



IP Laws and Electronic Data: Issues and Actions

Issues and Actions

○ Agenda

- Why eLN at all
- Intellectual Property Rights
- Replacing Paper Records with an eData System
- Working in Conjunction with GXP Requirements
- Data Integrity and Confidentiality

Why Have an eLN at all?

- R&D Today: Research & “e-Data”
- Paper Systems:
 - Print-to-Paper or Transcription
 - Data Volume (Gigabyte-per-day issue)
 - Lost meta data
 - Data integrity
 - Barrier to data sharing and verification
 - Difficult to parse or sequester proprietary data
 - Staff and storage
 - Costly to retrieve in litigation
- eLN handles or moderates all points



Intellectual Property Rights

- Patents
 - Obtaining a patent
 - Worldwide – First to File
 - US – First to Invent
 - Reliable, accurate records central to proofs
 - Defending a patent
 - Reliable, accurate records
 - Producing records
 - Term extensions
- Data Exclusivity Provisions
- Trade Secret Laws

Patents

- US – First to Invent
 - US Interference Practice
 - First to Conceive and Reduce to Practice with Diligence
 - Proving Conception and Reduction to Practice
 - “Totality of Circumstances” and “Rule of Reason”
 - Conception
 - Inventor’s statement inherently untrustworthy
 - Capture of concept in a trustworthy, change-evident medium
 - Trustworthy date/time data
 - Trustworthy evidence of authorship
 - Disclosure to knowledgeable 3rd party
 - Meta data critical to proving earliest date
 - Earliest date may not be reflected in paper LN
 - Reduction to practice with diligence
 - Trustworthy record of continuous effort up to filing date

Patents

- Prior Invention
 - Prior Invention
 - Obtaining a patent
 - US Grace Period
 - Can swear behind a reference to prove prior invention within 1 year grace period.
 - Invalidating a patent
 - Prior invention by another
 - Freedom to operate
 - Pre-existing activity may be exempted from infringement
 - Showing date and content of work prior to a cited reference
 - Capture of reliable meta data critical to proving earliest date
 - Requires trustworthy data tracking and recording methodology

Patents

- International Treaties Impacting US Practice
 - 35 U.S.C. §104
 - "... [M]ay not establish a date of invention by reference to knowledge or use thereof, in a foreign country other than a NAFTA ... or WTO member country"
 - NAFTA
 - 1993 Treaty permits use of Canadian and Mexican data in USPTO proceedings (Chapter 17)
 - WTO – TRIPS/GATT
 - 1994 Uruguay Round Agreements Act
 - Effective Date: 01 January 1996
 - Permits use of WTO signatory state data in USPTO proceedings

Replacing Paper

- Electronic data accepted by Courts and Regulatory Agencies
 - European Positions
 - EU Member States
 - [Directive 1999/93/EC](#)
 - Widely adapted in some form or another
 - EU Review: [International Journal of Law and IT](#), March 2005
 - Italy
 - Art 269702733 of Civil Code 1940
 - Decreto Del Presidente Della Repubblica (513) 1997
 - UK
 - Civil Evidence Act of 1995 – “[Document](#)”
 - [Electronic Comm. Act 2000](#)
 - EPC – Permits online filing and official records are .pdf files

Replacing Paper

- US Administrative and Courts
 - USPTO
 - In [interferences](#): "... [T]o the same extent that electronic records are admissible under the Federal Rules of Evidence."
 - [37 CFR § 41.152\(a\)](#) "Generally. Except as otherwise provided in this subpart, the Federal Rules of Evidence shall apply to *contested cases*. * * *"
 - Impact of NAFTA and GATT Enabling Legislation
 - Federal IP Litigation
 - U.S. Federal Rules of [Evidence](#)
 - Business Record exception to Hearsay Rule – [803\(6\)](#)
 - Residual Exception - [807](#)
 - Authentication of Evidence - Rule [901](#)
 - Records -- Rule [1001](#)
 - Impact of NAFTA and GATT Enabling Legislation

Replacing Paper

- US “eLN” Decision
 - *In re Jolley*, (64 USPQ 1901, Fed. Cir. 2002)
 - E-mail to knowledgeable 3rd parties
 - Integrity of the e-mail not challenged
- Microsoft Anti-trust litigation
- Arthur Anderson/Enron collapse
- Frank Quattrone conviction

Replacing Paper

- Minimum System attributes
 - Integration of
 - Content
 - Trustworthy record of author
 - Trustworthy record of date and time
 - Change-evident/Audit trail of data, date, author
 - Reviewer or Witness workflow tool
 - Recorded with audit trail
 - Long-term Archival Scheme
 - Non-proprietary format
 - Add hash value to LTS data file
 - Retrievable and human readable over data's retention period
 - Content must not be compromised when output to storage format or when retrieved
 - Robust indexing system – a file becomes “needle in haystack” over time

GXP

- Working in Conjunction with GXP Requirements
 - 21 CFR, Part 11
 - Default for R&D groups subject to GXP requirements
 - Part 11 rules result in capturing data reliably
 - Part 11 does not have a non-inventor witnessing requirement
 - Add witnessing workflow tool to system for use as needed

Data Integrity and Confidentiality

- eLN
 - More difficult to dry-lab experiments because it compiles disparate, machine-generated data controlled by another independently
 - Easier to review data online
 - Access to eLN
 - Employer owns data
 - Limit access, e.g., “need to know”.
 - Much easier to sequester 3rd party data or pull same
 - Server-generated meta data can collect information on file access and usage
 - May be possible to more readily identify employees who may require assistance

Summary

- A record is a record is a record
- Currently available e-systems meet regulatory and legal standards for admissibility of a record
- Long-term archiving of e-records is possible

Conclusion

George Bernard Shaw: "You see things; and you say, 'Why?' But I dream things that never were; and I say, 'Why Not?'" *"Back to Methuselah" (1921), part 1, act 1*