



Protect Your Scientific Intellectual Property:

Proof of Lab Informatics Data Authenticity
is Your Best Legal Defense

Executive Summary

Executives of R&D-based organizations have a fiduciary responsibility to maximize and protect the value of their company's assets. Intangible assets drive nearly 70 percent of a bio-technology company's market value, predominantly in the form of scientific intellectual property¹. Intellectual property (IP) is a collection of intangible assets, such as formulas, patents, trademarks, copyrights, trade secrets and institutional knowledge that gives an R&D company its competitive advantage, differentiation and unique value in the market place. There are documented cases in the life sciences, bio-technology, manufacturing and computer software industries in which a company's loss of intellectual property, either to a competitor or to the public domain, has led to hundreds of millions of dollars in lost revenue, legal fees, reduced market valuations and damages related to class-action lawsuits.

Today, insurance providers cannot adequately cover the risk of intellectual property loss. Because this risk is far too great for a company to assume, senior executives must consider their fiduciary responsibilities and take immediate action to mitigate the risk. The best way to do this is to ensure that the company can prove that the scientific records supporting its IP ownership claims are credible, authentic and legally defensible.

One of the most insidious types of unethical behavior is the growing problem of data manipulation by trusted insiders. Because more than 90 percent of all corporate records are electronic,² it is not difficult for employees to tamper with records to meet objectives or to maximize profits. The following are a few examples where this unethical behavior allegedly occurred:

- **Manipulated Research:** Dr. Hwang Woo Suk, a South Korean scientist, was fired from his professorship at Seoul National University, and was charged with fraud and embezzlement, after

admitting that he manipulated photo images of stem cells in his research, funded by millions of dollars in state and private funding.

- **Mutual Fund Late Trading:** Daniel Calughar, and his former broker dealer Security Brokerage Inc. (SBI), settled with the SEC for \$150M for electronically backdating financial transactions.
- **Sales Contract Backdating:** 15 executives from Computer Associates were fired or forced to resign and another five pleaded guilty to charges of fraud, conspiracy and obstruction of justice in connection with backdating more than \$3.3B of sales contracts.

While these are just a few examples, this kind of activity is happening every day, worldwide. When challenged, if a company is unable to prove the authenticity of its electronic lab data supporting its IP claims, it is at risk of losing that asset and any assets developed from it. Data manipulation calls into question the authenticity of all its electronic records and content.

Truly innovative life sciences and bio-technology companies take scientific intellectual property protection seriously, and integrate data-level security controls, such as trusted timestamping, into their electronic lab informatics systems and workflows. They understand that litigation-readiness is a critical part of the IP protection process and that having the power of proof is an essential safeguard in winning a future patent or legal challenge.

Surety's AbsoluteProof® is a third-party, trusted time-stamping solution that when integrated into a company's electronic lab informatics management processes, enables the organization to prove, independently of their people, processes and systems that their scientific records have never been manipulated since the time they were created, "signed" and "sealed."

The Value of Scientific Intellectual Property

Bringing a new healthcare product, drug treatment or fuel additive to market can mean an investment of many years and millions of dollars for bio-pharma or bio-tech organizations. Lab automation technologies and electronic tracking systems are taking the bio-R&D world by storm – streamlining research and driving discoveries and new-product development like never before.

At the same time, they are generating massive amounts of R&D data, records and audit logs – electronic evidence of scientific intellectual property that one day could be called upon to support claims of first-to-invent and ownership. Unfortunately, if just one of these electronic records or data files has been tampered with, or even stolen, the entire investment could be lost.

The best strategy available to organizations is to be prepared to defend their scientific intellectual property in the face of a patent or legal dispute, especially if litigation is the likely route.

How Scientific IP Disputes Arise

Because scientific intellectual property is a critical strategic asset, life sciences and bio-IT companies can go to great lengths to protect their scientific intellectual property rights, or to limit the IP rights of their competitors. Scientific intellectual property disputes arise

when multiple parties claim usage rights or ownership of a given IP asset.

The two factors that drive many scientific intellectual property disputes are:

Knowledge Diffusion. Institutional knowledge, knowingly or unknowingly, can be sent outside the organization to potential competitors. Once a scientific IP asset is in the hands of others, it can be very difficult for companies to prove that they own the asset. A recent example in which knowledge diffusion may cost a company dearly is the Starwood Hotels case against Hilton in which Starwood contends two former Starwood executives who joined Hilton stole more than 100,000 electronic and paper documents containing "Starwood's most competitively sensitive information." Probably the most well-known case, however, is the thwarted attempt by a Coca-Cola employee to sell formula trade secrets to Coke's rival, Pepsi, in July 2006.³

Concurrent Development Among Competitors. In an increasingly competitive marketplace, it is common to have many biotechnology companies racing to develop and launch solutions first. In the U.S. where the patent system is based on the principle of "first-to-invent," a company must prove when it conceived its idea and also when it reduced the idea to practice. Without the ability to defend the lab records that prove these critical dates and content, innovative companies can lose their scientific IP to competitors or to the public domain. Knowledge diffusion and a competitive marketplace are inescapable realities facing executives. The best strategy available is to be prepared to defend their scientific intellectual property in the face of a patent or legal dispute, especially if litigation is the likely route.

Proving Scientific IP Ownership: The Importance of Authentic Lab Informatics Data

When companies are faced with IP challenges and risk losing valuable intellectual capital assets, all relevant electronic and paper documentation is discoverable and admissible in court. The Federal Rules of Evidence (FRE) allow for electronic records, including electronic lab notebook (ELN) content, to be equally admissible as paper records in patent or legal proceedings, provided that **(i)** they are kept in the course of regularly conducted business activity; and **(ii)** the source of information or the method of preparation is trustworthy⁴.

Opposing counsel will not only challenge the authenticity and credibility of a company's lab data, but also, the trustworthiness of the people, processes and systems responsible for their safekeeping. Companies can present scientific content that credibly supports their IP claims, but without irrefutable proof of their authenticity, they may be successfully challenged and eliminated as evidence. Such a challenge derives from the fact that unprotected electronic records can be easily altered or fabricated. Opposing counsel will attempt to show that employees of the company have motive and opportunity to manipulate records. Proving authenticity is the lowest common denominator in getting evidence upheld, and its importance is increasing as electronic records proliferate inside the enterprise.

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Risk Factors to Authentic Scientific Records and Data

The two primary factors inside the enterprise that drive the need for R&D organizations to protect the integrity and prove the authenticity of their electronic records are: **(i)** motive and **(ii)** opportunity.

Motive. More than 60 percent of all IT security breaches are caused not by outside hackers, but by trusted insiders who have access to corporate intellectual property assets⁵. Given the importance of intellectual property assets to a company's success, it is not surprising that executives face pressure to retain rights to those assets. This pressure is often transferred to their employees. As a result, employees can easily succumb to unethical behavior, such as manipulating invention dates and altering metadata to meet rigorous objectives.

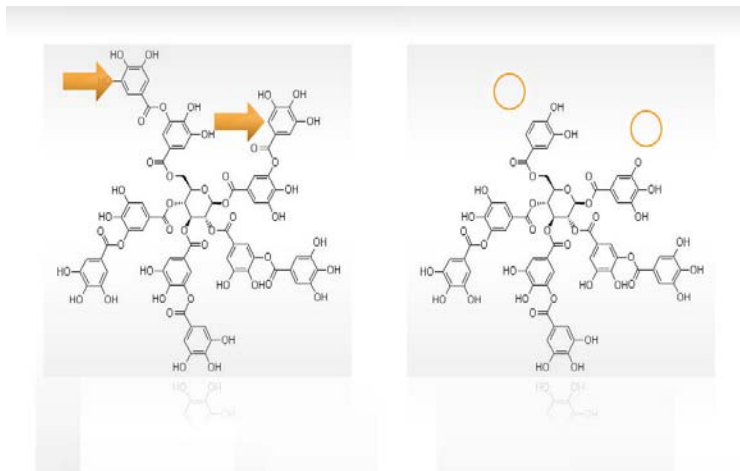
Opportunity. With more than 90 percent of all lab records and data now generated electronically⁶, there are innumerable opportunities to tamper with electronic content. Forging or tampering with electronic records is easy to do and difficult to detect. Also, because of the workflows of most lab informatics systems, electronic records can be generated in one department, managed in another, and archived in yet another, there are multiple points in the organization where manipulation can occur. This decentralized lab data management process poses a significant risk to researchers and executives, who when challenged must be able to prove the legal credibility and authenticity of these records throughout their chain-of-custody or risk losing their company's scientific IP assets.

The Risk of Losing or Settling a Patent Interference Case⁷

In 2001, a global, multi-billion dollar semiconductor company was mired in a technology patent interference case. At stake was the rightful ownership of a core patent that drove \$200MM of annual process equipment revenue to the company. In this case, an employee left the company and joined a competitor that soon thereafter, prepared to launch a competing piece of scientific equipment with what seemed like an identical method. The company chose to vigorously defend its patent but bore the burden of proving its ownership claims to the asset. Two years, \$1MM in legal fees, and seven years of discovery later, the company could not authenticate one credible lab or research record to support its claim. The company was forced to settle with its competitor and lost the competitive advantage that it once enjoyed.

“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.”

-- Judge Paul W. Grimm



True Case - the molecular structure for a cutting-edge cure to an epidemic under review by the FDA – could you tell if slight alterations to the research data were made that could impact its approval?

Managing Scientific Intellectual Property Risk

R&D organizations have three options to consider when managing the risk of losing their scientific intellectual property - they can **assume** it; they can **transfer** it; or they can **mitigate** it.

Scientific IP Risk #1: Too Much to Assume

The first option is to **assume** the risk. Companies that assume the risk of losing scientific intellectual property must hope that they never face a patent or legal challenge – a considerable risk, no matter how trustworthy their people, processes and systems may appear to be. According to the American Intellectual Property Association, the average cost to litigate a patent infringement lawsuit is greater than one million dollars.

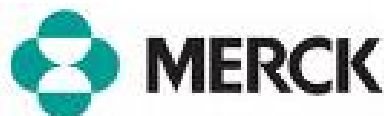
When companies lose scientific intellectual property, the costs include damages, legal fees and often, unfavorable publicity – all of which impacts their earnings and their shareholders. Consequently, executives also risk collateral damage, such as product loss, class-action lawsuits and lower quarterly sales forecasts. These risks to the organization and to its shareholders are far too great for executives to bear.

Even smaller firms in the biotech and pharma markets would see little value in purchasing such a limited insurance policy to protect the future value of their scientific intellectual property.

Scientific IP Risk #2:
Impossible to Transfer

In theory, a company's second option may be to **transfer** the risk of losing their scientific intellectual property to an insurance company. However, scientific IP is virtually uninsurable today. Though intellectual property insurance does exist, underwriters are only willing to cover up to \$25MM of risk exposure⁸. The massive legal fees and damages that can result from scientific IP litigation make such policies unattractive to R&D-driven organizations that need full coverage for their risk. Furthermore, neither the opportunity cost nor lost revenue due to litigation is covered under such policies. As a result, the intellectual property insurance market is small (slightly over \$100MM in premiums written in 2008, versus \$1B for the D&O insurance market) with modest prospects for growth.⁹

To illustrate, the maximum policy coverage available today of \$25MM would cover approximately 4% percent of pharma giant Merck's total intangible asset value¹⁰.



No insurance provider would cover Merck's considerable risk exposure. Even smaller firms in the biotech and pharma markets would see little value in purchasing such a limited insurance policy to protect the future value of their scientific intellectual property. Therefore, R&D-driven organizations do not have a realistic means to insure their growing body of scientific intellectual property and most likely, they never will.

Scientific IP Risk #3:
Mitigation is the Best Option

The final and best option for R&D organizations is to **mitigate** the risk of losing scientific intellectual property. The best way to mitigate this risk is to put in place security controls that enable the company to validate the integrity and prove the authenticity of the electronic lab data it needs to support its scientific intellectual property claims. Such controls can prevent these files from being successfully challenged and eliminated as evidence, and can stand up and successfully be defended in terms of "ownership."





Mitigate Risk of Losing Scientific Intellectual Property: *Digital Timestamping and “Legally Defensible” Ownership*

Digital timestamping by a trusted, third party is a data-level security control that enables R&D organizations to validate the integrity and prove the authenticity of the electronic lab data and other digital content that support their scientific intellectual property development and discoveries. These methods, when integrated into electronic lab informatics processes, enable R&D companies to prove, independent of their people, processes and systems, that their formulas, research and clinical data existed at a point in time and has not been altered since. This “sign and seal” control enables companies to legally defend their ownership of such critical research data.

Surety’s AbsoluteProof time-stamping methodology enables organizations to digitally “sign and seal” their electronic lab content.

When considering which time-stamping methodology offers the best protection against losing scientific intellectual property, informatics specialists should require the following attributes be included:

- **Independently Verifiable.** The digital time-stamping method must provide objective proof of electronic file integrity, independent of a company’s people, processes and systems.
- **Standards-based.** The digital time-stamping method must be compliant with either an international standards body such as ISO, or a domestic standards body such as the American National Standards Institute (ANSI), to ensure future reliability and performance.

Surety’s AbsoluteProof® service is an accredited, digital time-stamping service, under both ISO 18014-3 and ANSI X9.95 time-stamping standards. It is the only time-stamping method on the market that offers long-lasting protection, provides objective validation of record integrity independent of an organization’s people, processes and systems, and is compliant with both a domestic and an international standards body. Surety’s AbsoluteProof patented, digital time-stamping methodology enables organizations to digitally “sign and seal” their electronic lab informatics content. It satisfies each of the afore-mentioned requirements in a seamless, cost-effective manner to enable R&D companies to be both legally protected and accountable in the defense of the ownership of their scientific intellectual property.

Software modules for Microsoft Windows, SharePoint and Exchange, as well as for electronic lab notebooks and other bio-informatics systems, enable customers to integrate AbsoluteProof into any platform where “signing” and “sealing” critical content is required. Easy-to-use software development kits also enable seamless integration into any “home-grown” lab informatics system, as well.

- **Long-lasting Protection.** The digital time-stamping method must provide unimpeachable proof of electronic file authenticity far into the future, despite hardware, software and service-provider dependencies.





Content Authenticity | Protection for the Long Term

R&D-oriented organizations must preserve their records between 15 and 100 years or longer. At any moment, you might be called upon to verify the integrity of every record or audit log in defense of a product liability investigation or patent. Losing that claim could cost millions or even the business's existence. As a result, you must be able to validate the authenticity of your research records years – or even decades - after their creation. That's where AbsoluteProof, integrated into an electronic lab environment, comes in.

Unlike PKI-based digital signatures that expire over time or have keys that can be comprised, thus weakening the defense of your ownership, only the Surety Integrity Seal, a digital, cryptographic time stamp, provides evidence of data integrity and authenticity – for the life of the content - guaranteed.



Let Scientists Practice Science... Leave the "Signing & Witnessing" to Technology

With AbsoluteProof integrated into any lab informatics system, a legally defensible, digital time stamp is applied to your most valuable asset – your scientific intellectual property. As a result, the integrity of your electronic research content is beyond challenge, eliminating the burden and time scientists experience having to "sign and witness" volumes of ELN or lab systems pages and freeing them up to do what they do best – research, discover and create.

AbsoluteProof delivers transparent assurance of the long-term protection of the integrity and authenticity of your lab data. When research team members create, change or witness a record, it is automatically "signed and sealed," and the work is not interrupted.

AbsoluteProof delivers independent, cryptographic proof that your research was created and signed and locked down at a specific point in time...that the contents have not changed since that time...and that it is rightfully owned by your organization.

Legally Defensible Proof of Authenticity

Electronic lab content time stamped by AbsoluteProof qualifies for Surety's Legal Defensibility Guarantee, a program backed by a leading international litigation support firm and designed to give customers confidence that their "sealed" lab data will withstand the most rigorous legal scrutiny. The guarantee provides customers access to sworn affidavits and expert witness testimony to the quality and defensibility of the underlying technology, confirming that the Seals provided by the AbsoluteProof service are authentic and have not been compromised. A money-back guarantee is included should a court decide that Surety has not been able to satisfy its claims – a payout we've never had to make!

Exp. Code	Status	Date	OK?	AbsoluteProof
3 M-00-00001	Validated	20-AUG-2009	✓	No Seal
4 M-00-00012	InReview	20-AUG-2009	✓	No Seal
5 M-00-00016	InReview	20-AUG-2009	✓	No Seal
1 M-00-00017	InReview	08-SEP-2009	✓	Valid
8 M-00-00033	InReview	09-SEP-2009	✓	Valid
9 M-00-00001	InReview	09-SEP-2009	✓	Valid
6 M-00-00017	InReview	11-SEP-2009	✓	Valid
7 M-00-00017	Validated	11-SEP-2009	✓	Valid

AbsoluteProof can integrate seamlessly into any lab informatics or ELN system, automating the "signing and witnessing" process, and making it transparent to the user so they can focus on their IP research and development work.

Conclusion

R&D executives have a fiduciary responsibility to their shareholders to maximize and protect the value of their organization's assets. Scientific intellectual property, the most important of these assets, is often exposed in many innovation-driven companies because of the risk of losing that IP in the face of a patent or legal challenge. The most effective way to handle this risk is to integrate data-level integrity controls inside the company's electronic lab management systems. These controls will detect and deter data manipulation – either by outsiders or by trusted members of the organization, and best position you for long-term defensibility.

Trusted, digital timestamping is an effective data-level integrity control that R&D-based companies can use to prove the authenticity of their electronic records. The most effective time-stamping methods should offer long-lasting protection; provide objective proof of record integrity independent of a company's people, processes and systems; and be compliant with a domestic and/or international standards body. Surety's AbsoluteProof satisfies these requirements in a seamless, transparent and cost-effective manner. When integrated into a lab informatics system or ELN, the integrated solution:

- Digitally “seals” lab content, safeguarding scientific intellectual property data;
- Improves productivity of research teams;
- Guarantees trustworthy records and content;
- Enables legally defensible proof of authenticity and ownership;
- Delivers long-lasting content protection;
- Enables flexible workflow processes, completely transparent to users; and
- Mitigates risk, and provides proof of compliance.

AbsoluteProof from Surety

With millions of electronic records, files and scientific data worldwide “sealed” by its service, Surety is a leading provider of data integrity protection solutions. Surety's AbsoluteProof digital time-stamping service easily integrates into your lab informatics systems, and can help mitigate risk, create significant business value, and protect and legally defend the integrity and authenticity of your scientific intellectual property, now and decades into the future.

AbsoluteProof ensures against content tampering by providing a “digital wax seal” for all types of electronically stored data and content.

To learn more about how the AbsoluteProof service can help you defend the integrity of your electronic records supporting your scientific intellectual capital assets, visit www.surety.com.



Think of us as the modern-day “Digital Wax Seal”



Footnotes

- 1 "Intellectual Property Risk Management," Ocean Tomo.
- 2 ARMA International, www.arma.org/erecords/index.cfm
- 3 Appendix I: "Coca-Cola Almost Loses Secret Formula".
- 4 "Federal Rules of Evidence," <http://www.uscourts.gov/rules/>
- 5 The CSI/FBI 2008 Computer Crime and Security Survey
- 6 ARMA International, <http://www.arma.org/erecords/index.cfm>
- 7 Appendix II: "Semiconductor Company Loses Competitive Advantage"
- 8 Richard S. Betterley, "The Betterley Report: Intellectual Property Insurance Market Survey 2006."
- 9 "Intellectual Property Risk Management", Ocean Tomo.
- 10 "Intellectual Property Risk Management", Ocean Tomo.

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