

INTERVIEW

UNDERSTANDING THE LEGAL ISSUES SURROUNDING ELECTRONIC LABORATORY NOTEBOOK (ELN) RECORDS

In recent years electronic records have been used successfully as evidence in patent interference cases. Despite this, some companies are still hesitant in moving towards a fully electronic system for IP protection. In this interview we talk to one of United States' leading IP lawyers regarding the legal issues surrounding electronic laboratory notebook (ELN) records.



Colin G. Sandercock, Legal Expert at Proskauer Rose LLP, analyses the legal issues surrounding electronic laboratory notebook (ELN) records.

INTERVIEW WITH LEGAL EXPERT COLIN G. SANDERCOCK

Colin G. Sandercock is a partner in the Litigation and Dispute Resolution Department of Proskauer Rose LLP, co-chair of our Life Sciences Group, and is co-managing partner of the Washington, D.C. office. He practices in the area of life sciences, including licensing, patent and trademarks, and intellectual property. Colin was named in the 2007 and 2008 editions of The Best Lawyers in America in the field of biotechnology law, and in the 2008 edition of Washington DC Super Lawyers, as one of the top attorneys in the Washington, DC, Metro Area in the field of Intellectual Property law. Since 1984, Colin has

counseled clients in life science matters including district court litigation, interferences, licensing and the management of domestic and foreign patent portfolios. His technical experience includes biotechnology, pharmaceutical chemistry, organic and inorganic chemistry, medical devices, and chemical and biochemical engineering.

CAN YOU DESCRIBE THE CURRENT SITUATION AND THE DIFFICULTIES?

Although there are still executives and lawyers who are concerned about the admissibility of ELN records in legal proceedings, such concerns are largely unwarranted. Provided that the ELN

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system contains reasonable safeguards to prevent tampering, and that companies take certain steps to comply with U.S. evidence laws, relevant ELN records will be admissible in court proceedings. Indeed, a growing percentage of records involved in U.S. litigation discovery are electronic records (ERs) such as e-mails and documents maintained either on separate storage media (e.g., backup media) or in document management systems. Companies are increasingly minimizing their use of paper and as time goes on, the majority of documents involved in litigation will have been generated and kept solely in electronic form.

To be clear, the admissibility of electronic records has been recognized by major U.S. courts for over 30 years. And in 2006, the U.S. Supreme Court promulgated new rules of the Federal Rules of Civil Procedure, which new rules specify procedures relating to discovery of electronic records. These new rules make clear what has been the practice in courts for decades, namely that electronic records (in human-readable form) are admissible evidence.

The only “difficulties” are associated with the implementation of safeguards in the ELN system and appropriate policies and procedures so as to prevent unauthorized creation of, and/or tampering with ERs. Provided that reasonable safeguards and policies and procedures are implemented, such difficulties become fairly minimal.

DO YOU SEE ANY RISKS WITH ELECTRONIC RECORDS?

The fundamental issue with ERs is the perception that they can be easily altered and that such alterations will be difficult or impossible to detect. In reality, reputable companies will

implement ELN system safeguards, as well as policies and procedures for how they create and archive ERs such that alteration would be extremely difficult if not impossible. Furthermore, it will be the rare case when alterations go undetected because such alterations typically will be inconsistent with the rest of the evidence in the case. Ironically, despite all of the concern about ELN records, most ELN systems will create ERs that are far more credible and reliable than records from the paper-based systems they replace, which systems typically have had relatively few safeguards.

HOW DOES ONE CREATE RELIABLE ERs?

It cannot be overemphasized that there is no set formula for creating a reliable ER. Any ELN system that contains reasonable safeguards against tampering, and provides sufficient assurance that the ER will be available in human-readable form for an indefinite period (at least 35-40 years) can be acceptable. Importantly, however, reliability typically will be a function not only of the system itself, but also the policies and procedures used to create the ERs, commit them to the system, and then maintain them as an archived record. Hence, the ability of any ELN system to create reliable records must be viewed holistically within the overall context of how ERs are created and archived. The ultimate question of whether an ELN system creates reliable records often can be assessed simply by answering the following questions: If a company wants to falsify a record, can it do so? If so, how many people must collude to falsify the record? Obviously, the more difficult it is to falsify a record and the more people who must be involved in the collusion, the more credible the ER will appear.

WHAT ABOUT THE USE OF ERs IN COURT PROCEEDINGS?

As mentioned, ERs have long been used in court proceedings. Indeed, it is almost unimaginable that any significant court proceeding would not involve a substantial number of e-mails and other electronically created and stored documents. As with any evidence that comes into a courtroom, the ER must be both authenticated and admissible under a specific rule of evidence. Authentication of an ELN record often will be provided by the author of the record, but companies also must prepare for the possibility that the author will be unavailable. When the author of an ELN record is unavailable, the Federal Rules of Evidence, which govern both the federal courts and USPTO, permit a “custodian” of the record to authenticate the record provided that certain requirements are met. It is imperative for companies to understand the foundation that they must establish in order to permit the custodian to introduce the ELN record as a “business record” under the “business record exception” to hearsay (FRE 803(6)). Provided that companies establish a proper foundation for the ELN record

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to be a business record within the meaning of FRE 803(6), then the record will be admissible, assuming that it qualifies under one of the rules of evidence. Generally speaking, all relevant evidence is admissible and so if the ELN record is relevant, then it likely will be admitted into evidence.

Admission into evidence, however, is only part of the story. The other issue is whether the record will be deemed credible and reliable by the court and/or jury. Where the ELN record is entirely consistent with the rest of the evidence, there will likely be no challenge to the credibility of the record. Likewise, there will likely be no challenge to an ER where the ELN system, as well as the

policies and procedures governing creation and archiving of ELN records, have reasonable safeguards to prevent unauthorized creation and/or tampering. In those infrequent times when the ER is not consistent with the other evidence, then the ELN system may come under scrutiny, which is why it is smart to have the system reviewed by counsel long before litigation arises.

WHAT MUST ELNs PROVE?

The records created by an ELN must prove exactly the same thing as a paper laboratory notebook record, namely, who created the record, when it was created, and what its content was on the date of creation. Additionally, the ELN system should also be able to prove that the record has not been altered since it was created. Again, this last point is a function of both the ELN system itself and the policies and procedures by which ERs are created and archived.

WHAT ABOUT THE FUTURE?

ERs are not a future, inevitable development; rather, they are here and fast becoming common place among every large pharmaceutical and biotech company, and also among many smaller pharmaceuticals and biotechs. As the saying goes, “the train has left the station.” This development is due to several factors.

First, the gain to the enterprise from an ELN in terms of knowledge management can be enormous, especially as compared to the paper laboratory notebook, which rarely facilitates collaboration among researchers in different areas of a company. There are many stories about companies that have reviewed their paper records only to find that they have “recreated the wheel” several times over. Essentially, paper laboratory notebook records can create silos of information known only to specific researchers or groups, whereas ELN systems facilitate building on prior work anywhere in the company and using materials and reagents that already have been created by others

Second, the gain in efficiency in terms of recording experiments can be significant in some areas of research such as discovery and process chemistry. Electronically creating or “cloning” experiments can save significant time, especially for researchers who only are making slight changes to prior experiments. An associated benefit is often a more complete, thorough, and

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legible record of the experiment. The ELN also can facilitate review by superiors for productivity (a potentially sensitive point among researchers), good technique and compliance with good notebook keeping procedures.

Third, companies simply will have to have state-of-the-art tools such as ELNs to attract top researchers. Such researchers are very proficient with computers and databases and frankly will expect any substantial research organization to have an available ELN system. The corollary to this is that the more companies adopt ELNs, the more that other companies will have to “keep up with the Joneses” in order to stay competitive for top talent. It becomes a very real and self-fulfilling prophesy.

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Interview conducted by Contur Software AB, 2008. Mr. Sandercock is currently with Perkins Coie LLP.