New Debates over Intellectual Property Protection and ELN

Proper attention must be paid to organizational policies to minimize litigation risks

During the first five years of the “modern” age of ELN, people deliberated the capabilities of ELN to support intellectual property (IP) at various seminars and conferences. Questions such as “How can ELN protect intellectual property?” and “Are ELN admissible into court?” were extensively discussed. In those days, large pharmaceutical companies — a majority of the early adopters of the technology and the majority of the overall ELN customer base — had the greatest concerns.

With changes to U.S. court procedures in late 2006 accepting electronic records with equal weight to other forms of evidence, there was a general easing of fears and a greater acceptance of the technology. This accelerated the move to paper elimination: 62 percent of implementations are fully electronic, i.e., no printing to paper and wet signatures, and another 19 percent are migrating away from the old hybrid approach.

It is interesting to note the majority of large pharmaceutical companies do not even consider ELN to be the primary repository of IP. Many have multiple ELN products to serve different domain requirements; a downside being the products representing records in different formats. And they desire long-term archiving — capabilities notably absent from most products. Many also question whether their chosen suppliers in a dynamically changing market will even be around 20 years from now. Therefore, ELN is the tool for IP authoring and the support of scientific knowledge management. IP records for long-term retention are increasingly being published in formats like PDF/A, digitally signed outside ELN, and pushed to solutions like enterprise content management (ECM).

Proper attention must be paid to organizational policies to minimize litigation risks. We are seeing a growing use of records forwarded to third party archive services like Iron Mountain as an additional precaution against data loss.

The movement of ELN into smaller organizations and markets like food, medical devices and consumer products is triggering new debates about the relationship between ELN and IP. Many of these companies do not have the resources or funding to implement additional repositories like ECM. Smaller organizations generally do not have ready access to general counsels, and even fewer have good records management practices. Also, the trend toward outsourced research is raising fresh concerns regarding the capturing of contractor-generated IP.

LABORATORY NOTEBOOKS AND PATENTS IN THE UNITED STATES

There is a fundamental difference in applying for a patent in the United States versus other countries. United States patent law is based on a first-to-invent basis as opposed to the principle.
of first-to-file. In other words, you cannot just file an application and expect the rights of a patent holder — you must prove you had the idea first. This leads to a rather litigious environment, with challenges to the U.S. Patent and Trademark Office (USPTO), i.e., “interferences,” or in civil court. As it stands today, a patent for a successful new molecular entity will almost guarantee that a battle will erupt somewhere down the line. The first-to-invent concept is defended by some as a means to better protect individual inventors over large corporations, but this is a hotly debated topic among lawyers and politicians.

There have been several attempts in the U.S. Congress to reform patent law over the years. In 2007, reform passed the House of Representatives, but it died in the Senate. Most recently, The Patent Reform Act of 2010 introduced by Senators Patrick Leahy (D-VT) and Orrin Hatch (R-UT) was another attempt to move the U.S. to first-to-file. Since the 2007 bill was mostly favored by democrats (the majority of house republicans voted against it), the recent party shift in Congress combined with the nation’s economic climate may well spell doom for the 2010 bill as well.

In a first-to-invent process, there are many important considerations: the date of the conception, diligence, reduction to practice, and corroboration. It is not simply enough to come up with an idea — it is essential to prove that you diligently worked on proving that the invention did what you said it would. This must be backed up by documented evidence substantiated by another not directly involved in the work. Often, it is more difficult to prove diligence in reduction to practice than the actual date of invention. You cannot merely start and stop working on an idea over the course of many years expecting to hold onto the rights of a first inventor.

Therefore, notebook records, regardless of form, can be vital in winning or losing a patent in the U.S. Bad notebook policies (or not following good ones) can lead to a loss of patent rights. In our consulting practice, we were often surprised at how poorly notebook records are maintained — e.g., a lack of policies or enforcement, individual methods of documentation, no custodian, lack of corroboration — but no longer. We find this state to be the norm rather than the exception at smaller organizations that depend on IP for their life blood.

Will an ELN help? Yes, ELN helps to enforce established policies and core capabilities such as time stamping and audit trails are a big improvement over paper. Organized and searchable records can better prove diligence and reduction to practice. But, if there are no policies or a custodian of record, ELN is no better than paper. Good practices trump technology any day. Companies who are considering ELN must focus on establishing a proper foundation for IP management first — then leverage ELN to further improve the current state.

**ADMITTANCE OF LABORATORY RECORDS**

The U.S. Federal Rules of Evidence (FRE) govern whether or not evidence like laboratory records are admissible in a patent interference or a civil case. To allow the admission of records, offered evidence must be proven to be authentic per FRE section 901 which states “the matter in question is what its proponent claims.” Notebook records, whether in electronic or paper form, are considered hearsay and therefore non-admissible unless proven otherwise. Hearsay is defined by FRE as “a statement [either oral or written], other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted.” Thus, records must be properly corroborated if they are to be used to support date of invention, diligence or reduction to practice.

There are two ways to admit laboratory notebook records. First, the author who created the records of the experiments can testify as to their validity. This would satisfy the requirement that the evidence was made by the declarant. But, what if the case is many years later, and the inventor is no longer available? The second way is to classify them as what is commonly called the “business records” exception to hearsay (Rule 803). This exception allows business materials, e.g., lab notebooks, to be admitted as evidence if a proper foundation is established to prove their authenticity. This consists of five elements:

1. Records must be kept in the ordinary course of the business.
2. The particular record at issue must be one regularly kept.
3. The record must be made by or from a knowledgeable source.
4. The record must be made contemporaneously.
5. The record must be accompanied by testimony by a custodian.

An often overlooked consideration is the custodian. A custodian is an individual who, in the usual course of a company’s operation, is responsible for the management of business records. A custodian can be called into court to attest to the company’s policies and procedures for documenting and securing the records desired to be admitted. They will be asked to substantiate that procedures are generally followed and the records in question adhere to those standards. Without a designated custodian, there is a risk of non-admittance — again, independent of electronic or paper form.

In the past, courts have not allowed the business records exception to be applied to notebook records due to either a lack of policy or the inability of the organization to prove they followed the policies they have. In Chen v. Bouchard, the U.S. Court of Appeals found Chen’s use of laboratory notebooks did not qualify as business records and were therefore, not admissible. According to the court, there was insufficient evidence that Chen’s company required laboratory scientists to make notebook entries. Notebooks of other non-witness scientists, therefore, were considered hearsay.

In another example, Glaser v. Strickland, Glaser asked the court to allow records to be admitted under the business record exception. The patent board rejected the request; they felt there was not a proper foundation for the records. Without a custodian or “other qualified witness” who could explain how the records were maintained, they were treated as hearsay.

**CONTRACT RESEARCH AND IP**

The fastest growing portion of biopharmaceutical R&D is contract research, comprising 25 percent of pharmaceutical R&D spending. At a compound annual growth rate of over 20 percent, and with overall funding flat, contractors could garner the lion’s share of expenditures in less than a decade.

For many years, contractors were confined to later stage domains like toxicology and clinical trials manufacturing. Now, there is a dramatic increase in the use of outsource partners for discovery functions and patentable concepts. What started as library synthesis has evolved to encompass screening, drug metabolism, pharmacokinetics and in vivo pharmacology. The importance of knowledge capture and retention is even greater, since the data output of the contractor is an asset of the funding source; but the persons creating the inventions are not employees.

The rate at which discovery contractors are growing is outpacing considerations for proper records management and IP capture for many. Small minorities of organizations are demanding contractors in Asia to use their ELN. Most are sending files back and forth via e-mail, then copy/pasting these documents to their ELN or into a paper notebook; often this is done without the active participation of records management or patent departments.

The assumption is that the local notebook will be sufficient for patent support. This is a dangerous assumption. First, the person who came up with the idea and diligently reduced it to practice may not be around years from now to testify in court. Employee turnover is particularly high with many Asian contractors; there is also no way to compel them to appear in a U.S. court. The business records exception must be attempted to avoid hearsay. But, if the records custodian (if there is one) has never visited them, set policies for how the contractor should document the research to the company standards, or audited them for compliance with the standard, you run a high risk of non-admittance of notebook records. So, contract research organizations must be considered as extensions of your research — with the same level of care and governance.

In summary, the emergence of electronic laboratory notebook technology has helped hundreds of organizations to organize records and retain research knowledge. It is, however, just a component of an overall approach to intellectual property management. Regardless of whether records are in paper or electronic form, proper attention must be paid to organizational policies and practices to minimize litigation risks. ELN does not eliminate the need for proper records management.

**REFERENCES**

2. federealevidence.com/downloads/rules.of.evidence.pdf
3. federealevidence.com/rules-of-evidence#Rule803
5. www.bitlaw.com/source/mpep/716_09.html

Michael Elliott is CEO of Atrium Research & Consulting. He may be reached at editor@ScientificComputing.com.