

The Rules have Changed

The management of electronic research records is more important than ever before

Michael H Elliott

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A patent provides rights to an inventor to restrict the ability of others to make, use, or sell an invention. To obtain a patent, an inventor must submit a novel and unique concept to a government agency. In the scientific domains, laboratory notebooks are typically used as the primary evidence to prove inventorship of a concept and the details of its first successful use or what is known as "reduction to practice." The particulars of the research and associated dates and times are especially critical to the establishment of proprietary rights in the United States. The reason for this is that the U.S., versus other countries, awards patents on a "first-inventor" basis rather than on a "first-to-file." This puts the responsibility in the hand of the inventor to have accurate and corroborated records to prove they created and successfully demonstrated the innovation before others. Being so critically relied upon, entries in a laboratory notebook must be clear to demonstrate how and when the work was performed, signed by the author, and corroborated by a witness not involved with the original work.

It is not atypical for copies of printouts from spreadsheets, instrument data systems, images, and other data that was generated by a computer to be cropped and pasted onto a notebook page. Except in areas that fall under the control of 21 CFR Part 11, the original electronic records are often managed haphazardly on local client computers or servers. The researcher is left to their own devices to come up with a mechanism for file storage and backup.

The use of Electronic Laboratory Notebook (ELN) technology has risen sharply in the past four years, having now penetrated over 20% of all biopharmaceutical companies.ⁱ ELN has not only led to increases in laboratory efficiency and improved leverage of institutional knowledge, but also to enhanced protection of Intellectual Property (IP). Based on technology to manage the underlying electronic records, ELNs can provide the access security, version control, record authentication, and automated time stamping their paper forbearers cannot.

However, for even those who have implemented ELN, old habits die hard. Instead of a paper printout glued onto a notebook page, data is copied and pasted from another computer application into the ELN. The originating records are again left to be managed randomly, as the notebook page is entrusted to be the only record required to support a patent. For example, some electronic records might be destroyed immediately, some are kept only as long as the creating scientist is with the company, and others may be kept for a year or longer. Additionally, over 70% of companies who have implemented an ELN still create paper printouts and apply "wet" signatures of the author and witness or what is known as the "hybrid model".ⁱⁱ In these cases, organizations have faith that paper records are sovereign and the underlying electronic records are needed only for knowledge sharing amongst their scientists.

In December 2006, the risk of ignoring the proper management of patent-supporting electronic records changed appreciably with amendments

to the United States Federal Rules of Civil Procedure (FRCP). These changes alter the procedures of discovery, which is the process of requesting, or compelling, information from one party to another in a civil case. Based on the realization that electronic records were the predominant source of corporate records, the Judicial Conference of the United States amended FRCP to address the current environment. Since 97% of records have their basis in electronic form, these changes effectively make all discovery now electronic discovery or “e-discovery.” This has a wide-ranging implication which affects the retention of research data, IP records management practices, organization of data, and data storage formats.

Occurring before a trial, discovery can include the collection of laboratory notebooks, documents, presentations, or other information that is deemed necessary to uncover evidence. Before the FRCP changes, one party may have had the information in electronic form, but in most cases they could produce it in another format, such as paper printouts. The previous rules didn’t specifically address the admissibility of e-records (however, patent cases have been won based on electronic records.)

Changes in FRCP

In the amended FRCP, electronic records are now explicitly classified as having the same weight as paper records. Specifically, Rule 26(a)(1) A and B state:

“Except in categories of proceedings specified in Rule 26(a)(1)(E), or to the extent otherwise stipulated or directed by order, a party must, without awaiting a discovery request, provide to other parties:

(A) the name and, if known, the address and telephone number of each individual likely to have discoverable information that the disclosing party may

use to support its claims or defenses, unless solely for impeachment, identifying the subjects of the information;
(B) a copy of, or a description by category and location of, all documents, **electronically stored information, and tangible things** that are in the possession, custody, or control of the party and that the disclosing party may use to support its claims or defenses, unless solely for impeachment;”ⁱⁱⁱ

Rule 34(a) goes on to say:

“Any party may serve on any other party a request (1) to produce and permit the party making the request, or someone acting on the requestor’s behalf, to inspect, copy, test, or **sample any designated documents or electronically stored information** — including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations **stored in any medium from which information can be obtained** — translated, if necessary, by the respondent into reasonably usable form, or to inspect, copy, test, or sample any designated tangible things which constitute or contain matters within the scope of Rule 26(b) and which are in the possession, custody or control of the party upon whom the request is served; or (2) to permit entry upon designated land or other property in the possession or control of the party upon whom the request is served for the purpose of inspection and measuring, surveying, photographing, testing, or sampling the property or any designated object or operation thereon, within the scope of Rule 26(b).”

Though one party may desire to provide only paper printouts, the court can compel production of the original source records. Despite a company

using a hybrid ELN model with printed and signed notebook pages, these pages are not only redundant, but are now in effect unnecessary. Those with a hybrid ELN are somewhat reducing their risks as paper is another form of backup; but they are adding to the complexity of their research processes. In fact, they may be causing other problems. If changes are made to the ELN database that are not being reflected in the paper version, this makes it much more difficult for the user to explain to a judge or jury that they have properly maintained their intellectual property. Not only are they introducing doubt, expense and efforts are doubled managing these "two sets of books."

Rule 34(b) has implications for those allowing scientists to individually manage data or for those using scientific data management systems, instrument data systems, LIMS and other electronic record generating technologies that may be used in the creation of a new compound or product. This is whether the data is transferred to an ELN or a paper notebook. For example, you crop and paste chromatography data system (CDS) printouts into your paper notebook. The other party may want to re-analyze the data looking for peaks that could not be seen on small renditions pasted into the notebook, so they ask for access to the CDS raw data files. Because a lack of consistent data management practices, some files are available, some are not. The opposing counsel now works to put doubt into the minds of the judge or the jury that you have selectively deleted data you thought would harm your case or that you are hiding something.

It is within the rights of the opposing counsel in discovery to gather these records unless you can convince a judge that the records are no longer accessible, it would be a major burden, they are not needed, or the records are confidential information with regards to other projects. If the

requested data is not accessible, the court does allow in Rule 26(b)(2)(B) that:

"A party need not provide discovery of electronically stored information from sources that the party identifies as *not reasonably accessible* because of undue burden or cost. On motion to compel discovery or for a protective order, the party from whom discovery is sought *must show that the information is not reasonably accessible because of undue burden or cost*. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery."

Though "accessible" is not well defined, this would be counter to the entire philosophy of an ELN – that research records *are readily accessible*. In the CDS situation, if some are available and others are not, how could it be that all records are not reasonable accessible? It would be very difficult to explain to a judge that the original source records could not be "reasonably accessible" from an ELN when scientists are using it to search and share information every day. However, Rule 26(b)(2)(B) could be used as a defense if you are using a paper notebook and have established business practices and procedures that require you to delete the source data after a specific period of time. The key is to have consistent, audited, and proven record management practices that are enforced across the organization. You can no longer let researchers arbitrarily manage records that were generated for supporting a patent. The "Safe Harbor" clause of Rule 37(f) states:

"Absent exceptional circumstances, a court may not impose sanctions under these rules on a party for failing to provide electronically stored information

lost as a result of the routine, good-faith operation of an electronic information system.”

If you have established records management practices that call for the destruction of your research records on a published basis, e.g., once every five years, then this could be considered “good-faith operation.” If you just by happenstance delete records, then this isn’t a routine operation of your business. A critical component of managing your scientific IP is to not only define your record management practices, but to prove you actually follow them! *If you are not prepared for e-discovery, you have significant risk of loss of your patent rights.*

Record Production

If you are compelled to provide your patent records electronically, what format do you provide? There are conflicting historical cases as to what a judge will deem acceptable. Under the new rules, 26(f) instructs attorneys to attempt to agree on a number of items at least twenty one days prior before a scheduling conference, including record formats and media type. Expect the other party to demand to know what records you have for the invention, their formats, what media it can be produced on, if there is any software required to view them, any claims of confidentiality (data that might also relate to another invention for example), and timing for compliance before these discussions begin.

There are a plethora of patent cases involving electronic records where there was a lack of agreement on data format. Recently, *Hagenbuch v. 3B6 Sistemi Elettronici Industriali* was a patent case where the format of the electronic evidence was in dispute. Hagenbuch requested CDs and DVDs of electronic records in their original format but the defendant responded with TIFF images. Hagenbuch claimed the records were not usable

in this form and that they did not have any associated metadata for searching. In this case, the magistrate agreed with the plaintiff saying that TIFFs “differ in design and content from the materials plaintiff designated, are not identical to the documents shown to plaintiff, and contain less information (especially about the documents themselves) than the originals.”^{iv} In *CP Solutions Pte., Ltd. V. General Electric Co.*^v, G.E. produced primarily TIFF images of files, including e-mails. The Plaintiff protested, filing a motion for their production in their native format. Coming before the FRCP rule changes, the judge in this case ruled that since the files were readable, TIFF was allowed, but any records that were not readable had to be produced in their original format. In the 2006 patent dispute, *Nova Measuring Instruments, Ltd. v Nanometrics, Inc.*^{vi}, the defendant was compelled by the judge to produce all records in their native format including any associated metadata.

The format allowed is very dependent on an attorney’s ability to prove need of a specific record type. At a minimum, if IP records are kept under your business rules, original formats should be maintained along with a conversion to a standard such as PDF/A, TIFF, or human readable XML.

It is not only experimental data that requires proper maintenance, authentication, security, and archiving. Other data sources can have a major impact on your ability to support a patent. In *Re Scott T. Jolley*,^{vii} Scott Jolley appealed the awarding of a patent to Phillip McGraw for a new ester lubricant. Jolley claimed to have established conception of the lubricant on June 2, 1988, while McGraw claimed to have done so on May 20, 1988. Jolley contended that McGraw did not have sufficient evidence to prove his asserted creation date. But, McGraw produced an e-mail dated May 20, 1988 exchanged between him, his co-inventor, and other Dow employees discussing

the blending of previously patented compressor lubricants for a new application use. Therefore, an electronic record – an e-mail – was used to establish sufficient grounds for the critical date of invention creation and Jolley lost the case.

In summary, electronic records are increasingly being used in court proceedings throughout the world. The December 2006 changes to the US Federal Rules of Civil Procedure now explicitly address the admissibility of these e-records. These changes affect all organizations who file patents in the US. It is essential to establish record retention policies, business rules, procedures, and controls for all records that support a patent, not just their paper printouts. If not destroyed by such a policy, records must be proven to be properly maintained, authentic, accessible, and time stamped. If you aren't ready for e-discovery, you increasing your risk exposure - daily.

ⁱ *2006 Electronic Laboratory Notebook Survey*
Atrium Research & Consulting, Wilton CT USA

ⁱⁱ *Electronic Laboratory Notebooks: A Foundation for Scientific Knowledge Management Edition III*
Atrium Research & Consulting, Wilton CT USA

ⁱⁱⁱ Cornell Law School "Federal Rules of Civil Procedure"

<http://www.law.cornell.edu/rules/frcp/>

^{iv} *Hagenbuch v. 3B6 Sistemi Elettronici Industriali S.R.L.*, Case No. 04C3109, 2006 U.S. District Court, LEXIS 10838 (N.D. Ill. March 8, 2006)

^v *CP Solutions Pte., Ltd. V. General Electric Co.*, 2006 U.S. Dist. LEXIS 27053 (Feb. 6, 2006)

^{vi} *Nova Measur. Instruments, Ltd. v Nanometrics, Inc.*, 417 F.Supp.2d 1121 (N.D. Cal. 2003)

^{vii} *In Re Scott T. Jolley*, 308 F.3d 1317, 64 USPQ.2d (BNA) 1901 (Fed. Cir. Oct. 29, 2002) (Interference Nos. 103525 and 103526)
<http://www.ll.georgetown.edu/federal/judicial/fed/opinions/01opinions/01-1646.html>