Documentation of Inventions

W. MARK CROWELL, *Associate Vice Chancellor for Economic Development and Technology Transfer, University of North Carolina at Chapel Hill, U.S.A.*

ABSTRACT

Documentation of research is a critical aspect of best practices in IP management. This is true because research and development activities that give rise to inventions must be thoroughly documented in order to successfully manage patents, including determining patentability, drafting and prosecuting patent applications, and later, if the need arises, protecting patents against third party challenges, for example, a patent interference proceeding. Maintaining, for each invention, a complete record of who made the invention, when it was made, and how it was made, must therefore become a formal component of a university's policy and training programs and must be carried our according to specific protocols. An organized and methodical approach to documentation will support patent management, provide a readily accessible source of critical information, ensure the capture of maximum value of inventions, and protect patent portfolios against challenges when, and if, the need arises.

1. INTRODUCTION

Documentation of inventions is an extremely important issue, and yet this relatively straightforward activity is one of the most forgotten, overlooked or, simply, carelessly neglected aspects of invention management. A lack of attention to this activity can result in the loss of patent rights that the applicant would otherwise possess. The technology transfer office has a responsibility to facilitate understanding among researchers of the importance of keeping good records. In addition, the technology transfer office must establish fail-safe systems for documenting and diligently pursuing the invention disclosures that the office receives.

Why is record keeping so important? In a research environment, good research records are essential for a number of reasons—including for assisting the institution in meeting its progress-reporting requirements to research sponsors, for documenting expenditures, and for promoting research integrity. However, for the technology transfer manager, U.S. patent laws provide an altogether different reason for promoting good practices in invention documentation.

Among the first lessons that U.S. technology managers learn is that the patent laws dictate that a patent is awarded to the first party to invent. In the United States, unlike virtually every other country, priority of invention is established by the first-to-invent rule. However, the majority of nations follow a priority rule by which the party who is first to file is entitled to a patent. What this means, then, is that a contest can ensue between parties who dispute priority of an invention, that is, who was actually first to invent.

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Such a contest is adjudicated by the U.S. Patent and Trademark Office (PTO), Board of Patent Appeals and Interferences, in an administrative proceeding called a *patent interference*. The patent interference proceeding determines who was the first to invent, has priority, and thus is entitled to the patent.

So, when two competing patent applications claim the same subject matter, the PTO declares an interference, that is, the patent applications "interfere" with each other. Each inventor then seeks to prove priority of invention, and reliable evidence is sought that can document which party was, in fact, the first to invent. Under U.S. patent law, the inventive process, by definition, begins with conception of an invention and proceeds to reduction to practice (either actual construction of the invention *or* filing of a patent application with the PTO). To comply with patent law, the first party to conceive a patentable invention must carry out certain activities to proceed with reasonable diligence toward the development and patenting of an invention. In other words, it is possible that the first to conceive an invention can fail to prevail in an interference proceeding if he or she did not diligently work toward reduction to practice of the invention or did, in fact, diligently work toward reduction to practice but *cannot produce any documentation* as evidence to prove having done so. Therefore, an inability to prove who is the first to conceive, or a lack of evidence to refute a charge that an inventor was not diligent in pursuing an invention, can lead to the loss of valuable patent rights to which the inventor and institution may otherwise have been entitled.

Therefore, within the notoriously complex context of an interference proceeding, careful documentation of inventions and the inventive process, from conception to reduction to practice, will be extremely important in order to prevail if such legal challenges arise. In addition to interference proceedings, patents are, not infrequently, challenged on such grounds as incorrect naming of inventors or newly raised references that challengers argue should have been submitted to the PTO as proof of prior art at the time of the patent application. In such situations, research records can be invaluable for documenting who contributed to the invention and the critical dates and facts of conception and reduction to practice of the invention; these dates would refute the claim that raised references identified relevant prior art if the records documented conception and reduction to practice (invention) as having occurred before the raised references. This example underscores the importance of maintaining clear, meticulous chronological records. *Nothing* will substitute for comprehensive records if, and when, complex legal challenges to a patent or patent application arise. Always assume that there could be trouble, and assemble records accordingly so as to protect valuable investments in research, development, and commercialization.

2. THE PRACTICAL IMPORTANCE OF RECORD KEEPING

In reality, there are occasions on which an invention disclosure form (IDF) itself, or possibly a grant application, will be the first viable record that a researcher has adequately, and diligently, proceeded through the inventive process, from conception of the invention through to reduction to practice. In such cases, the technology transfer office must ensure that such records are safely stored, properly witnessed, and readily available when the need arises. A lot depends on such care being taken, and an investment in managing and maintaining records will pay off in the long term.

U.S. patent practice places immense importance on witnessed records when two or more parties claim the same invention. For example, an applicant involved in an interference proceeding must be able to prove the date of conception (the date when the inventor formulated in his mind a definite and complete idea of the invention) and the date of reduction to practice (the date when the conceived invention was actually built, with every element of the conceived invention) even if it is not yet commercially perfected. It is critical to make clear to staff that the IDF used by the technology transfer office must avoid using language that refers to date of *first* conception or date of *first* reduction to practice. Should legal adjudications

arise, such a statement could be construed to be an admission that no earlier conception or reduction to practice occurred (when in fact it has), significantly damaging the institution's position in a priority contest. Instead, the IDF should simply ask that the location of records documenting conception and reduction to practice be identified.

In addition to documenting the dates of conception and reduction to practice, the PTO interference proceeding may turn on the diligence shown by the contending inventors. In this situation, the inventors' witnessed records must demonstrate that the invention's development, including the act of filing a U.S. patent application, was pursued in a reasonably diligent manner, pursuant to the statutory requirements of U.S. patent law. In an interference proceeding, the party that can prove that it was the first to conceive will likely be awarded the patent. If one party proves it was the first to conceive of an idea, but a second party conceived of the idea and pursued reduction to practice in a more diligent manner, the second party may prevail in the interference proceeding.

In the private sector, most industrial research is carried out under guidelines that impose strictly enforced record-keeping practices as a matter of routine practice. Often, these records are made on a daily basis, dated, witnessed, and stored. If researchers working under such conditions are the inventors named on a patent application involved in an interference proceeding, proving the date of conception and reduction to practice should be without ambiguities and informational gaps and, hence, relatively simple and straightforward.

On the other hand, research record keeping in universities can be lax to the point of sloppiness, and, in such cases, much more challenging to organize and manage. Laboratory research tends to be conducted at any and all hours of the day, and researchers often find it difficult to find the resources, witnesses, or other means by which documentation can be facilitated. Furthermore, the culture of some universities is such that practices of this type historically have been viewed as inappropriate or unnecessary. Researchers may neither understand, appreciate, nor wish to be inconvenienced by attending to detailed and chronologically consistent documentation, and thus simply perceive such a requirement as another annoying administrative burden. Indeed, in some laboratories, directors of research might push staff to maximize time at the bench and minimize time at the desk; record keeping will inevitably suffer as a result of such prioritization of time. And in some cases, graduate students who come and go, and who work on research projects, believe, or perhaps are told, that laboratory notebooks belong solely to the students. If important facts about the conception or reduction to practice of an invention are included in such notebooks, the documentation may not be available (that is, it has "walked away" with the student) at some future date when a patent is being challenged.

Despite any difficulty that universities may face with strict record-keeping protocols, the importance of this activity cannot be overlooked. Most research universities now have active patenting and licensing programs, and sound research documentation and record keeping is an essential component of successful programs. This cannot be ignored or left to chance; there is just too much at stake, and the stakes only get higher.

3. GUIDELINES FOR RECORD KEEPING

Good laboratory record-keeping practices should not be driven merely by IP (intellectual property) concerns. Good laboratory records have long been viewed as "good science," and good laboratory records can be extremely helpful if a lab should ever face charges (however specious) of scientific misconduct. Essentially, the same record-keeping practices that are considered good science and appropriate for responding to scientific misconduct charges are also good practices for purposes of managing, securing and protecting IP rights.[1]

The following guidelines for record keeping are contained in the North Carolina State University manual of patent and copyright procedures and are highly recommended:

1. A good practice is to use bound notebooks for records. Entries should be made on a daily basis. The use of a "diary format"

provides a day-to-day chronology. (This can be extremely important in documenting diligence or other important issues.)
2. Use the notebook to record a conception (a complete description of a means to accomplish a particular purpose or result, ideally including all elements of a conceptualized invention), laboratory data, drawings, or other observations. Each entry should be dated, headed with a title, and continued on successive pages.
3. Entries in the notebook should be made in ink. Under no circumstances should entries be erased or "whited out"; a line should be drawn through text or drawings that are being deleted, and the corrected material should be entered. Any blank spaces on pages should be drawn through.
4. Any material that cannot be incorporated into the notebook should be glued in and referred to in a notebook entry.
5. All entries in the notebook should be signed, dated, and witnessed (by at least two people) at the time they are made. Witnesses should have read the entered material and be capable of understanding it but be impartial observers of the work and have no direct stake in the outcome. The witnesses could be, for example, colleagues from another laboratory in the same department. An extremely important or unusual discovery or observation (a potentially patentable invention) may warrant having more than two witnesses. Multiple inventors may not serve as witnesses for each other. If important records lack the requisite witness signatures, the records should be signed as soon as possible after the records are created. Even a witness signature made days or weeks after the record was created is evidence that the document existed prior to the date on which signature was made.
6. Laboratory heads should set aside a time for all in their laboratory staff to stop working at the bench (or, in agricultural research, the greenhouse or field) and record entries into their notebooks. This time should be carefully and consistently observed. Be sure to invite individuals who can witness the entries immediately after they are made.
7. In the event that notes are kept on a computer, be sure to make the appropriate entries into the computer system at the end of each day. Each daily entry should be printed out, signed, and witnessed, following the same procedure as that recommended for written notebook entries. The final printed, signed, and witnessed document should be glued into a notebook.
8. Identify a safe method for storing and monitoring the records. Research data related to pending or issued patents should not be destroyed. Therefore, a retrievable archive system needs to be organized, implemented and maintained. Such an investment will pay for itself many times over in the event of a patent dispute.

4. CONCLUSIONS

In general, best practices in documenting laboratory research serves two purposes: scientific and legal (IP management and patenting). These purposes are not mutually exclusive, and indeed there is considerable overlap, as the means to the two objectives are entirely consistent. Best practices in documentation will provide the researcher with a clear record for assembling publications, grant proposals and, in the event of fraud or misconduct allegations, a clear record for establishing the facts. Similarly, a best practices approach to documenting research will greatly facilitate managing issues related to IP management and patenting. This could include, but is not limited to, patent application drafting and prosecution, patent challenges by third parties, and evidence production for patent interference proceedings. Each of these will require documentation of research and development activities. Documentation policy must, therefore, be carefully and thoughtfully institutionalized, as part of every university's required protocols. Such procedures and requirements should be an integral part of overall IP management and training that the technology transfer office provides to the university administration, staff, and scientists. A lot of value might be at

stake. The investment in building capacity and appropriate IP management systems will pay off in the long term. ■

W. MARK CROWELL, *Associate Vice Chancellor for Economic Development and Technology Transfer, University of North Carolina at Chapel Hill, Box 4000, 312 South Building, Chapel Hill, NC, 27599-4000, U.S.A.* *Mark_Crowell@unc.edu*

1 See, also in this *Handbook,* chapter 8.2 by JA Thompson.