ELECTRONIC LAB NOTEBOOKS -
“READY FOR PRIMETIME??”

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WHY ARE LAB NOTEBOOKS IMPORTANT IN RESEARCH?

EVIDENCE OF INVENTORSHIP: CONCEPTION AND REDUCTION TO PRACTICE
REFRESHER ON INVENTION

“CONCEPTION” (MENTAL PART)

"COMPLETE PERFORMANCE OF THE MENTAL PART OF THE INVENTIVE ACT…..” Coleman v. Dines 754 F.2d 353, 359 (Fed Cir. 1985)

“THE CONCEIVED INVENTION MUST INCLUDE EVERY FEATURE OF THE SUBJECT MATTER CLAIMED IN THE PATENT.” Sewell [v. Walters], 21 F.3d [411,] 415 [(Fed. Cir. 1994)]
“REDUCTION TO PRACTICE”
(PHYSICAL PART)

DEMONSTRATION THAT THE INVENTION WORKS FOR ITS INTENDED PURPOSE
EVIDENCE OF INVENTORSHIP MUST BE INDEPENDENTLY CORROBORATED

FINA OIL AND CHEMICAL CO. v EWEN 123 F.3d 1466, 1474 (FED CIR 1997)

NEED FOR CORROBORATION STEMS FROM HISTORICAL DISTRUST OF UNCORROBORATED EVIDENCE OF PRIOR INVENTION
CORROBORATION

TYPICALLY TAKES FORM OF

• TESTIMONY OF CO-WORKERS WHO ARE NOT NAMED AS INVENTORS

• NOTEBOOK RECORD “SIGNED AND UNDERSTOOD” BY A NON-INVENTOR

AS A MATTER OF LAW, CAN’T ESTABLISH INVENTION DATE WITHOUT CORROBORATION

LAB NOTEBOOK WIDELY USED TOOL FOR INVENTION DATE/CORROBORATION IN USPTO INTERFERENCES
PROVING INVENTION DATE / CORROBORATION
HISTORICAL EVIDENTIARY TOOL
THE CLASSIC “PAPER” LAB NOTEBOOK

PROPERTIES:

• CONSECUTIVELY NUMBERED PAGES
• CONTINUOUS RECORD
  • Information recorded & witnessed from conception to reduction to practice
• PERMANENTLY PRESERVED
  • Bound Book
  • Paper lasts for centuries
• COMPLETE
  • Everything in one package – narrative, corroboration, dates
• RELIABLE
  • techniques for authenticating: ink & paper dating
ADVANTAGES/DRAWBACKS

PAPER NOTEBOOKS VS ELECTRONIC NOTEBOOKS

PAPER NOTEBOOKS:

- LIMITED CAPACITY - HUGE DATA DUMPS IN MODERN RESEARCH
- RESTRICTED DATA FORMATS - NMR, IR SPECTROGRAPHS, PHOTOGRAPHS
- NO CONNECTION TO OTHER LOCATIONS/LABS/PEOPLE
- HARD TO SEARCH - CAN’T INDEX KEY WORDS
- DIFFICULT TO COPY AND SHARE
- LONG DELAY BETWEEN ENTRY, SIGNING AND CORROBORATING VIEWED WITH SUSPICION
ADVANTAGES/DRAWBACKS
ELECTRONIC LAB NOTEBOOKS (ELN)
OVERCOME DRAWBACKS OF PAPER

• EASY TO ASSEMBLE AND MANAGE LARGE QUANTITIES OF DATA
• SEARCHABLE (KEY/WORD/SUBJECT)
• STORE INSTRUMENT GENERATED INFORMATION/IMAGES
• RAPID RETRIEVAL FROM DISTANT LABS
• DATA CAN BE SHARED EASILY

REALITIES OF 21ST CENTURY RESEARCH FAVOR ELN
WHAT IS AN ELN ANYWAY??

ELECTRONIC RECORD THAT COMPLETELY REPLACES PAPER LAB NOTEBOOKS

WHAT AN ELN “IS NOT”

INK SIGNED COPY OF COMPUTER PRINT-OUT

KEEPING PAPER RECORDS IN ELECTRONIC FORM
ELECTRONIC LAB NOTEBOOKS
ADVANTAGES/DISADVANTAGES

IN PAST – ELN’S FAULTED BECAUSE NOT CLEARLY ACCEPTABLE IN LEGAL PROCEEDINGS AS SUBSTITUTE FOR BOUND HANDWRITTEN RECORDS

BASIS FOR UNWILLINGNESS TO ACCEPT ELN’S

1) DATES/ENTRIES SUBJECT TO TAMPERING
2) HARD TO PROVE AUTHENTICITY OF SIGNATURES
3) COMPUTERS UNRELIABLE – POWER LOSS; SYSTEM CRASH; HACKING; UNCONTROLLED ACCESS

QUESTION: HAS TECHNOLOGY OVERCOME THESE DRAWBACKS?
BY THE WAY!

ARE ELECTRONIC RECORDS ADMISSIBLE IN PATENT INTERFERENCES?
ADMISSIBILITY OF ELN

USPTO COMMISSIONERS NOTICE MARCH 10, 1998:

“PURSUANT TO 37 CFR § 1.671, ELECTRONIC RECORDS ARE ADMISSIBLE AS EVIDENCE IN INTERFERENCES BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES TO THE SAME EXTENT THAT ELECTRONIC RECORDS ARE ADMISSIBLE UNDER THE FEDERAL RULES OF EVIDENCE”

“WEIGHT TO BE GIVEN ANY PARTICULAR RECORD NECESSARILY MUST BE DETERMINED ON A CASE BY CASE BASIS”

USPTO

“[T]he Federal Rules of evidence shall apply to Interference Proceedings”
ADMISSIBILITY OF ELN

ADMISSIBILITY OF A WRITTEN RECORD (PAPER/ELECTRONIC) IN USPTO AND COURTS

• GOVERNED BY FEDERAL RULES OF EVIDENCE
• TWO-STEP PROCEDURE
  1) AUTHENTICATION/IDENTIFICATION
  2) ADMISSION UNDER SPECIFIC RULE IN FRE OR UNDER AN EXCEPTION

AUTHENTICATION AND ADMISSIBILITY ≠ CORROBORATION
RECORDS OF INVENTIVE ACTIVITY USUALLY AREN’T ENOUGH BY THEMSELVES, SEE ANDERSON V. PIEPER, 442 F.2d 982, 983-984 CCPA 1971)

“Notebook records or reports of persons not testifying can not be regarded as proof of the experimental work recorded therein.”
ADMISSIBILITY OF ELN

LEGAL FOUNDATION FOR AUTHENTICATING
ELECTRONIC DOCUMENTS

RULE 901 FEDERAL RULES OF EVIDENCE

GOVERNS AUTHENTICATION OF EVIDENCE

REQUIREMENT OF AUTHENTICATION IS “...SATISFIED BY
EVIDENCE SUFFICIENT TO SUPPORT A FINDING THAT THE
MATTER IN QUESTION IS WHAT ITS PROponent CLAIMs.”
ADMISSIBILITY OF ELN

AUTHENTICATING ELECTRONIC EVIDENCE REQUIRES RIGOROUS FOUNDATION THAT CAN BE HARD TO PROVE

IN RE VIN VINNHEE, DEBTOR, AMERICAN EXPRESS TRAVEL RELATED SERVICES COMPANY INC. V. VIN VINHEE 336 B.R. 437 (B.A.P. 9TH CIR 2005)

- ILLUSTRATES NATURE OF EVIDENCE REQUIRED FOR AUTHENTICATION/ADMISSION OF ELECTRONIC RECORD
ADMISSIBILITY OF ELN

VINHEE

• CHAPTER 7 BANKRUPTCY PROCEEDING
• AMEX SOUGHT TO EXCEPT $41K FROM DISCHARGE
• MONTHLY STATEMENTS OF ACCOUNT IN ELECTRONIC FORM
• OFFERED UNDER BUSINESS RECORDS EXCEPTION
• AMEX CUSTODIAN KNEW LITTLE ABOUT COMPUTERS OR SOFTWARE
• “THERE’S NO WAY COMPUTERS CHANGE NUMBERS”
• QUALIFICATIONS OF DECLARANT WERE DEFECTIVE
• NO INFORMATION ON AMEX COMPUTER POLICY, SYSTEM, CONTROL, OR ACCESS
• RECORDS NOT ADMISSIBLE
ADMISSIBILITY OF ELN

VINHEE COURT EVALUATED EVIDENCE USING TESTS DESCRIBED BY E.J. IMWINKELRIED IN “EVIDENTIARY FOUNDATIONS” (§4.03[2])

SUGGESTED AS:
“MODERN FOUNDATION FOR COMPUTER RECORDS”

1. BUSINESS USES A COMPUTER
2. COMPUTER IS RELIABLE
3. BUSINESS HAS DEVELOPED A PROCEDURE FOR INSERTING DATA INTO COMPUTER
4. PROCEDURE HAS BUILT-IN SAFEGUARDS TO ENSURE ACCURACY AND IDENTIFY ERRORS
5. BUSINESS KEEPS COMPUTER IN GOOD STATE OF REPAIR
ADMISSIBILITY OF ELN

6. WITNESS HAD COMPUTER READOUT CERTAIN DATA
7. WITNESS USED PROPER PROCEDURES TO OBTAIN READOUT
8. COMPUTER WAS IN WORKING ORDER AT TIME WITNESS OBTAINED READOUT
9. WITNESS RECOGNIZES EXHIBIT AS READOUT
10. THE WITNESS EXPLAINS HOW HE OR SHE RECOGNIZES READOUT
11. IF READOUT CONTAINS STRANGE SYMBOLS OR TERMS, WITNESS EXPLAINS MEANING OF SYMBOLS OR TERMS FOR TRIER OF FACT
AS TO FOURTH TEST, VINHEE COURT SAID,

“THE BUILT-IN SAFEGUARDS TO ENSURE ACCURACY AND IDENTIFY ERRORS IN THE FOURTH STEP SUBSUME DETAILS REGARDING COMPUTER POLICY AND SYSTEM CONTROL PROCEDURES, INCLUDING CONTROL OF ACCESS TO THE DATABASE, CONTROL OF ACCESS TO THE PROGRAM, RECORDING AND LOGGING OF CHANGES, BACKUP PRACTICES AND AUDIT PROCEDURES TO ASSURE CONTINUING INTEGRITY OF THE RECORDS.”
“....Focus is not on circumstances of creation of the record, but rather on circumstances of the preservation of the record during the time it is in the file so as to assure that the document being proffered is the same as the document that originally was created.”

“...Entities policies and procedures for use of the equipment, database and programs are important. How access to the pertinent program is controlled and, separately, how access to the specific program is controlled are important questions.”
LORRAINE V. MARKLE AM. INS, 2007 WL 1300739 (D. MD MAY 4, 2007) GRIMM, J.

• 80 PAGE OPINION
• CONTRACT FOR SALE OF YACHT
• REFERS TO VINHEE, BUT GOES FURTHER
• EXPLAINS INTERPLAY OF FRE WITH FRCP
• ELECTRONIC EVIDENCE PRIMER
• WAY EVIDENCE IS GATHERED, PROCESSED & PRODUCED CAN IMPACT ADMISSIBILITY
LORRAINE V. MARKLE

“IF IT IS CRITICAL TO THE SUCCESS OF YOUR CASE TO ADMIT INTO EVIDENCE COMPUTER STORED RECORDS, IT WOULD BE PRUDENT TO PLAN TO AUTHENTICATE THE RECORD BY THE MOST RIGOROUS STANDARD THAT MAY BE APPLIED.”
SO, WHAT'S THE POINT?
NEED TO BE ABLE TO PROVE THAT THE ELECTRONIC LAB NOTEBOOK IS WHAT IT PURPORTS TO BE!!

HOW INFORMATION WAS GATHERED, PRODUCED, PROCESSED, STORED
AUTHENTICATING ELECTRONIC INFORMATION

NOT ENTIRELY NEW ISSUE

MACHINE PRODUCED EVIDENCE ROUTINELY USED IN COURTS FOR MANY YEARS

EXAMPLES:

• X-RAY FILMS
• NMR’S
• MASS SPECTROGRAPHS
• ELECTRONIC INVOICES
THRESHOLD QUESTION FOR TRIER OF FACT – IS ELN EVIDENCE ADMISSIBLE?

IS EVIDENCE...

• RELEVANT?
• AUTHENTIC?
• RELIABLE?
• NOT HEARSAY?, OR
• WITHIN AN EXCEPTION TO HEARSAY RULE?
ONCE ELN IS ADMITTED, NEED TO ADDRESS “CREDIBILITY”

• IF EVIDENCE IS ADMITTED, HOW MUCH WEIGHT WILL IT BE ENTITLED TO?

• COURT CAN CONSIDER ALL FACTORS INCLUDING CRITERIA FOR ADMISSIBILITY

• IMPORTANT TO ESTABLISH WITNESSES AND EVIDENCE ARE RELIABLE AND TRUSTWORTHY
HOW TO ESTABLISH AUTHENTICITY OF RECORD BEING OFFERED?

PAPER NOTEBOOK - ESTABLISH BY TESTIMONY OF CREATOR

ELN - ESTABLISH BY TESTIMONY OF CUSTODIAN THAT RECORD BEING PROFFERED IS ACCURATE COPY OF ELECTRONICALLY STORED INFORMATION; DETAILS OF COMPUTER SYSTEM, SOFTWARE, ACCESS, ETC.
FACT ISSUES TO BE RESOLVED BY TRIER OF FACT WITH RESPECT TO ELN RECORD BEING OFFERED

SYNTHESIS OF IMWINKELRIED FACTORS:
• WHO CREATED IT?
• WHAT’S BEING OFFERED?
• WHY WAS IT CREATED?
• WHO WITNESSED IT?
• HOW WAS IT MADE?
• WHEN WAS IT MADE?
• HOW WAS IT KEPT?
• HAS IT BEEN REVISED? (HOW CAN I TELL?)

NYCLE CREDIT CODE 805
PROBLEM WITH AUTHENTICATION AND RELIABILITY OF ELN RECORDS

NEED TO PROVE RECORD IS WHAT IT PURPORTS TO BE AND HASN’T BEEN MODIFIED:

• HAVE TO AUTHENTICATE INFORMATION AND COMPUTER, PROCESS USED TO ENTER, MAINTAIN AND RETRIEVE
• PROVE COMPUTER AND PROCESS USED WERE RELIABLE
• PROVE RETRIEVED DATA IS IN ORIGINAL FORM

HOW TO DO THIS FOR AN ELECTRONIC RECORD?
“The use of electronic laboratory notebook (ELN) technology has risen sharply in the past four years, having now penetrated over 20 percent of all biopharmaceutical companies.” FN¹

“ELN technology has not only lead to increases in laboratory efficiency…. but also to enhanced protection of intellectual property (IP).”

“…over 70 percent 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.”

FN¹ – See 2006 Electronic Notebook Survey; Atrium Research Consulting, Wilton, CONN.
ELECTRONIC LABORATORY NOTEBOOKS

• HYBRID MODEL – POTENTIAL PROBLEM
• ADVERSE PARTY ENTITLED TO DISCOVERY OF PAPER AND ELECTRONIC RECORD (2006 AMENDMENTS TO RULE 26 FRCP)
• WHAT HAPPENS IF ELECTRONIC RECORD IS ALTERED – DOESN’T AGREE WITH PAPER?
• PROBABLY BETTER TO RELY ON REAL ELN, IF ADMISSIBLE
WHO IS THE AUTHOR OF THE RECORD? WHO WITNESSED IT?

PAPER NOTEBOOK – METHODOLOGY: INK SIGNATURE OF AUTHOR AND WITNESS ON EACH PAGE

ELN – NEEDS METHODOLOGY FOR
• ASSOCIATING AN ELECTRONIC SIGNATURE WITH A NOTEBOOK ENTRY
• ASSURING DATE IS ACCURATE
• ASSURING DOCUMENT UNCHANGED

PROBLEM – HOW TO DO THIS IN AN ELN??
ELECTRONIC LABORATORY NOTEBOOKS

HAS TECHNOLOGY TILTED SCALES IN FAVOR OF ELN?

• ADVENT OF PUBLIC KEY INFRASTRUCTURE
• (DIGITAL SIGNATURE & DIGITAL TIME STAMP)
• CRYPTOGRAPHIC TECHNIQUES
• AIDS TO AUTHENTICATION OF ELN INFORMATION
ELECTRONIC LABORATORY NOTEBOOKS

PUBLIC KEY INFRASTRUCTURE

PKI

• RELIES ON PAIR OF MATHEMATICALLY RELATED CRYPTOGRAPHIC KEYS

• IF ONE KEY USED TO ENCRYPT INFORMATION, ONLY RELATED KEY CAN DECRYPT INFORMATION

• PUBLIC KEY – NOT SECRET – SEEN BY ALL USERS
  • Provides unequivocal proof you are who you claim to be

• PRIVATE KEY – (UNIQUE AND CORRESPONDS TO PUBLIC KEY)
  • Kept secret – not shared amongst users
SIMPLE EXAMPLE OF PKI IN USE

DIGITAL SIGNATURE

• 3rd Party (Inventor) uses Record Keepers (RK) Public Encryption Key to send RK Information

• RK uses private key to decrypt information encrypted with corresponding public key

• RK can be sure that information it can decrypt was intended for them
  • However, RK can’t be certain who information came from!

NOW WHAT?
• IF 3rd party (inventor) wishes to prove to RK that they are source of information, use separate assigned private key to sign message (digital signature) based on unique information in message.

• Contrast:
  - Handwritten signature – always the same
  - Digital signature – different every time it’s made (based on unique mathematical value)
OK, BUT WHAT ABOUT ESTABLISHING DATE OF DOCUMENT/SIGNATURES?
DIGITAL TIME STAMP

• DEFINED BY INTERNET ENGINEERING TASK FORCE (IETF)
• EXTENSION OF PKI USED FOR DIGITAL SIGNATURES
• TIME STAMP AUTHORITY (TSA) – SOFTWARE
• TRUSTWORTHY CLOCK FOR DATE/TIME
• RELIES ON UNIQUE FILE IDENTIFIER (BASED ON DOCUMENT PROFILE)
• TSA STAMPS RECORD (FILE IDENTIFIER) WITH DIGITAL TIME STAMP
• ONLY UNIQUE FILE IDENTIFIER SENT TO TSA (NOT INFORMATION ITSELF)
• TIME STAMP UNIQUELY LINKED TO DOCUMENT
• STAMP CLOCK USUALLY ACCURATE TO WITHIN ± 1 SECOND
• IF TIME STAMP VALID, CONFIRMS DOCUMENT NOT REVISED SINCE “STAMP” TIME
• CHANGE TO DOCUMENT INVALIDATES TIME STAMP
PKI DIGITAL SIGNATURE/TIME STAMP

OFFERS USERS:

• CERTAINTY OF DATA SENT/RECEIVED ELECTRONICALLY
• CERTAINTLY OF SOURCE/DESTINATION OF INFORMATION
• ASSURANCE OF TIME/TIMING OF INFORMATION STORAGE
• CERTAINTY OF PRIVACY
• ABILITY FOR 3RD PARTY VERIFICATION (TRUSTED AUTHORITY)
**ELECTRONIC LAB NOTEBOOKS**

**SUMMARY**

- **DIGITAL SIGNATURES/ TIME STAMPS IMPROVE RELIABILITY OF ELN INFORMATION**
- **USE TO ESTABLISH HOW AND WHEN RECORD WAS CREATED (AUTHENTICATION OF DOCUMENT)**
- **HELPS TO OVERCOME DRAWBACKS OF ELNS**
- **USEFUL TO SATISFY IMWINKELRIED TESTS/AUTHENTICATE RECORD**
- **BRINGING ELN’S CLOSER TO “PRIME TIME”, BUT …….**
ELECTRONIC LAB NOTEBOOKS

...THERE’S MORE (NO KIDDING)

WITNESSES HAVE TO TESTIFY TO HOW ELN RECORD WAS

• CREATED
• MAINTAINED – OPERATION OF SYSTEM / SOFTWARE / CONTROLLED ACCESS

BOTTOM LINE

PKI TECHNOLOGY CAN HELP TO AUTHENTICATE ELN INFORMATION, BUT STILL NEED LIVE WITNESSES
CONCLUSION

• TECHNOLOGY (DIGITAL SIGNATURE & DIGITAL TIME STAMP) SHOULD HELP TO MEET REQUIREMENTS FOR ADMISSIBILITY OF ELN RECORDS
• SAFE DIGITAL SIGNATURE SYSTEM FOR ELN IN USE AT PFIZER SINCE 2006 fn1
• STILL IMPORTANT TO CONTROL ACCESS TO ELN RECORDS
• STILL NEED WITNESSES THAT KNOW DETAILS OF SYSTEM/SOFTWARE
• USING HYBRID SYSTEM (“WET” SIGNED PRINTOUT)
  • DO SOMETHING TO SIMULATE BOUND/CONTINUOUS PAPER NOTEBOOK

Fn1 See, Pfizer Implementation of SAFE™ Digital Signatures for Electronic Lab Notebooks © Pfizer 2007
WILL NOTEBOOKS MATTER IN THE FUTURE?

PROBABLY!

FIRST TO INVENT VS FIRST TO FILE

—

COMING AT SOME POINT

(See March 10, Amendment to S.515)
NOTEBOOK RECORDS WILL STILL BE IMPORTANT

• HANGOVER INTERFERENCE / COURT PROCEEDINGS

• PROVE:
  • INVENTORSHIP / RESPECTIVE CONTRIBUTIONS OF INVENTORS
  • TITLE
  • TRADE SECRET ISSUES
SOME PLACES TO CHECK OUT FOR MORE ON THIS TOPIC

• Collaborative Electronic Notebook Systems Association (www.censa.org)

• PKI Tutorial (http://www.csauckland.ac.nz/pgut001/pubs/pkitutorial.pdf) by Peter Gutman

• Public Key Infrastructure (http://en.wikipedia.org/wiki/public_key_infrastructure)

• An Introduction to PKI (Public Key Infrastructure) (http://www.articsoft.com/public_key_infrastructure.htm)
THANK YOU!!

QUESTIONS?

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