Proper Use of Laboratory Notebook for Intellectual Properties Protection*

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*For Educational Purposes only

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Abstract

A laboratory notebook contains records of experiment that allow others such as successors to replicate what has been done earlier where further advancement may be built on. More importantly, it may be used to validate and defend one's invention and claims against any accusation of fraud. In this presentation, some general guidelines on the management system and specific recommendations on the proper use of laboratory notebook will be highlighted

Laboratory Notebook and Intellectual Property

1) Laboratory Notebook

- A primary record that documents hypotheses, experiments and initial analysis or interpretation of these experiments.
- It is a legal document
- It serves as an organizational tool, a memory aid, and can also have a role in protecting any intellectual property that comes from the research

2) Intellectual Property (IP)

- Creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

- Examples: patents, copyrights, trademarks

Invention

1) Idea Conception
   The "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice by one skilled in the art. Patentable but not strong

2) Actual Reduction to Practice
   The claimed invention is carried out and found to work for its intended purpose via actual operation, demonstration, and testing.

   One of the ways to show the evidence: Laboratory Notebook

Actual Reduction to Practice

To prove the actual reduction to practice,

1) No need to be in a commercially viable state but must operate well
2) Evidence of a constructive reduction to practice may not be enough
3) Requires a viable final product.
4) If a device is simple and straightforward enough, successful construction alone may serve as an actual reduction to practice.
5) Testing under lab conditions must either duplicate every condition of actual use or demonstrate a relationship between the subject matter, test condition and intended functional setting of the invention
6) Consult the expert for clarification

Importance of Novelty

Granted patent may be invalid if there is no prove that the claims work, or are obvious, anticipated, of prior art.

Experts may be called to testify what is claimed when disputed

Case Study

Shen Wei Vs Sempermed. For the full article:
https://casetext.com/case/shen-wei-usa-inc-v-sempermed-usa/

> In sum, the Court holds that all of the claims of the '582 Patent are invalid. Claims 1-16, 18, 22-23, 25-29, 33-35 and 44-51 are anticipated by the prior art Ostar® glove and manufacturing process. Claims 17, 19-21, 24, 30-32 and 36-43 are obvious in light of the prior art.

Note: '582 = US Patent 6953582

Importance of Laboratory Notebook

Externally, as evidence for

- Invention; reduction to practice, defending data against accusations of fraud
- Invalidating claims in granted patent owned by others
- Proof of novelty: not within the scope of prior art
  : not obvious / anticipated

Internally, as records for

- Reproducing the invention in the absence of the inventor
- Reference for further improvement, enhancement by others

One does not own lab notebook. It belongs to the institution for which he is working.

One cannot take it home for any reason.

Photocopy for reference is normally allowable

General Guideline for Laboratory Notebook SOP

Part of QMS

SOP for QA department and user

SOP for QA

- Registration, signature, records on date of issue, date of return, ID of lab note book
- Safe keeping of archive copy, in-out movement
- Implementing & revising SOP's for QA and users
- Conducting training, training effectiveness, auditing to ensure SOP compliance
- Practical, clear with examples, user-friendly.

Input from all stakeholders

SOP for notebook User

- SOP training, and retraining when SOP is revised
- Using laboratory notebook according to the SOP
- To be audited

Typical Format of a Laboratory Notebook

Bound copy, not too thick
Notebook ID number in sequential,
QA to register user's name, Notebook ID
Date of issue and date of return (for archive),
Project name/title, project code for notebook
Page number on each page
Table of content (page no, date, experiment title), for easy finding a particular experiment
Table of abbreviations used in notebook
Format for each page:
    - Title / subject,
    - Space for record / entry,
    - Date of record, name and signature of user,
    - Date, name and signature of witness

Entries / Experimental Records in Laboratory Notebook

Title

Objective: Brief statement of purpose

Background of study, Introduction

- Include discussions, thoughts on the goal.
- Paste suggestions from team members (e.g. email), superior such as email.
- Idea from other industry, photos, link to video

Procedure, Protocols, Methods, Reagents / Equipment used

- Print out & paste ok.
- Indicate test plan, sample size, goals, target results (acceptance criteria)
- Explain each step in the experiments
- Calculation methods, e.g. statistics
- Source of materials / chemicals, e.g. commercial, university, colleagues. Include the relevant information (date produced, expiry date)

Entries / Experimental Records in Laboratory Notebook

Observations:
Description of all that is found during experiment
Records on environment factors, temperature, humidity, air movement, vibration (environment factors important for reproducibility / repeatability) – operating conditions
Raw experimental data records
Information or reference to data location
Data analysis:
Processing of raw data, graphs, interpretations, discussion
Complete records should be done within a specific time specified in SOP
References, ideas for future experiments
Each page contains the date of record, name and signature of investigator and witness
Witness to be done within a specific time period specified in SOP
No back dating

General Guideline

Records should be in sufficient detail, self-explanatory, to allow others to replicate the experiment, reproduce the same / similar results

Permanently paste attachments such as grafts, charts using adhesives such as glue.

- At least include date, experiment name, reference number and initials
- The signature should cross both attached material and notebook page.

Start a new page for a different experiment, or on a different day

When different experiments are conducted in parallel or different investigators, summarise the results in a new page in one notebook with references to the experiments

For repeat experiment, references to the earlier page may be made without repeating the description, or with minor modifications indicated

Only project related matters are recorded objectively

Common Issues

Transfer from another notebook / jotter, not recorded directly
Records not updated timely
Not witnessed timely
Incomplete records / description. Examples: machine / instrument number, oven number
Important reference used not cited
Records no legible
Unused space not crossed out
In-house terms / abbreviations without explanation / definition
Attachment not permanently pasted
Scattered data without a summary
Location of raw data not indicated
Raw data not processed
Statistical tools not used in the data analysis, results inconclusive

Dos and Don’ts

Do	Don’t
Record directly as the experiments progress, preferably on the same day	No copying from or pasting of other notes, such as jotters. No back dating

Do	Don’t
Use permanent ink writing tools	Don’t use erasable pens or pencils

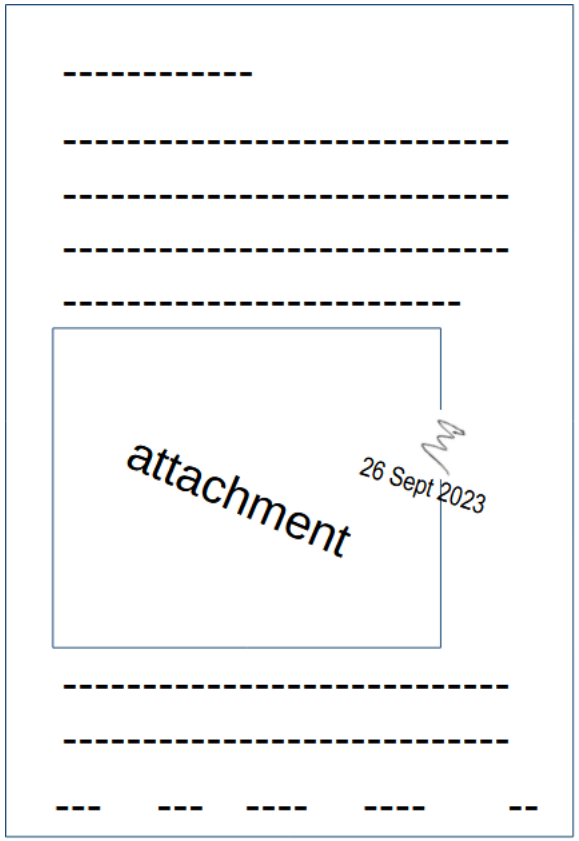
Do	Don't
Cancel any error with a single line, initial and date by the record-keeper ~~Erorr~~ 26 Sept 2023 Error ✓	Don't over-write errors. Don't use correction fluid. [redacted] 26 Sept 2023 ✗

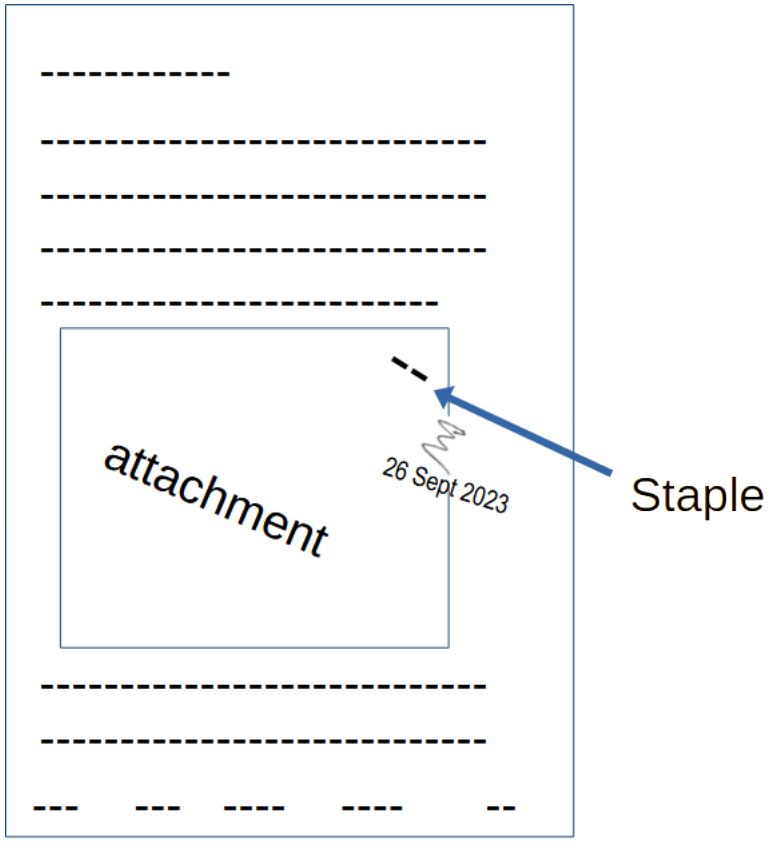
Do	Don’t
Draw a diagonal line across the unused portion of a page	Don’t leave any empty space in a page. Don’t skip any unused page

Do	Don’t
First day of March 2023 should 1st March 2023 or 01 March 2023 Use am/pm for time in records	Don’t express the date as 1/3/2023 Don’t express time without indicating am/pm

Do	Don’t
Record other experiments on a different page or different lab notebook	Don’t record different experiments on the same page

Do	Don't
Attachment permanently pasted, e.g. glue, dated and signed across	No loose attachment, e.g. with a staple





Do	Don’t
Records must be consecutively dated	No earlier date on later page, vice versa

Do	Don’t
Record objectively and explain clearly.	Don’t pass personal judgement, e.g. “experiment failed”, unexplained mark “?”

Do	Don’t
Explain discontinued experiment and close	Don’t leave uncompleted experiment hanging

Do	Don’t
Use standard language where others can understand	Don’t use slang, internal terms which may be misconstrued or misunderstood

Do	Don’t
Keep notebook clean and in “original” conditions	Don’t tear or remove any page

Do	Don’t
File all supporting documents orderly and indicate the storage location in notebook	Don’t get mixed up other project

Concluding Remarks

Laboratory note could be evidence of invention, reduction to practice and scrutinised by external parties

Important to keep the records authentic

Imperative to have a guideline in the form of SOP, with examples, for consistency and uniformity

SOP needs to be practical for implementation. Not just looks good and impressive

SOP needs regular reviews and revisions to stay relevant. Input from the users

Regular audit is needed to ensure notebook records are in compliance with the effective SOP

Traceability of supporting documents not in the notebook is equally important

End of Presentation
Thank you