Mea culpa: On-sale bar, prior art, and patent grace periods in the U.S. and various foreign countries

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LAKC 11th Annual IP CLE
Thursday, March 7, 2019

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Background

Basic requirements for patentability:

- 35 U.S.C. 101 – Patent-eligible subject matter
- **35 U.S.C. 102 – Novelty**
- 35 U.S.C. 103 – Obviousness
- 35 U.S.C. 112 – Disclosure requirements

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Background - AIA

- **America Invents Act** took effect: March 16, 2013
- MPEP now updated to reflect pre-AIA and FITF AIA provisions
- **MPEP 2152** contains detailed discussion of "new" 35 U.S.C. 102
- USPTO Guidance documents reflect its current interpretation of certain new statutes and implementing regulations

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Background - AIA

Ambiguities with "new" Statute:

1. Congress picked the same words as in old statute, because it wanted the same meanings*
2. Congress used similar terms, but added new context, and assumed the whole thing would be reinterpreted

*In its proposed rules and guidelines, the USPTO refers to existing precedent to support its interpretation of certain terms in the statute.

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35 U.S.C. 102(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;

USPTO position: Section 102(a)(1) is similar to "old" 102(a) and (b) categories of prior art.

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35 U.S.C. 102(a) – Novelty & Prior Art

Notable differences:

- Expands "public use" and "on sale" prior art to *anywhere* in the world (used to be limited to "in this country")
- Also adds category of "**otherwise available to the public**"
- Changes "invention date" to "effective filing date" as relevant comparison time

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U.S. Grace Periods

- **Grace period**: Exception to a loss of novelty because of an action (usually a disclosure) that occurred prior to the patent filing.
- **35 U.S.C. 102(b)(1):**

- Disclosures made 1 year or less before the effective filing date shall not be prior art under subsection (a)(1) if—

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U.S. Grace Periods

Disclosures made 1 yr or less not prior art if:

(1)(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

(1)(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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U.S. Grace Periods

Plain English

102(b)(1)(A): One-year grace period for inventor's own "disclosure," or disclosure of the inventor's work by another.

102(b)(1)(B): Disclosure by a 3rd party is not prior art, if the inventor disclosed first (followed by patent filing within 1 year of that initial disclosure). Thus, an inventor's first disclosure can "immunize" the inventor against subsequent 3rd party disclosures.

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U.S. Grace Periods

Note: These exceptions are specific to **102(a)(1) categories of prior art** (i.e., patents, printed publications, public use, on sale, or otherwise available to the public).

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U.S. Grace Periods & Prior Art

Issues:

- Many of the terms used in current 102 have roots in old 102, and therefore come with a lot of "baggage."
- Statutory language imprecise

Question: Whether same/similar words should be given same/similar interpretation under precedent or new treatment altogether?

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Ambiguities re: Prior Art

Imprecise language of statute:

- 102(b)(1)(B) specifies "public" disclosure, while 102(b)(1)(A) does not say "public."
- What is the effect of the new catchall phrase "otherwise available to the public?"
  - What about *private* sales or *secret* commercialization?

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Ambiguities re: Prior Art

USPTO position: "**Public use**" is now limited to uses that are *accessible to the public*.

USPTO position: "**On sale**" has the same meaning as pre-AIA case law, *except that the sale must now make the invention available to the public*.

"AIA...does not cover secret sales or offers for sale" (2013 Guidelines, page 11075)

*Based upon this Guidance, NDAs seemed extremely important post-AIA to "save" any pre-filing activity from becoming a "sale" that triggers the 1 year grace period.

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Helsinn v. Teva

U.S. Supreme Court – January 22, 2019 (17-1229)

- Teva challenged Helsinn's patent.
- Helsinn executed a contract for distribution of its patented drug nearly two years before it applied for the U.S. patent. Distributor obligated to keep the invention confidential. Claims cover specific formulation that was the subject of the contract.
- Question: Did this commercial contract place the invention "on sale" under the statute?

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Helsinn v. Teva

U.S. Supreme Court – January 22, 2019 (17-1229)

- "Much ado about nothing"
- A sale of an invention, pursuant to an obligation of confidentiality, still places the invention "on sale" for the purposes of 35 U.S.C. 102(a)(1).*

*"On sale" means that the invention is "the subject of a commercial offer for sale" and "ready for patenting" Pfaff v. Wells, 525 U.S. 55 (1998).

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Helsinn v. Teva

The date of the sale (or offer for sale*) starts the 1-year grace period clock under U.S. law, even if the sale didn't make the invention "available to the public."

* If other side can make it into a binding contract by simple acceptance of the offer.
* Offer for future sale can start clock and place the invention "on sale" as of the subsequent date of conception (August Tech, Fed. Cir. 2011).

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Helsinn v. Teva

Notable points:

- Court maintains long-standing view that commercial exploitation (even if in secret) can "bar" later attempts to patent.
  - "Every patent statute since 1836 has included an on-sale bar."
  - Commercialization is the key – not public accessibility
  - Special Devices v. OEA (2001); Woodland Trust (1998); Elizabeth Paving (1878); Consolidated Fruit-Jar (1877)

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Helsinn v. Teva

Notable points:

- Court was <u>not</u> persuaded that the new catchall phrase "otherwise available to the public" had *any* modifying effect on the list of actions or activities constituting prior art.
  - "substantial body of law interpreting §102's on-sale bar."
  - "we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial consideration of that phrase."
  - Catchall phrase was "fairly oblique way of attempting to overturn that settled body of law."

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Helsinn v. Teva

Take-Aways

- Still don't have an answer about what constitutes "otherwise available to the public."
- Somewhat safe assumption that **<u>any</u>** other language in the statute that is the same as old 102 will be subject to the entire body of case law and precedent as pre-AIA.
  - *Good reminder that USPTO Guidance is not the law.

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Prior Art & Grace Periods Outside the U.S.

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Argentina

- Grace Period? YES! ☺
  - 12-month grace period
  - Priority date counts to stop the clock
- Disclosures that can use the grace period?
  - "any communication media" by the inventor or applicant, except another published patent application
- Must invoke grace period at filing with information regarding the relevant disclosure.

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Australia

- Grace Period? YES! ☺
  - 12-month grace period
  - PCT or complete filing in Australia to stop the clock
- Disclosures that can use the grace period?
  - Public disclosure by the inventor or derived from inventor
- In limited circumstances, if a priority application (Paris convention) is filed within 6 months of the disclosure, then have (full) 12 months to file PCT or direct in Australia.

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Brazil

- Grace Period? YES! ☺
  - 12-month grace period
  - Priority date counts to stop the clock
- Disclosures that can use the grace period?
  - Disclosure by inventor
  - Publication of patent filed without inventor's consent
  - By another derived from inventor
- Must invoke grace period once filed in Brazil

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Canada

- Grace Period? YES! ☺
  - 12-month grace period
  - PCT or complete filing in Canada to stop the clock
- Disclosures that can use the grace period?
  - Public disclosure by the inventor or derived from inventor
- Loss of Novelty is specific to "public disclosures" – information shared under an NDA will not start the clock

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China

- Grace Period? MAYBE? 😕
  - 6-month grace period
  - Priority date counts to stop the clock
- Disclosures that can use the grace period?
  - Exhibiting at (Chinese) Gov't recognized event
  - Prescribed academic or technological meeting
  - Disclosed without consent of the applicant
- "Secret prior art" (previously unpublished Chinese application) – only available for assessing novelty

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Europe

- Grace Period? Not Really. ☹
- Two rare instances to invoke 6-month grace period:
  - "evident abuse in relation to the applicant"
  - "Officially recognized convention"*
    - Examples: Astana 2017 Future Energy; Dubai 2020 Connecting Minds, Creating the Future
- Direct EP or PCT filing date (not priority) counts to stop the clock

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Germany

- Almost identical to EPO ☹
- BUT German Utility Model has a 6-month grace period for novelty
  - No examination, 10 year term
  - Utility models generally don't apply to some inventions (e.g., methods or biotech)

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UK & France

- Almost identical to the EPO ☹
- 6-month grace period available only if:
  - Disclosure unlawful or breach of confidentiality of the inventor
  - Display at officially recognized international exhibition

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Japan

- Grace Period? YES! ☺
  - 12-month grace period
  - PCT or complete filing in Japan to stop the clock
- Disclosures that can use the grace period?
  - Public disclosure by the inventor or derived from inventor
- Petition to rely on grace period and evidence of disclosure due within 30 days of Japan filing

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Mexico

- Grace Period? YES! ☺
  - 12-month grace period
  - Priority date counts to stop the clock
- Disclosures that can use the grace peri
  - Disclosure "by any means of communication" by the inventor or applicant (except another published application)
- Must declare disclosure at time of filing in Mexico

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New Zealand

- Grace Period? YES! ☺
  - 1-year grace period (as of December 30, 2018)
  - PCT or complete filing in New Zealand to stop the clock
- Disclosures that can use the grace period?
  - Public disclosure by or with consent of patentee

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South Africa

- Grace Period? NO! ☹
- Any use of the invention constitutes "prior art" including secret use.
- Two rare exceptions (similar to EPO):
  - Unauthorized disclosure if inventor/applicant then applies with "all reasonable diligence" upon learning of unauthorized disclosure
  - Experimental use exception for actions *in* South Africa
- Filing must be direct in South Africa or PCT

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South Korea

- Grace Period? YES! ☺
  - 1-year grace period
  - PCT or complete filing in South Korea to stop the clock
- Disclosures that can use the grace period?
  - Public use, presentation at conference, printed publication (except another published patent application) by the patentee
  - Does not extend to third party submissions, and no "immunizing" self against an intervening 3rd party publication.
- Must request grace period with certificate and evidence.
- Interesting case: product publicly sold before filing date - but person skilled in the art not able to determine contents without undue effort, does not count as a disclosure. (Thus, even if 1 year has already passed, could still file.)

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SPECIAL THANKS!

- **Argentina**: **Emilio Berkenwald**, *BERKEN IP*
- **Australia/New Zealand**: **Deb Yin Foo**, *Phillips Ormonde Fitzpatrick*
- **Brazil**: **Priscila Thereza**, *Gusmao & Labrunie*
- **Canada**: **Trevor Newton**, *Gowling WLG*
- **China**: **Dan Xiang**, *Shanghai Patent & Trademark Office*
  Elliot Zhou, *Chofn Intellectual Property*
- **Europe**: **Anna Hally**, *Hanna Moore + Curley*
  Andre Guder, *Uexkull & Stolberg*
- **Japan**: **Nobutaka Yokota**, *FIELDS IP Attorneys*
- **Mexico**: **Karla Islas**, *Herrero & Asociados*
- **South Africa**: **Joanne van Harmelen**, *ENSafrica*
- **South Korea**: **Min Son**, *Hanol Intellectual Property & Law*

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Any Questions?

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Thank You!

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