Court determined that the “on sale” bar didn’t apply
• Federal Circuit reversed, concluding that “if the existence of the sale is public, the details of the invention need not be publicly disclosed in terms of sale” to fall within the AIA’s on-sale bar
• Question: “whether, under the AIA, an inventor’s sale of an invention to a third party who is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention”
**Helsinn Healthcare (2019)**

J. Thomas’ opinion for the Court

- Answer: the “on sale” bar applies
- “we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase”
- “Like other such phrases, “otherwise available to the public” captures material that does not fit neatly into the statute’s enumerated categories … [g]iven that the phrase “on sale” had acquired a well-settled meaning when the AIA was enacted, we decline to read the addition of a broad catchall phrase to upset that body of precedent.”