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.

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 BIOVIA ELN records in legal proceedings, such concerns are largely unwarranted. Provided that the BIOVIA ELN system contains reasonable safeguards to prevent tampering, and that companies take certain steps to comply with U.S. evidence laws, relevant BIOVIA 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 BIOVIA 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 BIOVIA 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 BIOVIA ELN records, most BIOVIA 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.
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 BIOVIA 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 BIOVIA ELN system, as well as the policies and procedures governing creation and archiving of BIOVIA 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 BIOVIA 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 BIOVIA ELNS PROVE?
The records created by an BIOVIA 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 BIOVIA 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 BIOVIA 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 BIOVIA 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 BIOVIA 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 legible record of the experiment. The BIOVIA 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 BIOVIA 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 BIOVIA ELN system. The corollary to this is that the more companies adopt BIOVIA 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.

ABOUT PROSKAUER ROSE LLP

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

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