MAINTAINING LABORATORY NOTEBOOKS

In the event of litigation, it may be impossible to prove what happened in the laboratory—when an experiment was performed or who performed it—unless all the facts have been recorded in the laboratory notebook. A notebook that provides a permanent, consecutive, complete, and contemporaneous record of what occurred can save an enormous amount of time and money should litigation occur, and could mean the difference between victory and defeat.

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Scientists and engineers keep laboratory notebooks to meet their own need for a record of their data and ideas. Laboratory records also may become useful in legal proceedings, and an R&D organization that maintains its notebooks in a form that provides credible evidence can enjoy a distinct advantage should litigation occur.

Laboratory notebooks and other documents play a particularly important role as evidence in litigation involving patents. Patent litigation often does not arise until years after the events at issue took place, when detailed memories of the lab work have faded and key personnel may no longer be available. Bald, undocumented statements by an individual claiming to have performed certain acts years ago may be given very little weight. When supported by well-kept laboratory notebooks, however, the same testimony may command credibility and prove decisive. Contemporaneous documents therefore assume a central role as evidence in patent cases.

A laboratory notebook, or any other such document, should have the following attributes:

- Its form and circumstances must convince the finder of fact that the document is authentic and has not been tampered with.
- It must provide a record of the facts to be proved in the legal proceeding.
- It must impress the finder of fact as being credible.

This article describes techniques for maintaining notebooks in a manner that will maximize their value as evidence in a future legal proceeding. Although most of the suggested practices are not absolute legal requirements, following them may provide significant advantages should litigation occur.

WITNESSING THE ENTRIES

By itself, a laboratory notebook ordinarily is considered to be hearsay; without the testimony of a witness who can attest to its authenticity and explain its contents, it is not admissible as evidence. There are exceptions to this rule, but generally it is desirable that the person who actually made the entries be the one to testify regarding the work described in the laboratory records and the practices that were followed in maintaining them. If the individual responsible for recording the

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experiments has followed a consistent procedure that ensures an accurate account of details and results, he or she will be able to confidently recount the facts concerning the work recorded on a particular page of the notebook when called on to testify.

Even when the person who actually made the notebook entries has died, is uncooperative, or is otherwise unavailable to give testimony, it is usually still possible for laboratory notebooks to be admitted into evidence. A common tactic is to rely on the testimony of a witness to the notebook entries. This is one of the benefits of the practice of a coworker's reading and signing of laboratory notebook entries. The greater the witnesses' familiarity with the work, and the nearer the witnessing to the period when the work was actually conducted, the more valuable will be the testimony in allowing the notebook record to be introduced as evidence.

Given their potential importance, both the witness and the person who actually did the work and kept the record should sign each entry in the laboratory notebook. In addition to supplying the identities of those most qualified to testify from firsthand knowledge regarding the facts recorded in the notebook, signatures can help refresh stale memories of work performed or witnessed years before, and can lend additional credence to testimony about the work described in the document.

Although it may seem that the person testifying about the document merely has to vouch for it and let the record speak for itself, the finder of fact will require someone to speak about the work described; documents such as the notebook will merely support that testimony. Faithful recording and signing of the notebook records will aid both in presenting that testimony and in supplying the supporting documentation.

TYPES OF LITIGATION

Laboratory notebooks figure prominently in two types of litigation: interferences, which take place in the Patent and Trademark Office (PTO), and patent infringement suits, which take place in federal district court. The rules in these two types of litigation differ, and the facts that are most important can also differ.

Interferences

An interference is a specialized litigation that occurs when the same invention is produced at about the same time in different, independent organizations, and each inventor attempts to obtain a patent. In such a situation, the PTO must decide which of the parties is entitled to the patent.

In every nation but the US, the patent is awarded to the first party to file a patent application. Instead of such a first-to-file system, the US has a first-to-invent system in which the testimony of witnesses and such evidence as laboratory notebooks are examined to determine who first conceived the invention and who first actually made it (or reduced it to practice) within this country. The individual deemed to be the first to invent has priority and is entitled to the patent.

Many outside the US charge that the first-to-invent system gives American inventors an unfair advantage, because the PTO will only consider evidence about inventive activities within the United States. Consequently, the PTO has been pressed to adopt a first-to-file system, and there has been much discussion regarding the possibility of conversion. So far, however, the approach to determining the first inventor has not changed, and laboratory notebooks and similar records will continue to play a vital role in interference proceedings for the foreseeable future.

One of the peculiarities of interferences is the requirement that someone other than the inventor provide independent corroboration. Hence, the PTO will not consider the inventor's notebook records to be sufficient corroboration, but instead will look to the testimony of an individual who is not an inventor but who is familiar with the work that the inventor conducted.

The corroborating witness may be a technician who performed experiments under the inventor's direction, a coworker who witnessed the inventor's notebook entries, a manager who is familiar with the inventor's ideas and how

Thorough, signed, and dated records of the details of lab work can make testimony easier, more reliable, and less subject to attack in future legal proceedings.

those ideas were reduced to practice, or any other individual who can substantiate the inventor's claims about when and how the invention was produced. Often, different individuals are required to corroborate different aspects of the inventor's story. In all cases, however, contemporaneous documents can shore up testimony and support the inventor's case.

Patent Infringement Suits

A more familiar form of litigation are lawsuits over patent infringement. A patent owner can sue another party for infringement. In some circumstances, a party that fears being sued for infringement can act first, by asking the court for a declaratory judgment that the patent is invalid or was not infringed. In either case, many issues will typically arise involving laboratory notebooks and other records documenting the experimental work of both parties.

The patent owner's laboratory notebooks are likely to come under intense scrutiny. The party accused of infringing the patent will employ discovery procedures to comb these laboratory notebooks for evidence of an invalid patent. On the other hand, the patent owner may use the notebook entries in the defense against charges of invalidity.

The notebook records of the accused infringer will be reviewed to determine whether the patent was copied or the product developed independently. The accused infringer's research work may be used to prove whether the patented invention is merely a minor variant or a major breakthrough.

In infringement litigation, corroboration by noninventors is desirable and often crucial, but it is not essential in the same way that it is in interference proceedings. Moreover, under the Business Records exception to the hearsay rule, certain records regularly kept in the normal course of business can be admitted into evidence without testimony from the individual who actually maintained them. However, because the PTO is less accepting of this exception in interferences, it is prudent for authors and witnesses of laboratory notebooks and other research records to maintain these documents as if they may someday be called upon to testify to the work described. They should prepare the documents so as to enhance their own ability to relate the facts recorded and reduce the risk that the record or their testimony will be challenged as inaccurate, incomplete, or unreliable.

Laboratory notebooks may also be used as evidence in other types of litigation (e.g., lawsuits alleging theft of trade secrets) or even academic investigations of alleged scientific fraud. The benefits of maintaining laboratory notebooks with an eye to their potential as evidence in patent infringement suits also apply to these other types of litigation and investigations.

PERMANENT, COMPLETE, AND CONTINUOUS RECORDS

One way to minimize the risk of challenge to laboratory records is to keep them in a permanent, complete, and continuous form. When this is done, inadvertently omitted information, such as undated work recorded between two dated pages, can be credibly deduced. It can also help to reinforce the impression that the records were not forged or recently altered. For the same reason, laboratory records should be kept in bound notebooks. Commercially available laboratory notebooks are a convenient medium and generally provide spaces for dates and the signatures of researcher and witness. Ideally, entries should be consecutive with no empty spaces.

Entering information consecutively without leaving empty spaces can be inconvenient when many experiments are underway simultaneously or experiments extend over long periods of time. One solution is to record concurrent experiments in separate notebooks or on data sheets that are later secured in the notebook or in separate notebooks. Another approach is to record multiple experiments in a single book and cross-reference the pages relating to the same experiment. Some researchers indicate at the top of each page the earlier page of which it is a continuation, and at the bottom of each page the subsequent one on which the next entry relating to the experiment can be found.

All entries should be made in indelible ink;

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pencils should not be used. Some researchers use pens with different-colored inks on the same notebook page, either because they grab pens at random or because they want to highlight specific notes. If the use of multiple colors conforms to a system meant to convey information, some key to their significance should be included in the notebook.

The fact remains, however, that the meaning of different ink colors is not likely to be recorded, and may well be forgotten by the time a researcher testifies. Doubt may be cast on exactly when a particular notation was made on the page. Furthermore, ordinary photocopies do not register color, causing information to be lost. Finally, ignorance of the meaning of the various colors can diminish the value of a witness. For these reasons, it is preferable for notes to be made in one color with one type of pen. If it becomes necessary to use noticeably different inks on the same page, the researcher should make note of the reason (e.g., the pen ran out of ink) so as to avoid these problems.

Frequently, loose sheets of paper have to be inserted between pages of the notebook. Such inserts may include graphs, computer printouts, printouts from recording devices, photocopies of standard protocols, photographs, or specification sheets for special reagents. Saving such materials inside the laboratory notebook is a desirable practice, but they should not remain loose. Instead, glue, staples, or tape should be used to affix them permanently to the pages of the notebook. These materials should be signed and dated when they are added to the notebook.

Sometimes it is necessary to change or amplify notebook entries—to correct calculations, complete a table once the data is complete, or note new ideas. When this occurs, each addition should be separately dated and initialed by the individual responsible. If the reason for a change or addition is not obvious, an explanation should accompany the alteration.

When an experimenter decides to discard data that has already been entered, it should be crossed out rather torn out of the notebook. Preferably, an explanation for the change should be recorded. If blank spaces remain on a page or pages have been skipped, a line drawn through them will serve to indicate that they are intentional.

Record Dates Religiously

Dates are often important in infringement litigation, and they are critical in interferences. Valuable patent rights can be lost if critical entries in an otherwise well-maintained laboratory notebook have been left undated. It is therefore important to make a practice of recording the date of every entry in the laboratory notebook.

Each entry should be signed and dated by the person making it. If an entry extends across several pages, each page should be signed and dated at the time the entry is made. When a single page contains several entries from different days, each entry should be dated separately. Signing and dating should not be limited to entries that record data; those that record ideas should also be signed and dated, as should entries setting forth protocols for future experiments. Subsequent corrections, additions, or alterations should also be dated and signed (or at least initialed).

Whenever extrinsic materials, such as raw data from recording instruments, photographs, or specification sheets, are added to a notebook, they should be signed and dated. Sometimes, researchers will stretch their signatures across the added document and the underlying notebook page, making it clear that the attachment was affixed to the notebook before it was signed.

NON-INVENTOR WITNESSES

After notebook entries have been signed and dated by the researcher, each page should be signed and dated by a witness. This should occur as soon as possible after the original entry was made. Although there is no legal rule that an entry must be witnessed on the same day that it is made, prompt witnessing is preferable to waiting for weeks or months afterward. If witnessing is not done regularly and promptly, it can easily be overlooked altogether.

The witness should be someone who can read

Such inserts as graphs, computer printouts, and specification sheets should be signed, dated, and permanently affixed to the pages of the notebook.

and understand the entry. Otherwise, the witness will be able to testify to signing the page, but probably not to its contents. A technically sophisticated witness, on the other hand, will be able to testify to the notebook's contents and perhaps even give evidence that a page has not been altered.

Because of the rule in interferences that evidence presented by an inventor must be corroborated, every notebook entry made by an inventor should be witnessed by someone who is not a joint inventor. Although notebook entries made by individuals not named as inventors on the patent do not necessarily have to be witnessed, it is foolish to fail to have entries witnessed on these grounds. Often a technician, student, or other worker who is not a principal scientist will make some intellectual contribution to a project, and therefore be listed as a co-inventor on the patent application. Such a person will then no longer be available as a corroborator. One way to avoid this problem is to use witnesses who are not working on the same project. It should be kept in mind that if a notebook entry is not witnessed by the noninventor until sometime after the original entry was made, the inventor in an interference may only be accorded the benefit of the later of the two dates.

The purpose of all this signing and dating is to insure that there is tangible evidence of when events occurred in the laboratory and to identify witnesses who can testify about those events. Although it may seem tedious, enforcing the practice of regular signing, dating, and witnessing of all entries is easier than attempting to continually evaluate each entry for its potential legal significance. There have been interferences in which the same critical events were performed independently in competing laboratories only a few days apart. Unless laboratory personnel make a habit of signing, dating, and witnessing every entry, the evidence on which a legal victory depends could be lost.

SELF-EXPLANATORY ENTRIES

If a laboratory notebook is to be useful as evidence, it must record the facts that need to be proved. Besides the date on which the entry was made and the identity of the author and witnesses, relevant information could turn out to be any fact or detail of the laboratory experiments. Because it is impossible to predict what will be important in any litigation, the records should err on the side of thoroughness. A rule of thumb is that a laboratory notebook should contain enough information for a technically sophisticated outsider, familiar with the field of research but not with the jargon or idiosyncratic practices of a particular laboratory, to understand what was done.

When notebooks have been maintained with this principle in mind, a great deal of time and expense can be saved during litigation. One of the most costly and time-consuming parts of litigation is discovery, in which all laboratory notebooks may have to be combed for relevant information. Moreover, specific types of information may be requested by the opponent during discovery. If notebooks are illegible and incomprehensible, this process can be excruciatingly slow and expensive. A great amount of money and effort may also be required to reconstruct and prove, using circumstantial evidence, important facts that should have been recorded. Indeed, if adequate details were not recorded at the time, it is not unusual years later for the researcher to be totally unable to remember what was done.

Entries should be legible, because people other than the author may have to interpret them. The notebook should include not only data but protocols and designs of experiments, not only final results but the calculations on which the results are based. Abbreviations should be explained. Explanation of terms is especially important when the same term (e.g., Sample 1) over time comes to refer to different entities. The goal should be a notebook that is self-explanatory.

Searching a notebook for specific information can be greatly simplified and accelerated if the entries relating to each experiment have a heading or title and contain a brief explanation of the experiment's purpose. It can also be extremely helpful when a separate index is included at the front of the notebook.

When the same type of experiment is repeated

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frequently, researchers may be tempted to note only departures from the standard. As a result, basic constant parameters, such as temperature and the manufacturer and model of equipment used, may not be recorded anywhere in the notebook. However, it is important that all such details be included. Standard protocols or recipes can be described once and then cross-referenced to other experiments. The burden of writing down the same details repeatedly can be eased by taping technical data sheets of reagents, photocopies of protocols from other notebooks, or methods sections from published papers into the notebook. It can also be useful to make cross references to pages within the notebook, and even in other notebooks, on which methods are described in detail or abbreviations are explained.

Although it may be a chore to include so much information in the laboratory notebook, such a record can be useful not only as legal evidence but also to coworkers or supervisors who need to consult the notebook when the original investigator is not available.

OTHER LEGAL CONSIDERATIONS

From a purely legal standpoint, it can sometimes help a case when a laboratory notebook contains a conclusion indicating that an experiment was a success. On the other hand, a conclusion stating that the experiment was a failure, or implying reservations about its success, can in certain circumstances hurt a case, even when in hindsight it is clear that the experiment was successful. For this reason, some attorneys feel that it is best to record only positive conclusions and results.

This practice, however, is counterproductive. A deliberate of slanting the contents of laboratory notebooks can diminish the overall credibility of the records. In any event, laboratory notebooks are kept mainly to assist investigators in their work, few become evidence in litigation. Therefore, investigators should not be prevented from recording in their notebooks whatever will be most helpful to their work, including analyses of failed experiments.

Finally, it is very difficult to anticipate what will be legally significant in future litigation. Sometimes, what at first appears to be failure may turn out to have application to a patentable invention. In general, it is unnecessary and unwise to censor laboratory notebooks with a view to their potential as evidence.

However, it is also true that a notebook should not contain remarks that could be an embarrassment if made public during litigation. For example, it might be difficult to explain away a note suggesting that an idea was stolen from someone else, even when made in jest and entirely untrue. Expletives and derogatory or facetious comments can be used by opponents to dramatize their case, and should be avoided.

It is also wise to avoid using terms that have a specific legal meaning. One such word is *obvious*. If a laboratory notebook states or implies that an idea is obvious in view of known information, it will be difficult to contend in court that the idea the basis for a novel, patentable invention.

Electronic Records

In many laboratories, computers have changed the way records are kept. Investigators who are already accustomed to using the computer as a tool for data analysis frequently use it to store their daily records as well. Observations and notes are entered using a word processor, and are printed only if needed. This form of record keeping is extremely convenient, but its acceptability for legal purposes is unclear. The problem is that computerized records can easily be edited, and the existence and timing of alterations cannot always be detected. A means of witnessing electronic records will also have to be devised.

Various ingenious methods have been proposed that would allow R&D organizations to store their electronic records in such a way that their authenticity could be established later on. These involve various methods for making duplicate, tamper-proof copies. One technology that shows promise is write-only optical disk storage, because records stored in this way cannot be erased. However, the legal rules pertaining to the use of digital records as evidence have not yet been worked out, so the safest policy is to print copies and then sign them and have them

Laboratory personnel should be permitted to record in their notebooks any information that will be helpful to their work, including the results of failed experiments.

witnessed like traditional notebook entries. Printouts should be attached permanently to a notebook, or otherwise bound into volumes.

Some investigators like to revise and annotate their electronic files as new information accumulates. When this is done, the revisions should be printed out, dated, and witnessed. The hard copy should be retained by a custodian who can vouch for their integrity.

A TOOL OF THE TRADE

Maintaining a clear, comprehensive laboratory notebook takes time and effort, but it can bring important benefits. A research organization should therefore provide the necessary time and support. Maintaining notebooks should be an expected (and rewarded) part of the job, rather than a task apart from research work, to be squeezed in when time permits. ■

CHEMISTRY | LAB 1 - TITRATION | 2/8/00

JUDY SMITH
PAUL GREEN

1:30 PM

Basic Information

A. TITRATION OF 50 mL OF 0.1M HCL WITH 0.1M NaOH

Procedure Description

NaOH ADDED (Independent Variable)	pH (Dependent Variable)
0.0 ML	1.00
10.0	1.17
25.0	1.48
45.0	2.35
48.0	3.01
49.5	3.30
49.75	3.60
50.00	7.02
50.25	10.40
55.0	11.68
60.0	11.96
80.0	12.01

MAY HAVE MISSED pH MARK

Notes on Important Events

COULD HAVE STOPPED HERE

Other Relevant Information

B. TITRATION OF 50mL OF UNKNOWN A WITH 0.1M NaOH

SOLUTION OF HCL AT UNKNOWN CONCENTRATION

NaOH ADDED (Variable Titles)	pH
0.00 ML (Units of Measurement)	0.90
5.00	1.08
15.00	1.97
20.00	2.56
22.00	3.77
22.50	6.82
22.75	9.94
23.00	10.45
30.00	11.55
40.00	11.89

BIOLOGY | LAB 2 Cells + Kingdoms | 1-27-00 12:45 PM

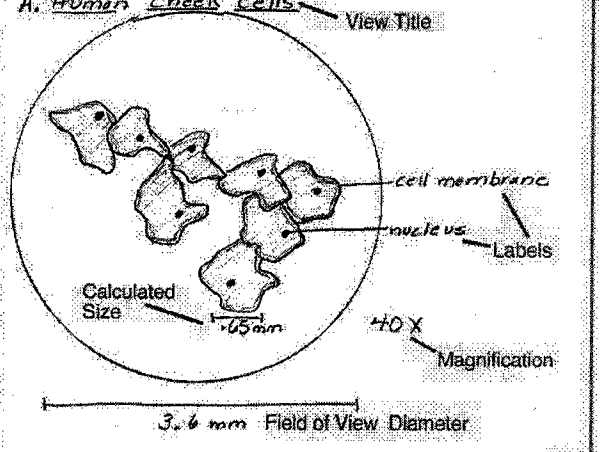
JUDY SMITH

Basic Information

I Draw a generalized plant/animal cell with Field of View, total magnification, and cell size.

Procedure Description

A. Human Cheek Cells (View Title)



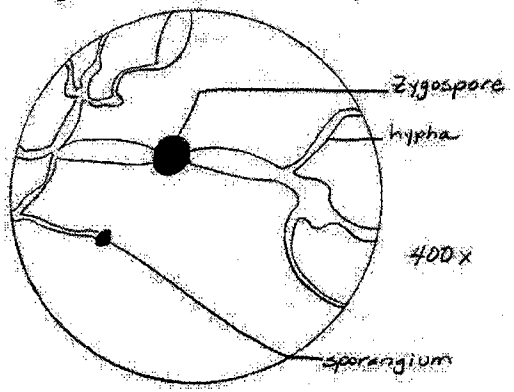
View

Notes:
- cells are irregularly shaped
- cells clump together

Other Relevant Information

II Draw representatives of each kingdom

A. Kingdom: Fungi Rhizopus



Notes:
- very thin strands
- in the class Zygomycota (Bread mold)