COMMENTARY ON THE KEEPING AND PRESERVATION OF RECORDS OF INVENTION AND SPECIMENS

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To date, more than seven million United States patents have been granted to inventors from all parts of the world. These patents represent not only a wealth of science and technology information, but also document the output from resources used for technological innovation. In addition, these patents serve, or have served, as a device that enables the inventor to reap the rewards from his or her investment in the invention.

In most cases Idea Notebooks or Laboratory Notebooks, with bound pages consecutively numbered, and carefully kept by the inventors, provide the underlying basis for these patents. A properly kept notebook serves as a depository for and preserves the fruits of research and development, a valuable asset for every technologically-oriented Company. Preserved specimens, or laboratory products, actually made in the course of research, are also of value in this respect. A properly kept notebook and properly labeled and stored specimens provide valuable legal evidence not only for patent solicitation but also in patent litigation and in proceedings in the Patent and Trademark Office to determine priority of inventorship between or among rival inventors.

A properly kept notebook serves to prove inventorship, to establish the date on which a particular invention was conceived, to establish the date when the invention was reduced to practice, as well as to show diligence in reducing to practice a conceived invention where such showing is legally required. Yet in many instances, valuable patent rights have been irretrievably lost only because proper records of invention had not been kept, and priority of invention could not be established as a result.

To safeguard the valuable technical information generated by a research and development staff of a Company, each individual in a position to make inventions should be issued a consecutively numbered, bound notebook in which the work done is to be recorded.

This notebook at all times is property of the Company. A central register should be kept by the Company showing which notebook is issued to whom, and also in whose possession a given notebook is at any given time. When a particular notebook has been filled, it should be returned to a central file (preferably a fireproof safe or vault), and a new notebook issued to the individual. In addition, when a particular project has been completed, it is a good idea to cross-reference all notebooks that contain information and/or data pertaining to that project. Some companies make microfiche backups of each laboratory notebook and store them separately from the notebooks themselves. When an individual investigator retires or leaves the Company, he/she has to account for all notebooks issued or charged to him/her and must return all such notebooks to the central file. The central register serves as a convenient checklist for this purpose.

The Company should also maintain a central repository of specimens of products produced in the laboratory, kept in suitably labeled containers and recorded in a central register.

Guides to making entries in idea notebooks and/or laboratory notebooks and to the labeling and storage of specimens are attached hereto. A copy of a typical notebook page is also attached. A laboratory notebook can also serve as an idea notebook.

Evidence to Preserve

Today's engineers and scientists need to be reminded that competitive companies (and Government laboratories) are often working diligently to solve the same problems and striving to be the first to file a patent application. This may be especially true in biotechnology or computer process inventions. Without proper records of invention, the second to file is a sure loser.

All R&D personnel should keep notebooks in which both ideas and experimental activities are diligently recorded, dated and witnessed. Reports of analytical records, x-rays, drawings, biological records and deposits, etc., should be signed, dated and preserved. This is also true of letters or memoranda that contain statements as to the work being carried out and the achievements made at that time. It can be very helpful if the notebook entries specifically refer to things kept separate from the notebook that are probative of activity and/or success, e.g., x-ray films, drawings, prototypes, SDS PAGE gels in biotechnology, etc. Often certain objects, e.g. photos, analytical reports, sketches, etc., can be signed, dated and attached to the notebook pages. To be effective as a record of a "reduction to practice" of an invention, the notebook should contain the details and results of any construction, mixture, analysis, testing, etc., and be signed and dated also by one who witnessed such acts.

It is also important to preserve a copy of any annual, quarterly or monthly R&D reports. All should be signed, dated and retained as possible evidence of conception, diligence toward a reduction to practice, etc. Correspondence between a Company's employed scientists or engineers and its outside consultants may also contain evidence useful in a patent interference; it may also throw light on whether or not the consultant contributed to the conception of the invention thereby making him or her a coinventor.

It is also more common in the 21st Century for a Company's scientists and engineers to discuss and correspond about their work with outside professional colleagues who have no contractual obligation to their organization before a patent application is filed on the subject matter. Needless to say, they should be warned not to do so, but that does not guarantee compliance. The Company should not only caution against such practice, it should also explain that it could cause the recipient of such information to accelerate his or her work in the same area. There have been instances where such conversations have caused inventorship problems with the outsider being held to be a coinventor, and thus a part owner, of the patent issued on the invention. Any pre-filing correspondence or conversations about the work with outsiders should be recorded, dated, witnessed and retained as a contemporaneous record of what was said and by whom.

Electronic Records for Proving Priority in Interference Proceedings

Electronic records may be used for proving priority of invention but they create unique problems from an evidentiary standpoint.

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. The weight to be given any particular record necessarily must be determined on a case-by-case basis, however.

An electronic record is a document or writing generated or stored by a computer. In order to serve as evidence in an interference proceeding the electronic record must have been generated or stored at some early point in time which is relevant to the proof of events that establish priority.

An electronic record submitted as evidence in an interference proceeding is admissible to the extent that it is admissible under the Federal Rules of Evidence. Therefore, a foundation for the admissibility of an electronic record must be established just like for any other kind of evidence. A party seeking to rely on an electronic record has to demonstrate the authenticity of the electronic record. A major challenge is authentication of the date of an electronic record.

If admitted into evidence, the amount of weight to be given an electronic record depends on the credibility of the electronic record. That is determined on a case-by-case basis.

Inventions Made Outside the U.S.A.

Revisions to 35 USC § 104 with respect to inventions made in NAFTA or WTO countries after January 1, 1996 make it possible to prove priority of invention based on work done in those countries. This revision represents a new opportunity for them to win an interference that previously would have been lost if they had a later application filing date. Given the size of the U.S. market with respect to many inventions, that alone should justify their adoption of an evidence preservation policy. While such inventors may have had little need for an evidence preservation program in the past because of their country's "first-to-file" system, failure to create and preserve records proving conception, reduction to practice, diligence, etc. may cause them to lose an interference in the U.S. that they might otherwise have won.

GUIDE TO MAKING ENTRIES IN IDEA NOTEBOOKS OR LABORATORY NOTEBOOKS

- The notebook should be a bound volume, not a loose-leaf book.
- Entries in the notebook should be made in ink or indelible pencil.
- Unused space on each notebook page should be lined through. When a page is only partially used, a horizontal line should be drawn just below the last entry and one or more diagonal or wavy lines in the empty space therebelow.
- Each entry and each page in the notebook must be dated and signed on the same day the entry is made. Each entry and each page of the notebook must also be witnessed, preferably on the same day the entry is made because the provable date is only the witnessing date, not the date the inventor made the entries.
- The witness should be an individual who **understands** the entry **but who is not a co-inventor**. A single witness normally is sufficient.
- If a particular experiment is important from a commercial or from a patent standpoint, repeat it in the presence of another witness who observes and understands what you are doing, and who subsequently also witnesses the notebook entry. It is even better to have a colleague repeat the experiment pursuant to the inventor's instructions.
- Any changes or additions to a given entry occurring subsequently (e.g., the entry of analytical data or observations on stability) should be noted separately and under their own dates, and if necessary, referenced back to the earlier information.
- If an error is made in making an entry, DO NOT ERASE. Instead, draw a line through the erroneous part and continue.
- If an entire page is wrong, do not tear it out, but draw a line across the page and continue to the next page.
- Entries should be made directly in the notebook or transferred there on the same day.
- Any loose notes, data, printouts, gels, photographs, charts or graphs can be stapled, glued or otherwise secured to a particular page, if necessary, but should also be dated, signed, and witnessed.
- The individual entries should be a clear, unbiased record of all pertinent factual data directly concerned with the invention or the experimental work that was done. **Do not** enter unnecessary conclusions or unnecessary opinions. Avoid negative or deprecatory entries.
- Use sketches freely, together with explanatory material as needed.
- Make consecutive entries on consecutive pages; do not reserve blank pages to be filled in later upon completion of a lengthy experiment.
- Include all pertinent details when recording experimental work. State the object and results of each experiment clearly and concisely. BE SPECIFIC IN YOUR ENTRIES.
- An exemplary notebook page is attached.

Exemplary Notebook Page:

SUBJECT Bug Repellents — Notebook No. CP-1144 Page No. 70 — Project CP-042-85

Continued from page no. 69 — Date 15 May 1985

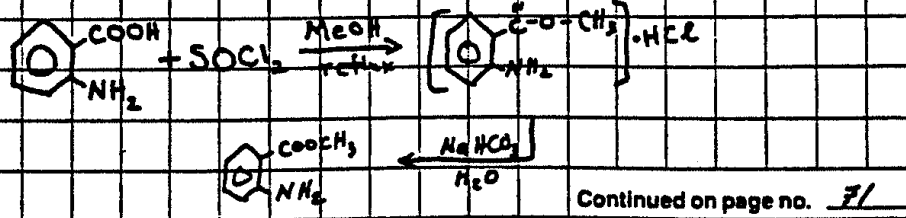
CHARACTERIZATION OF REAGENTS

I obtained 100g anthranilic acid, Kodak Cat. No. 29, lot # 427764. Put 10g in glass vial and sent to Dept. 2610 for elemental analysis. I obtained the melting point myself = 144-145°C. I gave the bottle to Jim Harris for IR. He ran the sample and found a perfect match to Sadtler # 2703. I stored the IR spectrum (no. CPIR-1144-70A) in project file.

Fresh, unopened bottles of methanol ("spectrophotometric grade", J.T. Baker lot no. C241671) and $SOCl_2$ (Mallinckrodt, lot no. ACZY) were delivered to me from our stockroom. Jim also ran IR of these two reagents -- they are spectroscopically pure. (Spectra labelled CPIR-1144-70B & 70C, respectively)

16 May 1985

SYNTHESIS OF METHYL ESTER OF ANTHRANILIC ACID



Continued on page no. 71

Recorded by G. Quiney — Date 15 May 1985

Read and Understood by Salvador — Date 16 May 1985

Related work on pages: _____

GUIDE TO THE LABELING AND STORAGE OF SPECIMENS

When a new product is made in the laboratory, an aliquot sample should be taken off, placed in a standard sized bottle or jar, labeled and delivered to a central storage facility for future availability, if feasible.

The central storage facility should keep a record book in which each new sample is given the next consecutive sample number and in which a brief (generally one line) description of the sample is entered along with the date and the notebook number and page on which there is a description of how the sample was prepared. The record book should be a bound book (not loose-leaf); and all entries therein should be in ink.

The person who has prepared the sample should indicate on the label of the specimen bottle or jar the nature of the product, e.g., "POLYMER," "SHAMPOO," "CELL LINE," "PLASMID," "BACTERIA CULTURE," "SYNTHETIC VACCINE," etc., and the notebook number and page where its preparation has been described. After receiving a sample number from the central storage facility, the sample number should be entered on the label and entered in the notebook (together with the date of the entry).

Samples of products on which a patent application has been filed should be retained for at least two years after the date of grant of any patent that might issue and in any case should not be disposed of without the concurrence of the patent attorney handling the patent application.

There should also be a procedure for disposing, after a given period, of samples of products on which no patent application has been filed. The length of the storage period for such samples should be decided after discussion with the patent attorney handling the general subject matter.