Maintaining Product R&D and Laboratory Notebooks in View of Intellectual Property Law

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What will happen years hence?

- Notebooks in patent prosecution
- Notebooks in patent litigation
  - Product(s) a commercial success
  - Patents infringed
  - Infringers will argue:
    - Not infringing
    - And besides, the patent(s) are invalid
  - Notebooks will be very closely scrutinized

Purpose

- Big picture
  - Protect the Company's patents (the patents are often a critical asset)
  - By creating legally sufficient evidence
  - And protecting yourself from becoming the focus of interrogations in a legal dispute
- IP Reasons
  - Determining inventorship – who? (may change in prosecution)
  - Prosecuting patent applications
    - Predating prior art (own accidentally/mistakenly created prior art)
  - Proving the origin of invention – When? Who? How?
    - Loss of invention to competitors because of bad record keeping
- Other Reasons
  - Supports integrity of the Company's research, technical reports, regulatory compliance
  - **Failure data to attack allegations of obviousness**

Legal Requirements for Use as Evidence

- Must be made in the regular course of business
- The entries in the record must be made by a person with personal knowledge of the acts or events recorded
- The record must be made at or near the time that the recorded act, event or condition occurred
- The record must have been kept in a consistent manner according to a set procedure (a procedure is created - it must be followed)
- If the record does not meet these tests, rules of evidence require that the person who authored the document can be cross-examined to determine his or her truthfulness
  - Depositions/trial testimony
  - Truthfulness interrogation may extend into private life

Factors that reduce the value and credibility of the notebook

- Illegible entries totally worthless
- Unsigned/undated pages are dangerous – mark each page
- Notebook pages that have not been witnessed are almost as bad as unsigned and undated pages (witness the signature and date)
- A long delay between the signing of the page by the inventor and the witness raises questions
- Consecutive notebook pages that are not dated in chronological order raise questions
- Missing notebook pages raise questions
- Erasures and deletions raise questions

Anatomy of an Entry

- Objective (the goal)
- Preliminary (approach—how to achieve objective)
- Equipment/reagent list
- Procedure (express or by accurate reference—all deviations recorded)
- Data
- Result/calculations
- Questions (with answer where known)
- Conclusion (factual and scientific)

Clarity

- The notebook must contain sufficient information to permit a technically sophisticated outsider, familiar with the field of research but unfamiliar with the jargon or practices of the Company laboratories, to understand the work that is recorded without the direct assistance of the original researcher

Must Tell

- What was done?
- Why was it done?
- Who suggested it? When?
- Who did it? When?
- Start date and completion date?
- What were the results? Positive and negative are important
- What does it mean?
- What conclusions were drawn?

Include

- Design and protocols of experiments
- Raw data and final results
- Calculations
- Abbreviation key
- Ideas and sources from meetings
- Plans for future protocols and experiments

Attach

- Readouts, printouts
- Drawings, photos
- Charts
- Signature crosses page and item edges

Practice

- OK to share notebook for given project if dated, witnessed and signed
- Cross reference material signed in different notebooks OK
- Lab notebooks coordinated to supplemental hard copy data *e.g.*, in binders (“LNXX#-Suppl A, B, C . . .”)

Maintaining the Integrity of the Evidence Permanent, Complete and Continuous

- Do not remove a page from a notebook for any reason, pages numbered
- TOC, abbreviations, codes
- Permanent, waterproof ink
- No skipped or blank spaces (draw lines through unused pages/zones)
- Legible
- Sign and date each entry
- Explain gaps in time (“working on other projects”)
- Corrections
  - Never erase, white-out or otherwise destroy legibility
  - One-line out, but leave legible, give reason for correction
  - Sign and date corrections; have them witnessed

Maintaining the Integrity of the Evidence Permanent, Complete and Continuous

- Each entry must be witnessed – same day best, within one week
- Witnessed and dated by a technically knowledgeable person who has read and corroborated the notebook entries
- Witness should not be co-inventor or co-worker on project, but someone who has basic knowledge of work
- If the entry involves a potential invention (which should almost always be the assumption), have it witnessed by a person who in not a co-inventor

Optimizing content

- Describe the purpose of each experiment (written description standard of patent law)
- Make conclusion factual
- Discuss new ideas generated by results
- Be careful with impressions
  - Legal standards of success or failure of a procedure, in the context of pursuing or defending a patent may vary greatly from your perceptions, and may vary from legal circumstance to legal circumstance
  - **Avoid** stating conclusions of failure or **abandonment**
  - Describe both successful and unsuccessful methods FACTUALLY and in detail, but don't editorialize and avoid facetious or malicious remarks—let the results speak for themselves
  - Avoid subjective entries "obvious", "didn't work"

Optimizing Content

- No comments on commercialization or effort required
- No negative comments re: project, results, quality or utility of results
- Avoid legal jargon/IP discussions/patentability opinions
  - Extends beyond notebooks
  - No matter how much you know - odds are you don’t know enough - rules change rapidly

Electronic data

- Read only CD cross-referenced to hard copy notebook
- Scan images, save pdfs, write to RO-CD
- Date and time
- TOC on CD in Word or Excel
- Digital certificate to each saved electronic document cross referenced to hard copy notebook
- Standardized naming conventions for folders and e-documents cross - referenced to hard copy notebook – consider ease of search in folder and file names, dating etc.
- Enter server back up data/routines in hard copy notebook
- At intervals, print screen-shots of folder and document hierarchies to affix in hard copy notebook – make it easy for successors to figure out
- Continuity of media storage, software maintenance, data must be available in form a human can read in perpetuity

Storing Lab Notebooks

- Fireproof safe or cabinet
- # by consecutive order, or per scientist's name
- Copied/scanned and stored at separate location

Advice

- Don’t let delays pile up
- If mistakes are made—don’t ignore them—fix them as best as possible and move on
- Don’t assume that experiments aren’t important
- Make sure significant events are recorded
  - Even though this usually is the busiest time
- Fix previously learned bad habits
  - If the job is to generate IP, a bad notebook keeper who is a brilliant, productive scientist is little better (and maybe worse) than a second-rate scientist/good note-book keeper from the perspective of the IP contribution to business value