

Electronic Notebooks in the Post-America Invents Act World

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ABSTRACT: The enactment of the America Invents Acts (AIA) lit a fire under the feet of the patent community in 2013 when the United States instituted a “first-to-file” system. At first glance, many believed that these new laws greatly reduced the need to be diligent in keeping laboratory notebooks. However, it is still imperative to maintain laboratory notebooks, especially in view of some of the potential pitfalls associated with electronic notebooks and their use in a court of law in this post-AIA world.

In this age of electronic documents and cloud computing, it may seem logical to rely on computers to record and store raw data. At first glance, this method of record keeping appears to be superior to paper record keeping. However, is electronic data keeping always the best and most practical method? Many may argue that electronic data keeping is the only method to utilize in this day and age. However, from a legal perspective, electronic data keeping has certain pitfalls and is surely not foolproof.

Personally, I never even thought about this aspect when I was in graduate school. As a patent agent, I now have a much different perspective regarding record keeping. Many companies have their own systems for laboratory record keeping, which differ drastically from haphazard methods of record keeping utilized by students during graduate school. In fact, many companies now use electronic notebooks, a concept that was not possible back during my time in graduate school.

Prior to the enactment of the Leahy–Smith America Invents Act (AIA), data memorialized in a notebook could also be presented¹ to an examiner or a court of law in an effort to show that they were the first to invent the subject matter of the pending claims, i.e., the US patent system was a first-to-invent (FTI) system. However, as of March 16, 2013, the FTI system was replaced with the first-inventor-to-file (FITF) system, which formed a part of the AIA.² It is now essentially a race to the patent office, with the winner being granted the right to pursue patent protection of the invention regardless of who allegedly invented the subject matter first.³

From certain perspectives, notebooks now serve a limited purpose in this post-AIA world. However, notebooks are still essential in defending an allegation of prior user rights, establishing or proving inventorship, establishing the rights of a company to a trade secret, and/or proving that an invention that was derived, i.e., stolen, from someone else. Therefore, it still may be necessary to use notebooks to prove conception⁴ and/or reduction to practice⁵ to show that an inventor was in possession of an invention.

Regardless of the “type” of laboratory notebook, the pages must show conception, design, development, and/or testing, among others, be maintained on a regular basis, and stored in a secure area. In 2006, the US Supreme Court⁶ ruled that electronic records were permissible evidence, thereby opening the doors for companies, including life sciences companies, to institute electronic laboratory notebooks, linking between

pages, adding data files, and reducing calculation errors. However, are paper or electronic notebooks preferable?

In the pre-FITF world, data was often presented to a US Patent and Trademark Office (USPTO) Examiner in the form of a Declaration to prove inventorship, conception, reduction to practice, or the like. In these types of Declarations, photocopies of laboratory notebook pages with the raw data were commonly attached as evidence. Often, the photocopies were of laboratory paper notebook pages. Because a USPTO examiner often has an advanced degree in science and knowledgeable about laboratory notebook pages, he/she would likely be accepting of electronic laboratory notebooks and less likely to question the validity of electronic data.

In this post-FITF world, data will more often be presented to a judge and/or jury in a court of law. Unfortunately, it is highly unlikely that a judge and/or members of a jury will have a scientific background, which is commensurate with a USPTO examiner, and may be less likely to believe the testimony of a scientist or the validity of electronic notebook pages. In fact, a court of law will undoubtedly question every piece of data and evidence supplied to support a pending claim in a patent application.

Electronic notebooks, at least on their face, have tons of great features such as facilitating collaborations between individuals at different locations, being searchable, may be cloud-based, and may be instantly stored off-site. Although technology and computer programs utilized in electronic laboratory notebook keeping are quite advanced, electronic notebooks may be open to attack by a court of law. For example, it may be necessary to prove the authenticity of the data and signatures and an opponent may question the following items:

- Was the data modified after the experiment was performed?
- Were proper security safeguards/procedures in place to prevent unintentional or intentional modifications/deletions?
- Were there security measures to prevent system failures or the like resulting in date or time changes of the pages?
- Was the work performed by the person who “digitally” signed the notebook page(s)?
- Can the digital signature of the witness be authenticated?

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In order to fully address these points, a party relying on a laboratory notebook as evidence will need to unequivocally convince a court of law that the electronic notebook is foolproof, i.e., that it was not modified, intentionally or not, after the initial entry, there were no system failures resulting in time or date changes, and that the inventor's electronic "signature" was, without question, entered by the inventor and is, in fact, his/hers.

The signature of the electronic notebook, from this author's perspective, is plagued with problems. The critical functions of a handwritten signature uniquely identifies a signor, links the signor with the work being discussed on the notebook page and indicates that the work was done by the signor. If necessary, a writing expert may be called to the stand in a court of law to prove, using established standards to validating a handwritten signature, that the inventor actually signed the laboratory notebook page. This type of testimony to a judge and/or jury is often quite credible and may be difficult to overturn. However, even with all of the safeguards in place, verifying the validity of electronic signatures in electronic notebooks may be quite difficult, if not impossible. There may always remain questions as to if the person who conducted the research entered their own e-signature, and it was not entered by a technician or secretary.

To further complicate matters, not only must the inventor sign and date each notebook page, but each page must be witnessed by a third party. In fact, in a court of law, testimony given by an inventor relying on notebook pages to establish conception or reduction to practice of the invention, where the pages have not been witnessed, is essentially useless and may not be considered as probative evidence by the court.⁷ However, properly witnessed notebook pages permit the witness to credibly testify that the inventor had disclosed the idea, thereby tying this testimony to a date.

In general, the following are "recommendations" for any credible witness:

- work for the same company and/or have duty of confidentiality
- never be another coinventor
- be able to understand the subject matter, i.e., have an appropriate technical background or a technician under the inventor's direction
- if attesting to conception: able to attest that he/she "read and understood" the information in the notebook
- if attesting to reduction to practice: able to attest that the work was done (does not need to understand the experiment)

Clearly, authenticating the veracity of a witness' handwriting is the same as authenticating the inventor's handwriting and may need to be proved to the court. However, there is no well accepted method for witnessing electronic notebook pages. Electronic laboratory notebook page witnessing not only varies from program to program, but varies from company to company. From a legal standpoint, it is virtually impossible for a witness to unequivocally convince a jury that his/her witness notation was inserted by him/her and not another, such as a secretary or a technician. In fact, a court of law may question the authenticity of the witness' signature, thereby requiring considerable testimony to be given by experts in the field of electronic notebooks. For example, not only may the witness need to testify in the court of law, but it may be necessary to provide testimony from database designers

describing the system and the accuracy of witnessing, security personnel attesting to the confidentiality and read-only aspect of the data, system administrators attesting to the use of the same company wide, among others. The presence of too many witnesses may result in confusing the jury and/or casting doubt regarding the veracity of the notebook pages, possibly resulting in invalidation of the patent.

In short, it is this author's opinion that, at least from a legal perspective, the "paper" laboratory notebooks are still the recommendation for having the best chance of maintaining their evidentiary weight, with the following being "best practices":

- make entries in permanent ink
- limit blank spaces
- explain each experiment
- put experiments in chronological order
- sign and date each pages as soon as possible; daily is recommended
- use a bound notebook, not loose leaf or perforated pages
- sequentially number pages; prenumbering preferred
- strike out all changes; place an "x" over full pages with visible errors and never tear out pages
- physically attach copies of spectral data

Simply put, paper laboratory notebooks can easily be physically examined by a judge and/or jury, are easily understood by the ordinary person in the jury box, have long been used in court proceedings, are well accepted, and are tamper evident. Go with the paper notebook; it is not worth the risk.

■ AUTHOR INFORMATION

Notes

Views expressed in this editorial are those of the author and not necessarily the views of the ACS.

The authors declare no competing financial interest.

■ REFERENCES

- (1) 37 C.F.R. §1.131.
- (2) The AIA is a U.S. statute that was signed into law on September 16, 2011.
- (3) There are some exceptions including the inadvertent publication of a journal article or the like less than one year before the patent application is filed. 35 U.S.C. §102(b)(1).
- (4) For example, conception of a chemical molecule would include (a) identity of the molecule, (b) at least one synthetic route to that molecule, (c) one use for the molecule, and (d) how to accomplish that use.
- (5) "Reduction to practice" shows that the conceived invention was completed.
- (6) See the amendments to Rules 16, 26, 33, 34, 37, and 45 of the Federal Rules of Civil Procedure.
- (7) *Gortatowsky v. Anwar*, 58 C.C.P.A. 1266, 442 F.2d 970, 170 U.S.P.Q. 41, 43, 1971.