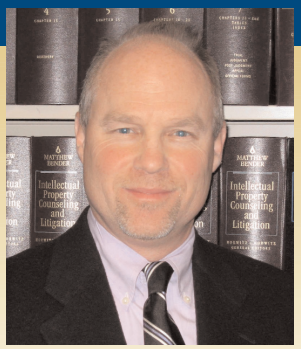

John W. Boger, Esq.
Heslin Rothenberg Farley & Mesiti P.C.

Laboratory Notebooks: Why They Are So Important

I had the honor of giving a presentation at OMTEC 2009 on the adequacy of invention disclosures. A lively discussion broke out regarding laboratory notebooks, including the use of hardcopy vs. electronic formats. (It is worthy to note that the audience members still overwhelmingly preferred paper lab notebooks rather than electronic/computer-based documentation systems.)

Lab notebooks are an inventor's most important documentation tool, and must be kept in a manner that evidences that the inventor is the one who invented an idea first. Unlike the rest of the world, the U.S. is a "first-to-invent" jurisdiction. Thus, if conflict arises between two people over gaining a patent on an invention, the patent will be awarded to the person who invented it first. All other countries follow the "first-to-file" doctrine, which results in a race by inventors to the local patent office to submit applications. Patent reform legislation is slowly making its way through the U.S. Congress, and it has been rumored that the final law may include a change from "first-to-invent" to "first-to-file." In the interim, all U.S. inventors should proceed with the "first-to-invent" mentality.

For an inventor to prove that he is the "first-to-invent," his lab notebook is the most critical objective evidence. A lab notebook, when kept properly, will provide clear evidence of the date on which the invention was conceived. Conception of an invention is defined per §2134 of the *Manual of Patent Examining Procedure* (MPEP) as "the complete performance of the mental part of the inventive act and is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice." The MPEP states further in §2134 that "conception is established when the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill." Clearly, the lab notebook and the entries made within it will likely be the sole location of any evidence of conception. Further, if used correctly, the lab notebook will also evidence that the invention has been reduced to practice. MPEP 2135.05 (II) sets forth that actual reduction to practice of an invention is found when the embodiment or process has operated for its intended purpose. By having clear evidence of conception and reduction to practice, one can then prove a priority right or, in other words, an earlier invention date over someone else's patent or application.

The strongest proof of priority is first corresponding oral testimony of a non-inventor of the occurrence of conception and reduction to practice. The second strongest proof is physical evidence, which typically exists in the form of a laboratory notebook that has been witnessed by a non-inventor learned witness.

Along the same lines of establishing the right priority for an invention, lab notebooks are also used to "swear behind" a cited reference when claims in one's application have been rejected, and the effective date of the cited prior art reference falls *after* the date of your invention. "When any claim of an application…is rejected, the inventor of the subject matter of the rejected claim…may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference." (37 C.F.R. 1.131.) Thus, for certain situations, an applicant may submit to the U.S. Patent and Trademark Office a "Rule 131" affidavit or declaration that shows that the inventor had previously invented the invention (i.e., what she did and when she did it) and where the work was done. To substantiate that an applicant has priority for an invention, she will need to establish that the invention was reduced to practice, or that conception of the invention

occurred and was coupled with diligence on the part of the applicant to actually reduce the invention to practice or to diligently file a patent application. As you would expect, written evidence of conception or reduction to practice includes, among other things, reproductions of lab notebook entries. These entries need to include actual dates of occurrence of conception or reduction to practice and dates of activities that show substantial diligence on the part of the inventor. Diligence may be established by presenting actual dates and descriptions of the corresponding steps/actions taken by the inventor following conception to actually reduce the invention to practice or to file a corresponding patent application.

Lab notebooks also play crucial roles for inventors when the time comes to complete an in-house invention disclosure form or when describing the invention to a patent attorney in preparation of filing an application. Lab notebook entries are the foundation for providing the patent attorney with the information necessary to create an adequate patent application specification that satisfies the legal standards listed in the patent law found at 35 U.S.C. §112. Specifically, the law indicates that the specification must provide a written description of the invention in full, clear, concise and exact terms so as to enable any person skilled in the art to make and use the invention defined by the claims without undue experimentation. The written description must also spell out the best mode to carry out the invention as contemplated by the inventor at the time of invention.

Finally, notwithstanding all of the legal reasons for keeping a lab notebook, there are many practical reasons to implement and follow such a procedure in your company or institution. For example, researchers may be requested to keep such lab records due to contractual obligations within a joint venture or sponsored research agreement. Specifically, such agreements routinely include a mandate that lab notebooks be used to document milestone achievements and track timelines for experimentation progress. In addition, it is common for both private and governmental funding grants to include provisions that require the inventor/investigator to maintain certain research records to evidence progress and to make these documents available for inspection when funding renewal reviews are performed. For example, the National Institute of Health has the legal right to audit and examine records relevant to any research grant award that they make. This would extend to laboratory notebooks.

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Having discussed the numerous scenarios that support the need for lab notebook maintenance, here are some guidelines on format and upkeep. As a preliminary matter, it is a best practice for any sized entity or institution to establish, distribute and train all research personnel on a written protocol for keeping both paper and electronic laboratory notebooks or records.

For numerous reasons, the majority of the scientific community continues to use paper lab notebooks. With this trend in mind, below are eighteen tips that may be considered when establishing your own internal laboratory notebook guidelines/protocol for your staff.

1) Use a permanently-bound notebook. The binding should be glued or sewn together. Three-ring or spiral notebooks should not be used. (See #3.) A resource for hard copy laboratory notebooks is the BookFactory®, shopping.netsuite.com/bookfactory.
2) Number, sign and mark the cover with a start date.
3) Consecutively number, sign and date each page of the lab notebook as the page is completed. Pages should never be removed or *torn* from the binding.
4) Dated and initial each entry in the lab notebook. An independent "learned" witness (i.e., non-inventor person who understands the technology) should sign and date each entry after the following statement has been printed "Read and understood by [name]." Of important note, a witness should be a person who is not connected with the invention. This prevents the problem of having a person who later may be deemed an inventor disqualified as an impartial witness to the records. Witnesses should sign the entries contemporaneously, if possible (daily is best, weekly is fine and monthly is marginal).
5) Make entries into the notebook in ink and in chronological order. If an entry contains an error, a single line or an "X" should be used to cross out the mistake and the correct text should be inserted adjacent to the deletion. Do not use Wite-Out® or other redaction materials. Some institutions will even recommend what type of pen is to be used for lab notebook entries. (See www.swarthmore.edu/natsci/cpurrin1/notebookadvice.htm.)
6) Avoid blank spaces or gaps within the lab notebook. If an empty space is left on a page, a line or an "X" should be drawn through the space. This will avoid any accusations of data insertion at a later date.
7) Outline the objective and basis for the experiments in the lab notebook, including flow charts, pictures and graphs.
8) Diligently record all relevant lab meetings and discussions, ideas and suggestions made by attendees and include the names of attendees making such suggestions.
9) Record all testing conditions and protocols in detail, including preferred ranges, temperatures, etc. and any alternative or optional materials/conditions. Record all test results and analysis of the results. Conclusions drawn from results should be brief and supported by the data. Do not include commentary or opinions.
10) Make no modifications or amendments to entries at a later date. If data or a result is omitted, the new data/result should be entered under a new date and a cross-reference note to the previous entry should be made. Experiments should be recorded *only* when performed.
11) Use past tense language, like "was mixed" to describe experiments or evaluations that have actually been performed.
12) Permanently attach loose materials, like computer printouts or graphs, to pages via staples or glue. The attachment and page to which it is attached should be signed and dated. If the loose materials cannot be attached, then the loose materials should be kept in a separate folder or notebook. The separate folder should be signed, witnessed, dated and referenced in the original notebook.
13) Include a table of contents and a key to any abbreviations used.
14) Outline new experiments, including the rationale and objective.
15) Identify all material sources (e.g., manufacturer, lot number, expiration date) and equipment information (e.g., model number, date of calibration, etc.) used in the experiments.
16) Record entries in English and use plain language.
17) Save, index and store all completed lab notebooks in a centralized secure location within the research facility.
18) Keep "in-progress" lab notebooks confidential and in a secured location when not in use by the investigator /researcher.

As briefly discussed above, the move from paper to electronic lab notebooks has been slow and full of unknowns, chief of which is whether courts will accept the latter as corroborative evidence of inventive activity. The basis for this uncertainty centers on the level of security of the recording software and the reliability and authenticity of the electronic signatures of the inventor and witness.

A quick Google search reveals many software packages currently available for the adventurous inventor. (See www.asapfolder.com or the E-work Booksuite at www.idbs.com.) On their faces, electronic lab notebooks have many advantages over their paper counterparts. The first is the potential for increased knowledge and informa-

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tion dissemination between trusted colleagues. (The caveat to this, of course, is that this ability to transfer information electronically may lead to inadvertent and improper disclosures.) The uniform format allows for consistent entries and the ability to electronically search the recorded data and observations. Having a standard electronic format may also allow for easier and more complete data and result recording. An additional advantage to electronic lab notebooks may include the ability to back up the records onto a separate hard drive for safekeeping while also creating a permanent stored record.

However, other than the security and signature issues noted above, cost may be a factor that weighs against moving towards electronic lab notebooks. One would need to not only purchase the software, but also to rely on the IT support department for troubleshooting and maintenance.

In the event you decide to transition to an electronic lab notebook system, in addition to the 18 hints outlined above for the paper format, please note the following hints that you should consider to increase the probability that your electronic lab notebook will be admitted into evidence. Again, it is a best practice to institute a written policy for electronic record-keeping that is provided to all research employees and is reviewed with such employees on an annual basis. Audits of compliance with the policy should be performed periodically.

1) Establish a schedule for creating permanent back-up copies of the electronic lab notebook. The data should be stored onto "write-once" media. All witnesses' signatures should be completed before performing the back-up. All back-up discs should be stored in a central location and, if necessary, referenced in a separate hard copy notebook that has been dated.
2) Number the discs in consecutive order with permanent labels designating the disk number, start date and end date for each respective disk.
3) Validate the computer system on which the software is housed to evidence that it is operating properly and free of viruses and other destructive applications.
4) Date all daily entries or use a separate server that time-stamps all entries. Consistently use an electronic or digital signature with all entries. Encryption software should be considered for use in conjunction with the electronic notebook application.
5) Use write once, read many times technology with the software package to prevent post-entry editing of research, results and observations.
6) Restrict access to the computer system. Institute screen and keyboard locks and password protection, as well as a policy for regularly changing user codes and passwords.

The main purpose for these tips is to ensure that there is no fraud with the entered data and reports, to support the assertion that the data and observations were actually entered by the inventor, that these entries were really witnessed by a second party, and that the data is true and accurate. Thus, the three elements of focus when one is preparing to purchase an electronic laboratory notebook software package should be alteration deterrence, a robust witness corroboration feature and enhanced computer system security. Being able to show that these elements are present increases one's chances of having the electronic lab notebook deemed admissible incCourt.

In conclusion, there are many well-established reasons to support that maintenance of a comprehensive and secure laboratory notebook (either in written or electronic format) is critical to protecting and establishing your invention. The simple hints detailed above should provide a good starting point for establishing a working policy that will serve you and your company well long-term.

As always, the readers of this article are reminded that the information provided within is not intended to be interpreted as legal advice. The contents of this article are only being provided to educate and assist with providing a better understanding of the importance of laboratory notebooks.

The author would like to acknowledge the contribution of Jason Sosa, a third-year law student at Albany Law School who assisted in the research for this article.

John W. Boger is an associate with the Albany, New York law firm of Heslin Rothenberg Farley & Mesiti P.C. and is a member of the firm's Medical Products and Technology Practice Group. Before attending law school, Mr. Boger worked for eight years with a large orthopaedic device manufacturer in various engineering and marketing positions, including as Product Development Engineer. He can be reached at 518-452-5600 or at jwb@hrfmlaw.com.

Heslin Rothenberg Farley & Mesiti P.C.
5 Columbia Circle
Albany, NY 12203 USA
518-452-5600 (phone)
www.hrfmlaw.com

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ORTHOWORLD, Inc.
8401 Chagrin Road, Suite 18
Chagrin Falls, OH 44023 USA
440-543-2101 fax 440-543-2122
email: usopn@orthoworld.com