

Protecting Your Company's Inventions: Optimal Internal Documentation Procedures Create Better Patents, Lower Costs, And Help Prepare For Future Litigation¹

Patent documentation procedures and records are put under a microscope of intense scrutiny in patent litigation. Will your company's records meet the challenge? Having a clearly marked trail for each invention that is documented consistently with records, physical exhibits, and proper witness corroboration can be the difference between winning or losing a lawsuit.



Long before a patent is litigated, starting with the company research that preceded the patent application, is when a company should be creating records of the invention that will stand up in court.² Neither management nor shareholders want to learn that a patent case was lost because a company kept inadequate records of invention. A careful review and implementation of internal document procedures can avoid this problem.

One purpose of this newsletter is to help corporate counsel, researchers, and business management understand the purpose and importance of optimal procedures. The importance of internal documentation procedures for patents is often not readily apparent to inventors or non-patent attorneys until litigation of a patent. By that time, it may be too late.

Another purpose of this newsletter is to provide an overview of optimal procedures that can establish a patent owner has complied with her obligations under the patent laws. If implemented, these procedures will not only assist patent counsel in preparing a better patent application for the company, but also provide competent evidence if the patent is ever the subject of litigation.

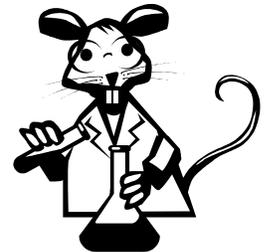
¹ **Anthony G. Vella**, the author of this newsletter, is an **Altera Law Group** patent attorney who is also licensed to practice in Minnesota, Illinois, and California. Mr. Vella is available to audit and install procedures that can recognize and protect your intellectual property. If you have any questions about this article, or any other intellectual property issues, please contact Mr. Vella at tvella@alteralaw.com or (952) 253-4123.

² I have participated in patent disputes, including patent litigation, where priority of invention was an issue. Problems such as inconsistent record keeping, lack of organization for records, and failure to corroborate evidence with a non-inventor can affect the outcome. If these problems are discovered during patent litigation, it is too late for that particular case. Thus, it is beneficial to review procedures before you are involved in patent litigation.

Procedure must be in place for gathering information contemporaneously during the inventive process. Relevant information should be earmarked for collection, and will be easier to retrieve when a company contemplates litigation. Invention protocols should identify relevant technical data such as the technical problems under research, inadequacy of current solutions to a problem, any publications or resources addressing problems and solutions, and the individuals involved in creating a solution. In addition to serving corporate research purposes, the records will assist patent counsel. Having this information readily available can help with the patent application process such as determining correct inventorship, and the mandatory disclosure of relevant prior art references during patent prosecution.

Patent litigation often occurs much later in the life cycle of a patent, and witness memories may need to be refreshed. Records kept in the usual course of research can refresh an inventor or witnesses' recollection many years after the patent grant.³ Proper record keeping procedures can help trial counsel classify documents and physical exhibits as "business records." Business records can overcome certain evidence objections like when a witness is unavailable or cannot recall the events at the time of the lawsuit.

The following checklists identify useful information for different stages of the "invention to patent" process:



Pre-Research Activities Through Conception of the Invention

Some important questions to ask and answer are:

1. What is the problem that we are attempting to solve?
2. What is the state of the art? What published materials on this subject matter are available? Are the inventors collecting relevant information in a file to be shared eventually with the patent attorney? Have we conducted a literature search, used existing publication files, or commissioned a search to determine the prior art?
3. Who are the people that will be working on this project? Are all of the people employees of our company? In the case of non-employees, are they under an obligation to assign the invention to us? Are we working with information or material provided to us from a third party? Are there

³ Most utility patents have a life of 20 years from the filing date of the patent application. This general rule is subject to certain exceptions; can depend on the date of filing and issuance of the patent, and is linked to the earliest non-provisional application to which a patent claims its right of priority.

any restrictions placed on this material or information? Are we working as part of a collaborative effort? Do we have or need a signed joint research agreement?

4. Do we need a freedom to operate opinion?
5. What IP protections do we already have in place?
6. Is patenting the invention outside of the United States important?
7. Do the personnel working on the invention understand that the project should be maintained in confidentiality, and be regarded as a trade secret that should not be disclosed to an outside party (at least until the patent application is filed)?
8. Do the personnel working on the invention understand that any disclosure of results or information about the project to third parties must be cleared in advance, and that third parties must be under non-disclosure agreements (“NDAs”) to preserve patent rights?
9. Has an offer to sell the invention been made to customers? If so, when was that offer to sell made, and what was described in the offer to sell? Was the offer labeled for budget purposes only, and not intended as an offer that a buyer could accept? Was the invention in an early conceptual stage or had it been reduced to practice? Do personnel working on the invention understand not to make an offer to sell the invention until after a patent application has been filed?
10. Have there been any public disclosures of the invention? When were the disclosures made and by whom? What was the content of the disclosures? Can the disclosure be characterized as an experimental use?
11. If the invention is a medical device or drug, have you provided the patent attorney with FDA submissions, such as a company’s 501(k) submissions, before the submissions are filed with the FDA to ensure consistent disclosure of relevant information to the Patent Office?⁴ Has the regulatory department of the company been notified to work with patent counsel before making a submission. Particular attention needs to be focused on substantially equivalent predicate devices, and any other information that may be viewed as inconsistent with statements in a patent application.
12. How does this patent fit into our IP strategy and business plan?

Reasons for the Questions:

⁴ Recently, the Federal Circuit, the exclusive appeal court for patents, invalidated a patent on the basis of statements of substantial equivalence provided to the FDA in a pre-market 501(k) submission, and awarded attorney’s fees to the patent defendant. *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005).

Inventions often arise from attempts to solve a problem. A clear understanding and statement of the problem or problems helps a patent attorney prepare a patent application. A “problem solution” approach to preparing patent applications is useful for national as well as international patenting of an invention. The identification of people working on a project helps to identify potential inventors, the need for a joint research agreement,⁵ and other legal issues.



U.S. Patent law regulation, 37 C.F.R. 1.56, requires inventors, attorneys, and other associated with the prosecution and filing of a patent application to disclose information believed material to patentability. The collection of relevant publications on the subject matter of the invention facilitates a patent attorney’s understanding, and also helps inventors meet their obligation to disclose material information to the US Patent Office.

A patent attorney can commission a patent search or search for prior art in the technology, and draft better claims when he or she is aware of the prior art (relevant technology predating the invention). Under current patent law and practice, it is better to draft claims of narrower scope followed by a continuation patent application to obtain claims with greater utility against a potential infringer.

Whether patent protection will be sought in the United States only or also in foreign countries allows a patent attorney to counsel a company on avoiding a loss of patent rights and preparing a more effective patent. In the United States, inventors have a one-year grace period in which to file a patent application after a public disclosure, sale, or offer of sale of the invention. However, most foreign countries have a standard of absolute novelty meaning that an invention must be maintained in secrecy until a patent application is filed.

Research & Storage of Records

Keeping proper records in lab notebooks, notes on inventor’s discussions in meetings, attachment of related records or test results, and linking and identifying any physical materials related to the invention is important for several reasons. This information can be useful for identifying who are the inventors, and reduction to practice (proof that an invention works for its intended purpose) of an invention. Proper record keeping also provides evidence that may be necessary to defeat another party’s claim of a prior invention titled a “priority of invention”

⁵ See (or request) a copy of Altera Law Group, February 2005 Newsletter on the CREATE Act, enacted December 10, 2005, for reasons to craft a joint research agreement before substantial work is done with outside research partners.

dispute or “interference.” In the United States, the one who can first prove he invented the invention in dispute wins.⁶

When a dispute arises as to who was the first to invent a particular invention, there are certain rules about what evidence can be used to establish a case. For example, co-inventors cannot corroborate lab notebooks of another co-inventor, and be accepted as evidence by itself. A non-inventor, who understands the technology and/or results, must corroborate the invention. Corroboration involves a non-inventor reading, discussing, dating and signing lab notebooks on a contemporaneous regular basis. Any unexplained or unreasonable delays in moving forward toward reducing an invention to practice may harm a party’s ability to win an interference.

Often research requires additional testing once an invention appears to solve a problem. Prototypes or samples may be made and tested to determine whether an invention accomplishes its purpose. The procedures for experimentation and records are important as discussed above. The testing should be done in a confidential setting, if possible; however, the testing can be done in a public setting under certain conditions. The participants in the testing should sign non-disclosure agreements, and the data from the tests should be routed to the person in charge of the project or designated by the company in the non-disclosure agreement. This protocol and documentation can help establish that uses that appear to be “public uses” (that bar one’s ability to get a patent) are actually uses that fall within a legal doctrine called “experimental use” (that do not bar one’s ability to get a patent).



Documents or records should be stored in a secure location, such as a locked cabinet or room, with limited access by third parties. As research projects and lab notebooks are completed, these records should be placed in long term storage. If inventors are provided with yearly calendars, which may include meeting dates or notes about inventions, the company should collect, store, and index the yearly calendars of the inventors similar to the inventor notebooks. The documents can be logged in and out by a custodian(s) of records.

The following outlines a primary system of record keeping, involving hard copy records, that is useful for invention documentation:

⁶ In most of the world, the “first to file” a patent application is the winner of any dispute. Congress is currently working on legislation that would change the United States to a “first to file” system. Until and unless that legislation is enacted as law, inferences determining who is the “first to invent” remain important. It is likely that the law would be prospective in its application even if it were to be enacted. The “first to invent” system will be around for quite some time even if Congress passes a new law.

1. Bound Invention Notebooks-only
 - a. Identify problem(s)
 - b. Identify potential solutions – advantages and drawbacks
 - c. Identify research directions or instructions
 - d. Identify participants involved in each aspect of the research
 - i. Names and/or initials of parties conducting research, any observers or witnesses present, research results, raw materials, equipment, procedures used, outsourcing of any tests (who, what, where, when, & how) and identifying other potential areas of research;
 - ii. Record brain storming meetings in the notebooks by identifying participants, and documenting each person's input or contributions to the invention or topics under discussion
 - iii. Identify reasons for any long delays – unavailability of raw material, illness of a researcher, vacation, etc.
 - e. Date and sign all entries;
 - f. Have a non-inventor who understands the technology, read, sign and date the lab notebook to confirm understandings of the details (contemporaneous regular corroboration, weekly, bi-weekly, monthly basis, by a non-inventor is very important)
 - g. All notebook entries should be made in non-erasable ink;
 - h. No blank spaces or pages should be left in the notebooks
 - i. A line or crossed out mark with a date and signature should be used when there is a blank space;
 - j. If you discover that data or information in the notebook is in error, identify the erroneous prior entry on a new page by cross referencing which page(s) the error is located in the notebook; however, do not correct the error in the prior page, the correction should be made in the new entry, sign and date as usual;
 - k. Experiments should be described in sufficient detail for replication by identifying the materials, and outlining the purpose and testing parameters;
 - l. Experiments that have already occurred should be discussed in the past tense (e.g., was filtered);
 - m. Abbreviations and codes should be explained in the context of the experiment, a table of abbreviations or glossary (cross reference as necessary);
 - n. Conclusions should be short and fact based, and should not include speculation or opinion;
 - o. Original notebook pages should remain in the notebook, and not be removed;

- p. Identify, cross-reference, and briefly describe any physical exhibits, such as photographs, graphs, CDs, DVDs, or videotapes in the notebook; label the physical exhibit; and if possible attach or staple to the notebook page at issue; and remember to also corroborate these attachments or physical material with a non-inventor by having the non-inventor sign, initial, and date the label on the exhibit;
 - q. Ensure there is a proper accounting for all lab notebooks by tracking the notebooks assigned to each author, date assigned, and date turned in to custodian of lab notebooks; and
 - r. Index each notebook according to subject matter, project numbers, and author; store and retain the notebooks for at least six years after the last patent on the subject matter expires (statute of limitations for recovery of a patent damages is six years).
2. Designate a custodian or custodians of these records to ensure limited access and demonstrate control over the records.

What About Storing Records on Computers?

Computer records are no worse or no better than handwritten records. The company's main concern, whether electronic or conventional paper records, should be the reliability and integrity of the system. Electronic lab notebooks are acceptable if the system: provides reliable, consistent records; allows a user to identify invalid or altered records; provides witness review and secure signature procedure; maintains the integrity of records during the record retention period; and permits ready retrieval during the records retention period. If there is any doubt as to an electronic system, a hard copy, made at or around the time of the entries and signatures, should be maintained as a back up.



Federal courts and administrative proceedings before the U.S. Patent Office do not forbid the use of electronic records as evidence simply because it is electronic. The U.S. Patent Office has stated that: “[e]lectronic 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. The weight to be given any particular record necessarily must be determined on a case-by-case basis.”⁷

The proponent of evidence, whether electronically stored or paper documentation, must first authenticate the evidence pursuant Federal Rules of

⁷ *Official Gazette*, January 12, 1998, Bruce H. Stoner, Jr., Chief Administrative Patent Judge

Evidence 901(a). Authentication “is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims.” Fed. R. Evid. 901(a). Assuming that the documentation are authenticated, and admitted under a proper rule, then the weight becomes the pivotal or important factor – the records must have indicia of reliability to accorded significant weight.

Before a company switches entirely to electronic lab notebooks and digital signatures for corroboration, ensure that IT personnel (or suppliers of commercial system) describe and authenticate the reliability of the system to be put in use, its security features, and will stand behind the system. The company may want patent counsel to participate in evaluating the system before implementing stand-alone electronic records. Invention records, whether electronic or paper, are placed under close scrutiny in patent litigation.

Some notable companies have chosen an electronic lab notebook and patent record system. Amphora Research Systems, a maker of Electronic Laboratory Records sold as PatentSafe® and PatentPad® identified “OxfordBioMedica, Bristol-Myers Squibb, Tibotec, Proctor & Gamble, Cancer Research Technology, Archer Daniels Midland, Kodak, Purdue Pharms, Celltech, and other research-driven organizations” as customers. Their web site is www.amphora-research.com.

Of the above named companies, Kodak relies solely on electronic records. One of the products marketed by Amphora Research Systems is the PatentSafe® electronic record keeping system that allows a party to transition to electronic records by selecting between three modes. In the most conservative mode, the system generates e-records and a hard copy that is signed and witnessed in ink. Thus, there is a signed physical hard copy, and a back up or redundant e-record that can establish the record is reliable. At the other end, there is: “paperless” electronic records that are signed & witnessed electronically; preserved electronically; and documented and verified electronically. The above information was paraphrased from the following web site url: www.script-safe.com/patent_safe.htm.⁸

When deciding on switching to electronic stand-alone records, companies should evaluate the system over time, and obtain a comfort level before making that decision. If the product has different modes that allow a hard copy and e-record, a company should start with that mode. During that evaluation period, the

⁸ Our reference to the products of Amphora Research Systems should not be taken as an endorsement or recommendation in favor of using their products. We have not tried their products, and have only included this information as a starting point for companies that may be interested in such products. For information on Amphora Research Systems, please contact them directly.

company can see if any compatibility problems arise when integrating the system into a company's network. If computer crashes arise or problems with virus or other malware arise affecting your confidence in the stability of the e-records system, you will have a hard copy signed and witnessed that can be preserved.

Another company selling an electronic lab notebook product is CambridgeSoft, with a website at www.cambridgesoft.com. Content on the website includes a powerpoint presentation on the benefits of its electronic notebooks, and addresses issues as to the reliability and verifiability of the records created under its system.⁹

Invention Disclosure & Patent Preparation Stage

Once the inventors believe that a useful, novel, and non-obvious invention has been developed during the research, the next step is typically obtaining company approval for filing a patent application or applications. The inventor(s) fill out an invention disclosure document with variations of the following data: the project, competitive products, the problem, the solution or solutions to the problem, flaws or problems with certain solutions, the benefit or uses for the solution of the invention, and best mode of the invention. The invention disclosure should also disclose publications (scientific, patents, or other information) relevant and material to the problem and/or solution.

With on-going research, other improvements or inventions may come out of a project. Thus, an inventor(s) may fill out subsequent invention disclosures with similar data, and cross-reference prior invention disclosures, specifically identify any new or added information that supports an invention, and attribute who among the inventors contributed the new information to the invention.

After the company decides to seek patent protection, the inventor should prepare a more detailed technical disclosure that describes the invention with an eye toward enabling a person of skill in the art (scientific field) to be able to replicate the invention without undue experimentation. Patent counsel will review the invention disclosures, interview the inventors, and set about working with the inventors to define the invention, and prepare claims of adequate scope.

Several procedures recommended in this newsletter help the inventor and the patent attorney with the patent application process, and aid in keeping patent costs down. Preparing a file with relevant literature during the research (that can

⁹ Our reference to the products of CambridgeSoft likewise should not be taken as an endorsement or recommendation in favor of using their products. We have not tried their products.

be supplied to the patent attorney) helps with the background section of the patent and in understanding the problem. If an issue presents itself as to who should be the inventors, reviewing the inventor notebooks can add some clarity. Detailed descriptions, similar to that required by peer reviewed publications, are very useful for meeting patent law requirement of enablement of a person in the art to practice the invention, written description of an invention, and best mode of invention (based on belief of inventors).

Debriefing Inventors Leaving the Company

When an inventor leaves the company, there should be a debriefing interview to discuss maintaining any inventions in confidence, and not disclosing trade secrets or inventions to third parties. Remind the inventor that she may be required to sign documents relating to inventions or cooperate with patent counsel during the patent application process. Remind her that all confidential information and documents are the property of the company, and any personal hard copies or storage media copies should be destroyed or returned to the company. A company may want to consider a contract with the former employee to become an independent consultant, and provide reasonable compensation for her assistance.

This debriefing interview should not be the first time that the inventor learns her participation may be needed in the patent application process. While an employee, she should have signed pertinent non-disclosure agreements and agreed to assist in the patent application process.

That being said, some inventors may not always want to assist or may have left on bad terms. If the inventor refuses to attend a debriefing or indicates that she will not assist in required activities, then the debriefing person should record notes as to any comments or activities at or around the time of the interview that indicate that the inventor may be a hostile witness. These notes along with contemporaneous records of the research may provide evidence useful in resolving and presenting reliable facts in a dispute or future lawsuit.

Summary

By creating solid patent records, a company can add armor to its inventions, and prepare for attacks in future litigation. If you follow the advice given in this newsletter, you will help ensure that your patents have a better chance of withstanding an adversary's attacks in court. If you need assistance with improving your procedures for record keeping of inventions, assignment of inventions by employees to the company, or any other matters discussed in



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