# Establishing First to Invent & Electronic Lab Notebooks

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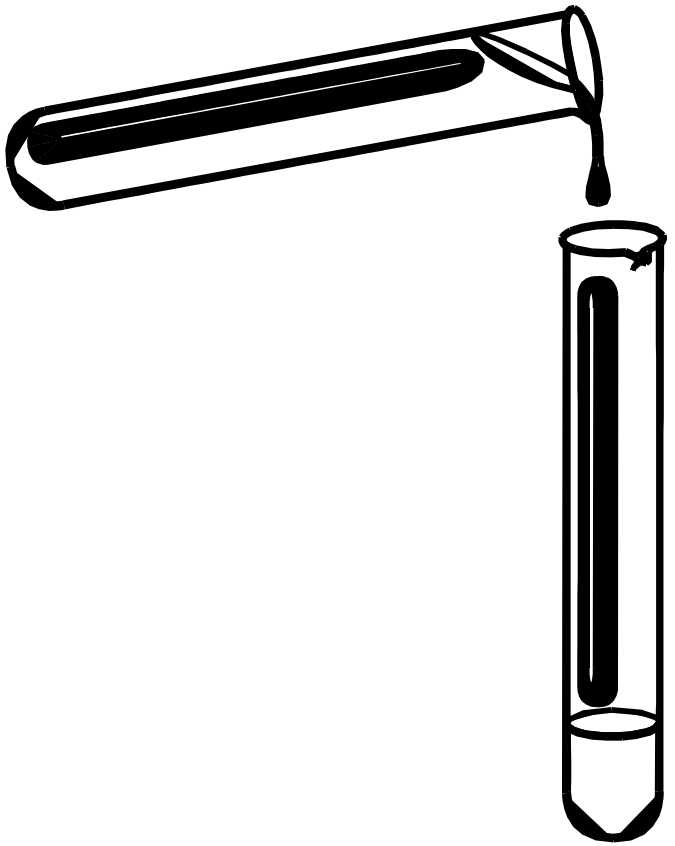
# Date of Invention

- Priority of invention
- Validity challenges



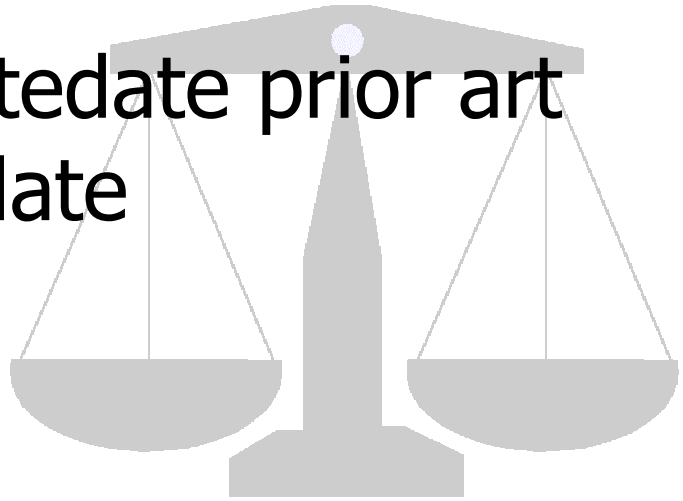
# Priority of Invention

- One patent per invention
- First to invent vs. first to file
- Interference proceedings
  - U.S. Patent and Trademark Office (USPTO)
  - District Courts

# Validity Challenges

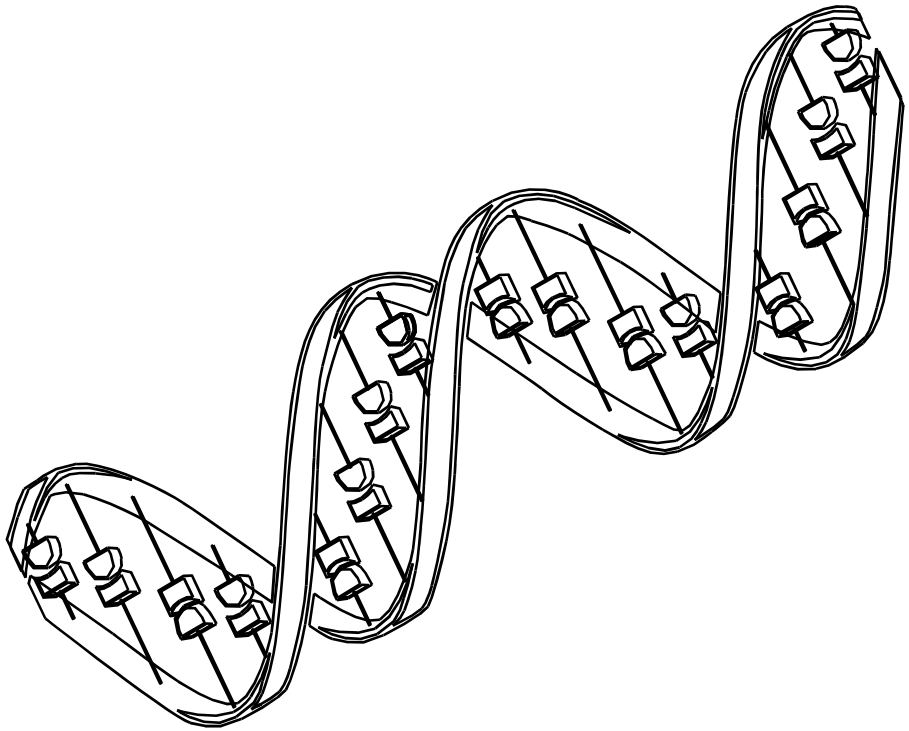
District Court litigation:

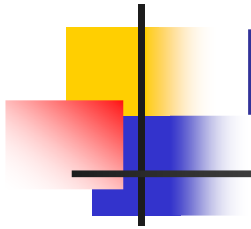
- Challenger relies on prior invention-type prior art
- Patentee seeks to antedate prior art with prior invention date



# Inventive Activity

- Conception (mental part)
- Reduction to practice (physical part)
- Diligence





# Basic Rule of Priority

First to reduce to practice wins,

*unless*

another conceived first and worked diligently toward reduction to practice.

# Proving a Date of Invention

- Admissible, credible evidence
- Contemporaneous with activity relied upon
- Corroborated

# Corroboration

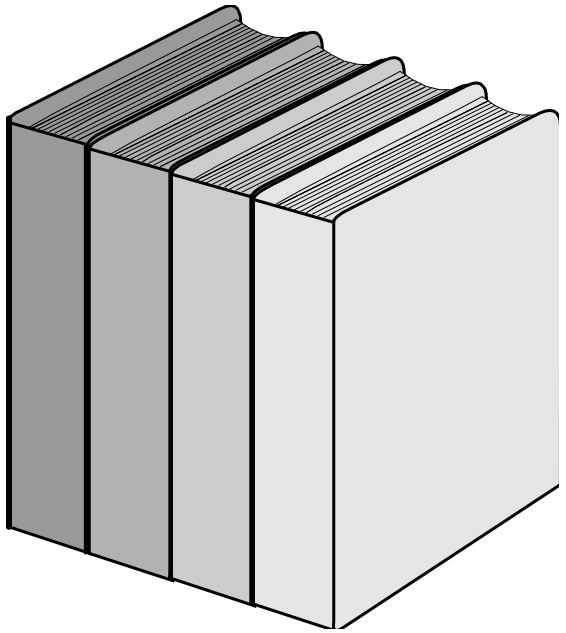
- Evidence emanating solely from inventor(s) must be corroborated by evidence independent of the inventor(s)
- Applies to testimony, documentary, and physical evidence
- Legal requirement:  As a matter of law, date of invention cannot be established without corroboration

# Evolution of Requirement

- Preference (1869 - ~1900)
  - (*Doughty v. Clark,* 1869 C.D. 14)
- Strict application: "over the shoulder " (~1900 to mid-1960s)
  - "for otherwise . . . great temptation to perjury"
- Today: "Rule of Reason"

# The Lab Notebook

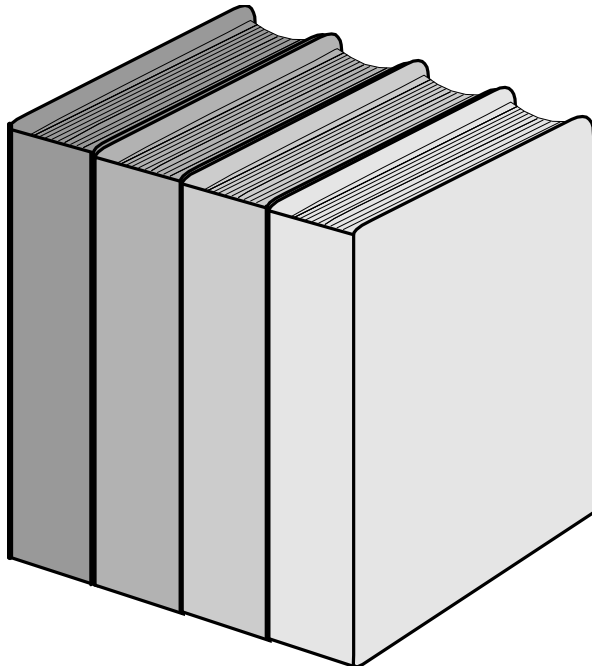
- Classic evidentiary tool
- Traditional attributes:
  - Permanent
  - Complete
  - Continuous



# The Lab Notebook

Record:

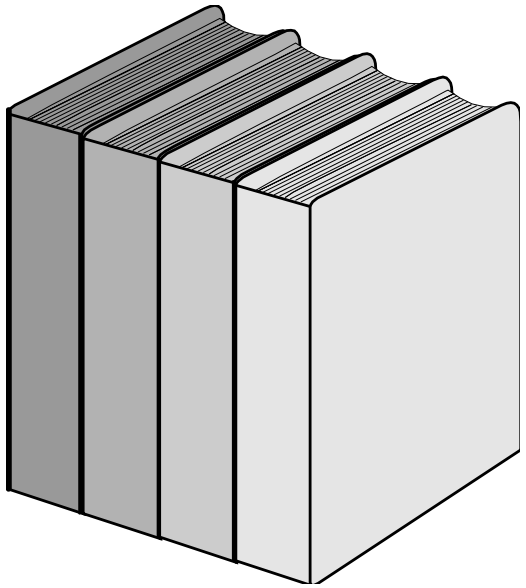
- Ideas (conception notebooks)
- Experimental protocols
- Results
- Observations



# The Lab Notebook

Standard Recommendations:

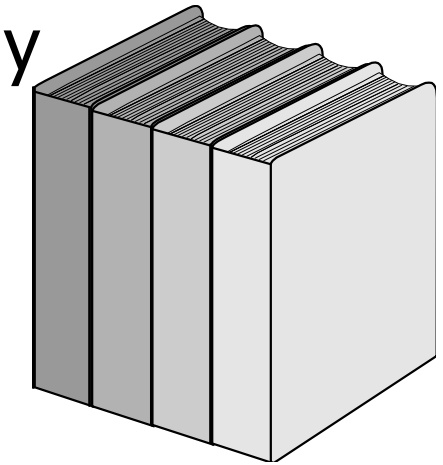
- Use bound notebooks having consecutively numbered pages
- Record entries in ink
- Enter information directly in notebook (no paper scraps)



# The Lab Notebook

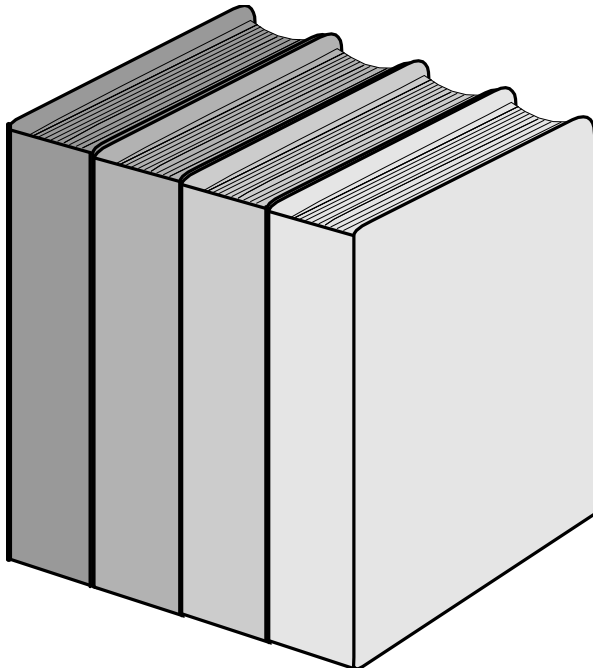
Standard Recommendations:

- No erasing (draw line through mistakes, sign and date corrections)
- Do not skip space
- Index for retrieval, store securely



# The Lab Notebook

- Sign
- Date
- Witness



# Electronic Research Records

Advantages:

- Convenient data handling
- Graphics capabilities
- "Searchability"
- Facilitation of data sharing
- Incorporation of instrument-generated data

# Electronic Research Records

Issue: will the USPTO Board and the courts accept electronic evidence of invention?

# Electronic Evidence

- The law:
  - District courts: over three decades of experience with electronically-generated/stored evidence
  - Federal Rules of Evidence: evidence is admissible if:
    - Relevant
    - Authenticated
    - Vouched for by witness or within hearsay exception

# Electronic Evidence

- Courts have generally admitted records despite objections:
  - Printout offered was prepared for litigation
  - Computer not shown to be error-free
  - It is possible to change stored data
  - Errors may have occurred during input
- Admissibility vs. credibility (weight)

# Electronic Evidence

- USPTO:
  - "[T]he Federal Rules of Evidence shall apply to interference proceedings."
- 1998 USPTO Notice:
  - "[E]lectronic records are admissible as evidence in interferences before the Board of Patent Appeals and Interferences to the same extent that electronic records are admissible under the Federal Rules of Evidence."
  - "The weight to be given any particular record necessarily must be determined on a case-by-case basis."

# Invention Date Evidence

- Admissible
- Credible
- Corroborated

# Admissibility

- Foundation testimony
  - Author/adopter
  - Custodian (business records exception)
- USPTO:
  - "Evidence consists of testimony and referenced exhibits"

# Admissibility

- Machine-generated reports/data have been admitted as evidence and relied upon as proof of invention for many years:
  - Nuclear magnetic resonance (NMR) and infrared (IR) spectra
  - IR scan and gas liquid chromatograph
  - Proton NMR
  - Elemental analysis, proton NMR, carbon 13 NMR, and high performance liquid chromatography
  - IR spectroscopy, differential scanning calorimetry, gel permeation chromatography, NMR, thermal gravimetric analysis
  - Email

# Requirement for Corroboration

- Applies to evidence of:
  - (the manifestation of) conception
  - (actual) reduction to practice
  - diligence
- Board:
  - "[T]he issue of corroboration is an issue distinct and separate from that of admissibility . . .."

# Corroboration: Rule of Reason

- While "over the shoulder" observation of a reduction to practice is "strong evidence", circumstantial evidence can suffice
- "[T]here is no final single formula that must be followed in proving corroboration"; all relevant evidence is to be considered "so that a sound determination of the credibility of the inventor's story may be reached"

# Corroboration: Rule of Reason

- Based on "recognition of the realities of technical operations in modern day laboratories"
  - "over the shoulder" requirement "plainly does not comport with the reality of technical operations involving numerous people necessarily separated from each other in time and distance and each involved in their own highly specialized part of a large operation"

# Corroboration: Rule of Reason

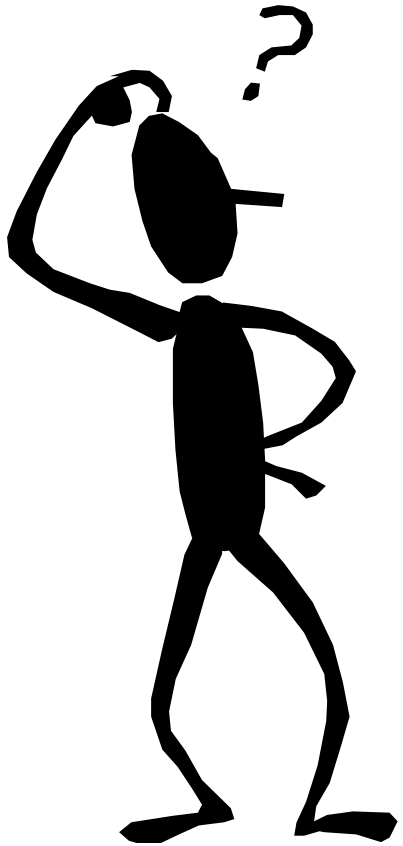
- E.g., *Lacotte v. Thomas*, 758 F.2d 611 (Fed. Cir. 1985):
  - Invention: process for copying video discs
  - Party Thomas' evidence:
    - Thomas' affidavit and notebook entries
    - Testimony of two (non-inventor) witnesses and additional documents:
      - Research associate's testimony that he had supplied the necessary starting materials to Thomas prior to the asserted reduction to practice
      - Thomas' requisition forms (bearing pre-RTP dates)
      - Another research associate's testimony that he examined the product of the process prior to Lacotte's invention date

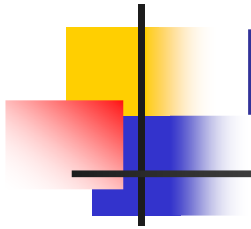
# Corroboration: Rule of Reason

- E.g., *Berges v. Gottstein*, 618 F.2d 771 (C.C.P.A. 1980):
  - Invention: cephalosporin compound (anti-bacterial)
  - Party Berges' "cohesive web" of evidence included:
    - Testimony of a Smith, Kline and French analytical chemist regarding her supervision of two elemental analyses of the sample asserted to represent the reduction to practice
    - Testimony of an SK&F sample custodian regarding her receipt of a "legal sample" pursuant to company procedures
    - Testimony of an SK&F lab director that "under his direction and according to routine," samples received from Mr. Berges were assigned a particular SK&F designation
    - Testimony of an "immediate supervisee" of Mr. Berges regarding his synthesis, at Mr. Berges' request, of starting materials intended for use in Mr. Berges' attempt to synthesize the compound in question
    - Plus testimony of microbiologists re in vitro and in vivo testing, and associated documents

# Credibility

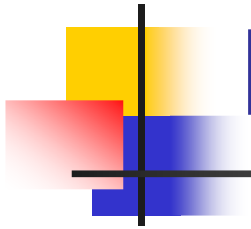
Problem:
How to imbue electronic records with the reliability of traditional research records?





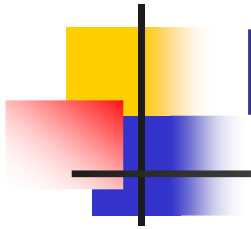
# Electronic Lab Notebooks

- Author's signature:
  - Neither necessary nor sufficient
  - Connects entries with authors (who can authenticate, and is he/she an inventor?)
  - Technologies:
    - "something you know"
    - "something you have"
    - "something you are"
  - Be prompt!



# Electronic Lab Notebooks

- Dating notebook entries
  - Accurate, automatic date-stamping
    - Internal document management system
    - Third-party “digital notary”/”surety” services



# Electronic Lab Notebooks

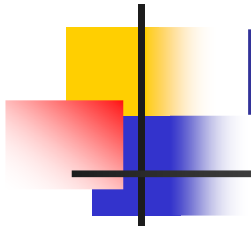
- Protection against alteration
  - Basis for many paper notebook procedures
  - Digital signature, digital notary, and “audit trail” technologies

# Electronic Lab Notebooks

- Witnessing notebook entries
  - Neither necessary nor (necessarily) sufficient
    - "on its own facts"
    - "evidence as a whole"
  - Benefits:
    - Witness' "signature" will corroborate the record's existence as of the witnessing date (assuming non-alteration safeguards) (Be prompt!)
    - Practical benefit: identify who is knowledgeable about relevant events

# Electronic Lab Notebooks

- Policy and procedures for use, storage, migration



# Electronic Lab Notebooks

- "The use of Electronic Laboratory Notebook (ELN) technology has risen sharply in the past four years, having now penetrated over 20% of all biopharmaceutical companies."
- "However, . . . over 70% of companies who have implemented an ELN still create paper printouts and apply 'wet' signature of the author and witness or what is known as the 'hybrid model.'"

Michael H. Elliot, *The Rules Have Changed*, Scientific Computing (May 2007)

# Electronic Lab Notebooks

- Additional resources:
  - Collaborative Electronic Notebook Systems Association (www.censa.org)
  - 21 CFR Part 11 ("regulations that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper") (http://www.fda.gov/ora/compliance_ref/Part11/frs/background/11cfr-fr.htm)

# Closing Thoughts . . .

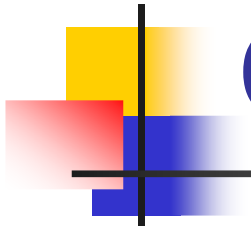
- Lab notebooks (paper or electronic) are one aspect of a larger system, including:
  - Policies and procedures
    - Regularity
    - Workability
  - People!

# Closing Thoughts . . .

- E.g., documents regarding inventive activity "do not ordinarily speak for themselves"
  - See, e.g., *Anderson v. Pieper*, 442 F.2d 982 (C.C.P.A. 1971) (notebook entries of deceased non-inventor, though admissible, are not "valid corroboration of [an] alleged reduction to practice")
  - USPTO Rule: "The significance of documentary and other exhibits identified by a witness in an affidavit or during oral deposition shall be discussed with particularity by a witness."

# Closing Thoughts . . .

- Bottom line: Invention dates don't prove themselves (whether the notebook is paper or electronic)
  - Legal definitions (e.g., conception, reduction to practice, diligence)
  - Does/how does proof align with subject matter (invention) at issue?
  - "Cohesive (corroborative) web"
  - Who can authenticate/testify as to what?



# Questions?