Importance of Laboratory Notebooks after the America Invents Act (AIA)
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- Trademark & Trade Secret
- White Collar Criminal Defense
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Leahy-Smith America Invents Act ("AIA")

- Effective on March 16, 2013
- First-Inventor-To-File provisions
- Notebooks/record-keeping play an important role under the old First-To-Invent system
- Notebooks are still important under AIA
- Moving to new law will not be a "clean break"
Importance of Notebooks

- Trade Secret Protection
- Prior Use Defense - AIA
- Establishing Inventorship
- Grace Period - AIA
- Derivation Proceedings – AIA
- Interferences
- Export Compliance
- Elephants always remember
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Trade Secret Protection

- A trade secret is information that
  1. Has “independent economic value,” whether actual or potential;
  2. Is not generally known to the public, or to others who can obtain economic value from it; and
  3. Is the subject of reasonable efforts to maintain its secrecy.

Cal. Civ. Code § 3426.1(d)
Trade Secret Protection

- "Know-how": techniques, processes, formulas, product specifications, computer software
- Includes “negative knowledge”: What methods don’t work?
- Manufacturing processes, e.g., precise cell growth conditions, purification process, characteristics of a cell that produces a drug
- Composition of matter & formulation, e.g., chemical compound structures
- Highly variable subject matter
Trade Secret Protection

- To maintain secrecy, reasonable measures are required internally
- Confidently marked documents & materials
- Restricted access to physical files
- Security passwords for computers/networks
- Any restricted access procedures for visitors
- Email correspondence
Trade Secret Protection

- Trade Secret Misappropriation – high stakes


- Forensic evidence showed former employee’s home computer had spreadsheets related to DuPont’s production capacity for Kevlar® yarn.

- $919 million judgment in favor of DuPont; permanent injunction; Kolon executives indicted for TS theft and conspiracy.
Trade Secret Protection

- *Eli Lilly & Co. v. Emisphere* (S.D. Ind. 2006) Parties entered into collaboration/option/license agreements to develop new chemical carrier compounds; negotiations failed for an expanded collaboration & Eli Lilly formed secret team to conduct MOA research

- Eli Lilly scientist working with Emisphere presented results to secret team, including slides marked “Confidential-Property of Emisphere Technologies, Inc.”; filed patent applications which eventually published

- Emisphere prevailed in a breach of contract lawsuit; Elli Lilly paid ~$18 million to settle the suit in 2007

- Illustrates importance of TS protection & good record-keeping during the course of collaborations.
Trade Secret Protection

- Notebooks and good record-keeping practices continue to be essential for the use of existing trade secrets & the development of new trade secrets.

- Train employees on proper procedures to preserve trade secrets.

- Have safeguards in place prior to sharing TS information with collaborators.

- Help preserve potential prior use defense in a patent infringement action.
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Prior Use Defense to Patent Infringement

- Pre-AIA, 35 U.S.C. § 273 - prior use defense for infringement of a business method patent; also referred to as “First Inventor Defense”

- Trade secret holder was at risk of having a subsequent inventor obtain a non-business method patent and assert against the TS holder.

- AIA § 273: expands the subject matter on which the defense may be asserted to include all methods or processes, as well as compositions of matter.

- Patents issued on or after September 16, 2011
Prior Use Defense to Patent Infringement

- AIA § 273 (a) A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

  (1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use; and
Prior Use Defense to Patent Infringement

- (2) such commercial use occurred at least 1 year before the earlier of either—
  - (A) the effective filing date of the claimed invention; or
  - (B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

- AIA 273(e)(1)(A) allows for the defense to be asserted by the entity that controls, is controlled by, or is under common control with such person.
Prior Use Defense to Patent Infringement

- AIA 273 (b) provides
  - Burden of proof.--A person asserting a defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

- University exception - AIA 273 (c)(2) provides a
  - use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, . . ., shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use . . .
Prior Use Defense to Patent Infringement

- High burden of proof to establish the defense

- Limitations of defense - personal in nature; cannot license or transfer; abandonment of commercial use may end ability to assert

- Properly maintained laboratory notebooks and other record-keeping practices can help trade secret owners demonstrate “internal commercial use” (or other commercial use) at least one year prior to the effective date of the claimed invention in a patent, thereby potentially establishing a prior use defense.
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Establishing Inventorship

- A significant part of a patent portfolio will remain governed by the old law.
- Applications filed prior to March 16, 2013 will be subject to the old law.
- Applications claiming priority to applications filed prior to March 16, 2013 may be subject to the old law.
- Pre-AIA law will coexist with new law until at least March 16, 2034.
- Good record-keeping protocols & lab notebooks should be maintained
Establishing Inventorship

- Inventorship remains important under AIA.
- All categories of prior art under the AIA are defined relative to the effective filing date of a patent application.
- The first inventor in the door at the USPTO (typically) wins.
- But: grace period for inventor’s own publications
- But: an opportunity to challenge anyone deriving an invention from another.
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Grace Period under AIA

- **Section 102(b)** as revised by the AIA defines a grace period as an exception to the prior art definitions of § 102(a).

- Grace period applies to the public disclosure of an invention within one year of the effective filing date of the application disclosing and claiming that invention, but only if the disclosure was by an inventor or one who obtained the invention “directly or indirectly” from an inventor.

- No longer can an inventor antedate a disclosure by another within one year of the effective filing date, unless that disclosure was obtained from the inventor (no swearing behind of other’s publication).
Grace Period under AIA

- An inventor’s disclosure within the one-year grace period eliminates from prior art any subsequent disclosures of the same invention by another occurring after an inventor’s disclosure but before that inventor files a patent application.

- Early public disclosure by the inventor can be used to protect the patentability of an invention while an application is prepared, but such a strategy results in surrendering most foreign patent rights.

- Possible question on the meaning of “another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor”

- How will this play out in collaborations? Press releases?
Grace Period under AIA

Scenario 1:
- A invents and immediately publishes
- B independently publishes subject matter of invention
- Within one year of his invention, A files patent application

Result:
- B’s publication is not prior art even though published before A filed application.

Inventor A made the first public disclosure
Grace Period under AIA

- **Scenario 2:**
  - A invents and immediately publishes
  - B independently **invents and files patent application**
  - Within one year of his invention, A files patent application

- **Result:**
  - B’s application (or patent) is not prior art even though filed before A filed application.

- Inventor A made the first public disclosure
Grace Period under AIA

- Scenario 3:
  - A invents and communicates to B as part of collaboration
  - B (a non-inventor) publishes
  - Within one year of B’s publication, A files patent application

- Result:
  - A may be entitled to a patent if it can establish inventorship & communication of the invention to B.

- A invented but B made the first public disclosure
- Properly maintained laboratory notebooks important for A to take advantage of the grace period.
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Derivation Proceedings

- Inquiry into whether the invention in a first-filer’s application or patent was derived from another inventor with a pending application before the Patent Trial and Appeals Board.

- To prove derivation, the first-filer must be shown to (i) have obtained the invention from the challenger, and (ii) have sought patent protection by filing a patent application without authorization from the challenging inventor.

- No inquiry into patentability. High burden to prove derivation.
Derivation Proceeding

- Replaces Interference Proceedings
- “True” inventor must have an appl’n on file
  - May copy the alleged deriver’s appl’n
- File petition w/in 1 yr of publication
  - Either US or PCT appl’n publication
- Pay Fee
- Showing by Substantial Evidence that derivation occurred
  - At least one affidavit addressing communication and lack of authorization to file
  - Showing of communication must be corroborated
Derivation Proceeding

- Watch competitors closely
  - Monitor all patent publications
  - Missing Deadline is fatal
  - Use of Post-Grant Review?

- Showing of Substantial Evidence
  - Will require more recordkeeping
  - Conception, Reduction To Practice, Diligence
  - Circumstances of Disclosure
  - May be difficult to show lack of authorization (i.e., proving a negative)
  - PTO does NOT have subpoena power
# Derivation Proceeding

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Interferences

- Pre-AIA 35 USC 102(g) – interference proceeding allowed one inventor to establish an earlier date of invention over another inventor.
- Well-maintained notebooks and good record-keeping play an important role.
- AIA First-Inventor-To-File provisions eliminate 102(g)
- However, transition provision under AIA 3(n)(2) creates situations where old 102(g) may still apply.
Interferences

- Under AIA 3(n)(2), pre-AIA 102(g) provisions apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time—
  - (A) a claim to an invention having an effective filing date . . . that occurs before the effective date set forth in paragraph (1) of this subsection; or
  - (B) a specific reference . . . to any patent or application that contains or contained at any time such a claim.

- Post-AIA application or patent contains claim(s) with a pre-AIA effective filing date.

- Application of pre-AIA 102(g) means an interference proceeding may still be possible.
Interferences

- Potential for complicated issues associated with post-AIA applications having a priority claim to a pre-AIA application.

- Addition of new matter may result in post-AIA treatment if the claims do not have a pre-AIA effective filing date.
  - Post-AIA non-provisional application claiming priority to a pre-AIA provisional application
  - Post-AIA Continuation-in-part application claiming priority to a Pre-AIA non-provisional application

- Continuation or divisional with the same disclosure
  - USPTO may determine that the claims in the post-AIA application constitute “new matter” vis-à-vis the pre-AIA application.
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U.S. Export Controls and Trade Sanctions

- **U.S. Export Controls**
  - Cover any item in U.S. trade
  - U.S.-origin items wherever located (jurisdiction follows the item or technology worldwide)
  - Excludes patents and patent applications, artistic or non-technical publications
  - Excludes technology in the public domain

- Exports of most high-technology and military items as well as associated technology require U.S. export authorization (either a license or an applicable exemption)

- Trade sanctions focus on financing, commodities – “who” rather than “what”
U.S. Government Export Control and Trade Sanctions Agencies

- State Department: munitions (the International Traffic in Arms Regulations or “ITAR”)
- Commerce Department: “dual-use” items (the Export Administration Regulations or “EAR”)
- Nuclear Regulatory Commission: nuclear materials and technology
- Treasury Department, Office of Foreign Assets Control (OFAC): trade sanctions, embargoes, restrictions on transfers to certain end-users, terrorism, anti-narcotics
International Traffic in Arms Regulations (ITAR)

- Covers military and space items ("munitions" or "defense articles"): **items capable of causing death or defending against death in a military setting**
- Includes technical data related to defense articles and defense services (furnishing assistance including design, engineering, and use of defense articles)
- Strict regulatory regime
- Purpose of regulations is to ensure U.S. security
  - No balancing of commercial or research objectives

Export Administration Regulations (EAR)

- Covers dual-use items
  - Regulates items designed commercial purpose but which can have military applications (e.g., computers, pathogens, civilian aircraft)
  - Covers both the goods and the technology
  - Licensing regime encourages balancing competing interests
  - Balance foreign availability, commercial and research objectives with national security
Trade Sanctions (Treasury Dept.)

- Sanctions focus on the end-user or country rather than the technology

- Embargoes administered by Office of Foreign Assets Control, U.S. Department of Treasury (“OFAC”)
  - Prohibitions on trade with countries such as Iran, Sudan, Cuba
  - Limitations on trade in certain areas of countries or with certain actors

- OFAC prohibits payments to nationals of sanctioned countries and to entities and individuals designated as terrorist-supporting
EAR Controls

- What the EAR controls
  - Items subject to more stringent controls appear on the Commerce Control List ("CCL")
  - CCL lists the reasons for control:
    - National Security ("NS")
    - Chemical and Biological Proliferation ("CB")
    - Nuclear non-proliferation ("NP")
    - Anti-terrorism ("AT")
  - Items listed in categories based on the type of item controlled (nine total categories)
    - Category 1—Special Materials and Related Equipment, Chemicals, “Microorganisms,” and “Toxins”
    - Category 2—Materials Processing
    - Category 3—Electronics
  - If not specifically listed on the CCL, controlled as EAR99 – lowest level of control
EAR Controls

Examples of a CCL entry:

- **1C351** Human and zoonotic pathogens and “toxins”, as follows (see List of Items Controlled)
  - Controlled for CB and AT reasons
  - Certain entries also controlled for Chemical Weapons (“CW”) reasons
  - 1C351.a: controls viruses identified on the Australia Group (AG) “List of Biological Agents for Export Control” (list provided)
  - 1C351.b: controls viruses identified on the APHIS/CDC “select agents” lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) “List of Biological Agents for Export Control” (list provided)

- **1C353** Genetic elements and genetically modified organisms, as follows (see List of Items Controlled)
  - 1C353.a.1: controls genetic elements that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c, 1C352, or 1C354
  - 1C353b.1: controls genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c, 1C352,
EAR Controls

- Not controlled at all (not “subject to the EAR”):
  - Fundamental research – basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community (non-proprietary research)
  - University research – research conducted at a university normally considered fundamental research
  - Patent applications –
    - information in a patent application and authorized for filing in a foreign country in accordance with PTO regulations
    - Information in a patent application prepared wholly from foreign-origin technical data where the application is being sent to the foreign inventor to be executed and returned to the U.S. for subsequent filing in the PTO

- Controlled research (“subject to the EAR”)
  - Proprietary research
  - Industrial/corporate research for which results are not intended for public dissemination
Physical vs. “Deemed” Exports

- License potentially required for all exports of items on the CCL

- U.S. export controls cover transfers of goods and technology overseas (inherently intuitive)

- But controls also apply to transfers within the U.S. (the transfer outside the U.S. is deemed to apply when a foreign national receives the information in the U.S.)
  - Applies to technology transfers under the EAR and the provision of ITAR technical data and defense services

- Visa status important
  - Permanent resident (“green card holder”) has same right to controlled information as U.S. citizen (no license required)
  - Non-immigrant visa holders must satisfy export controls (license may be required)
Physical vs. “Deemed” Exports

- Carrying a lab notebook with controlled technology out of the U.S. is a physical export.
- Access to controlled technology, for example in a lab notebook, is a “deemed export”.
- Mere visual access not enough (“museum” or “parade” rule); must be able to obtain more detailed, non-basic information about the item.
- Cases in which “deemed export” may arise:
  - Non-U.S. person working in laboratory.
  - Non-U.S. person visitors to laboratory.
  - Non-U.S. sponsors of laboratory research (non-public, proprietary research).
Determining if an Export License is Needed

– (1) WHO IS THE EXPORTER?
  
  • Determine whether the exporter is subject to U.S. jurisdiction (U.S. companies and persons in the U.S. are subject to U.S. jurisdiction as are any foreign nationals in the U.S.; overseas operations may be subject to U.S. jurisdiction)

– (2) WHAT IS BEING EXPORTED?
  
  • Classify the technology or goods involved (i.e., subject to State Department ITAR controls, Commerce Department EAR controls, or other controls)

  • Determine whether any license exemptions or exceptions are available (e.g., public domain, fundamental research, etc.)
Determining if an Export License is Needed

(3) WHO IS THE RECIPIENT, AND WHERE IS THE RECIPIENT LOCATED?

- Determine if a license is needed for the particular technology and particular end-use and end-user
- Determine whether any embargoes apply or whether any prohibited parties or destinations are involved
- Determine whether there are any “red flags” or other warning signs of possible diversion of the goods or technology

If a license is required, apply promptly. Keep records in any case

- State Department licensing requirements and forms available at: http://www.pmddtc.state.gov
- Commerce Department licensing requirements and forms available at: http://www.bis.doc.gov
- Treasury (OFAC) licensing requirements available at: http://ustreas.gov/offices/enforcement/ofac/
Possible Penalties

- **State Department (ITAR)**
  - Criminal violations: up to $1,000,000 per violation, up to 10 years imprisonment
  - Civil penalties: seizure and forfeiture of the articles and any vessel, aircraft or vehicle involved in attempted violation, revocation of exporting privileges, fines of up to $500,000 per violation

- **Commerce Department (EAR)**
  - Criminal violations: $50,000 to $1,000,000 or up five times the value of the export, whichever is greater per violation (range depends on the applicable law), up to 20 years imprisonment
  - Civil penalties: loss of export privileges, fines up to $250,000 per violation or up to twice the value of the export
U.S. Export Controls and Trade Sanctions
Penalties for Noncompliance (cont’d)

- Treasury Department (OFAC)
  - Criminal violations: up to $1,000,000 per violation, up to 10 years imprisonment
  - Civil penalties: $55,000 to $250,000 fines (depending on applicable law) per violation
  - Violation of specific sanctions laws may add additional penalties

- Most settlements with the Commerce, State or Treasury Departments generally become public. Court cases are always public!
Importance of Planning, Coordination

- Export authorities expect all involved to understand export control requirements and take responsibility for compliance
- Written compliance plan, policies and procedures critical
- Training imperative
- Encourage early contacts with compliance officials
  - License approvals can take months; failure to obtain licenses can trigger enforcement actions that span years
  - Enforcement actions take your time and resources; in serious cases, personal liability possible
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Elephants always Remember

- Keeping a good notebook is good laboratory practice in general.
- Assist in future Legal Proceedings, which usually occur years later as memories fade, where the other side will examine in detail, pick entries apart, and ask questions (i.e., depose you).
- Assist patent attorneys/agents with drafting patent applications that meet 112 requirements.
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