

# MAINTAINING LABORATORY NOTEBOOKS

Merchant & Gould

MINNEAPOLIS/ST. PAUL  
612.332.5300  
612.332.9081 (FAX)

DENVER  
303.357.1670  
303.357.1671 (FAX)

SEATTLE  
206.342.6200  
206.342.6201 (FAX)

ATLANTA  
404.954.5100  
404.954.5099 (FAX)

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# Maintaining Laboratory Notebooks to Document Invention Dates

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**M**ost countries use a “first to file” patent system. The first inventor to file a patent application receives the right to exclude others, including those who first invented the same invention, but filed at a later date. Under the United States system, the person who first invents is entitled to exclude others from practicing a claimed patented invention.

GATT legislation effective January 1, 1996, now allows all inventors, including those outside the United States, to establish a date of invention of January 1, 1996 or later for all patent applications filed in the United States after January 1, 1996. Adequate documentation of inventions in a manner that is acceptable to the United States Patent Office can preserve important rights.

The following brochure highlights a series of questions and examples which we hope you will find useful in understanding the U.S. rules and how you can document your invention.

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# Questions and Answers

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## *Why do I need to document invention dates?*

Inventors inside and outside of the United States will be able to prove a date of invention and establish priority dates earlier than the patent application filing date. In a contest of who invented first, the winner must provide adequate documentation.

As one example of how the law is applied, laboratory notebooks from an invention first conceived and documented on January 10, 1996, but not filed as a patent application until September 10, 1996, can be submitted to the U.S. Patent Office to overcome novelty rejections based on a reference by another disclosing the invention and published on April 10, 1996. This evidence is offered as proof that the inventor was in possession of the invention before the publication date of the reference.

## *What does this change mean to the inventor outside the United States?*

Inventors must establish rigorous invention documentation procedures to corroborate statements made to the United States Patent Office. United States courts have held that mere statements of invention and diligence are not sufficient. The inventor must provide corroborating evidence to establish what was done and when it was done. This evidence is preferably documentary in nature and is used to establish a “priority date.” The priority date is one of two potential dates; either the date the invention was conceived and reduced to practice prior to patent application filing or the date at which the invention was first conceived and subsequently worked on diligently until the patent application was filed.

## *When is establishing a priority date earlier than the patent filing date important?*

Proof of the priority date is useful in both litigation and patent examination within the United States Patent Office. Proof of conception and reduction to practice is important in litigation in any patent infringement case, when the date of invention is at issue. Invention dates are also important in trade secret misappropriation litigation.

During patent prosecution, evidence of the date of invention can be used to remove references from examination when the references are published less than one year before the patent filing date. Here, the inventor must document conception and diligence from a time prior to the publication date to the time the invention was either reduced to practice or filed as a patent application. Proving the date of invention is also critical in interference practice where the outcome of the proceeding rests upon a determination of which of two or more inventors was the first to invent the claimed invention. Finally, laboratory notebooks and invention disclosures may be used to remove prior art rejections from reissue and re-examination proceedings.

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*How is the date of invention, “the priority date”, established in the U.S. Patent Office?*

Under the U.S. system, invention begins with the conception of the invention; that is, the formulation of a definite and permanent idea of an operative invention. The inventive process ends when the invention is reduced to practice. Reduction to practice is said to occur when either the invention is reduced to a tangible and useful form or when an enabling patent application is properly filed in the United States or elsewhere. Priority is awarded to the inventor who first reduces the invention to practice or who first conceives of the invention and can prove that he or she has worked diligently on the invention toward reducing the invention to practice until a patent application was filed. Diligence has been held in the courts to mean consistent, mostly daily activity directed toward the goal of reducing the invention to practice. However, even if an inventor can prove conception and diligence in reducing an invention to practice, priority will be lost with proof that the inventors abandoned, suppressed or concealed their invention. Therefore, even under the U.S. patent system, timely filing of a patent application is essential.

*What type of references can be antedated using corroborating evidence?*

“Antedation” refers to the ability of the patent applicant to prove that he or she was in possession of as much of the information in a reference as the Patent Examiner is using to form the rejection. Evidence of prior conception and diligence in reducing an invention to practice is used to antedate patents, published patent applications or printed publications from anywhere in the world.

There are at least four basic exceptions to this rule. First, a reference cannot be antedated with corroborating evidence if the publication date of the reference is more than one year prior to the effective filing date of the patent application under examination. Nor can a reference be antedated if the reference is a patent issuing to the same applicant outside the United States prior to the filing date of the U.S. application where the non-U.S. patent application was filed more than twelve months before the effective date of the United States patent application. Third, one cannot antedate a U.S. patent claiming the same invention as claimed in the patent application under examination if the patent is issued to another inventor. This dispute is managed by an interference proceeding. Finally, an Examiner can refuse to enter evidence introduced to remove a reference from prosecution where the Applicant has previously admitted that the reference was prior art.

*What form of corroborating evidence is permissible?*

Laboratory notebooks, invention disclosures, internal memoranda, monthly reports and laboratory data sheets are all permitted documentary evidence. Invention disclosure forms can be prepared by the inventor to prove the date that the invention was first conceived. Signed and witnessed copies of these forms can be used to establish conception and, in some cases, reduction to practice. While invention disclosures, internal memoranda and monthly reports may be accepted by the Patent Office, they may also be viewed as self-serving. Similarly, laboratory data sheets that were not attached to a laboratory notebook at the time of their preparation may also be considered suspect.

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***Why isn't witness testimony enough to antedate a reference?***

Corroboration may take the form of independent testimony; however, when the testimony is provided long after the facts occurred, it may not be well received. In general, original exhibits, drawings, records or photocopies must accompany and form part of the affidavit or declaration by the inventor or their absence must be satisfactorily explained.

In some cases testamentary evidence is enough where the absence of documentary evidence can be adequately explained. Where the testamentary evidence is provided solely by an inventor or an interested party without supportive documentary evidence, the testamentary evidence may be viewed as self-serving. Third party testamentary evidence is rarely sufficient to antedate a reference because the third party must be able to swear to facts which would necessarily be documented in a laboratory notebook. Thus, the third party may be called on to swear to dates, details regarding laboratory experiments, results, and details relating to the progress of the invention. It is rare that a third party has first hand information related to these details or was available to view and review the experiments at each stage of the inventive process. The Patent Office is free to conclude that witness testimony is not credible or reliable.

***What type of corroborating documentary evidence is preferred?***

Legible laboratory notebooks are preferred as a corroborating source by the United States Patent Office because the notebooks represent an unbiased resource for the laboratory worker who is attempting to reduce the invention to practice. The notebooks were prepared contemporaneous with conception and reduction to practice. Thus, there is a presumption that these notebooks are an unbiased and true representation of the data. Notebooks should be signed and witnessed at or near the time of their preparation by someone (a non-inventor, under a duty of confidentiality) who has read and understood their contents. It is possible that a Patent Examiner will not accept notebooks that are not witnessed.

***How much documentary evidence is needed to antedate a reference?***

An applicant is only required to provide evidence of priority with respect to so much of the claimed invention as the references happen to show. Thus, it is not necessary that the laboratory notebook evidence demonstrate each and every fact provided in a particular publication. Rather, the applicant must demonstrate only that he was already in possession of the particular information in a reference that was used to form the novelty or obviousness rejection at the time the reference was published. The Applicant is also permitted to provide evidence demonstrating an obvious variation of the information provided in a reference that is being used to reject the application.

***When should laboratory data be submitted to the Patent Office to antedate a reference?***

Laboratory data, accompanied by the appropriate testimonial proof, must be timely presented. Patent Examiners generally will consider this evidence if it is submitted prior to a final office action. These rules change somewhat if a petition for expedited examination has been filed with the United States Patent Office. After final rejection the Applicant must

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provide a showing of good and sufficient reasons why the evidence was not earlier presented. Without this evidence, the Applicant may be required to file a continuation application in order to have the evidence submitted into the record.

*Is it necessary to disclose the date of conception to the Patent Office to antedate a reference during patent examination?*

No. Documentary evidence of conception and reduction to practice is enough if it is introduced together with sworn testimony that the dates of conception and reduction to practice or conception and diligence were earlier than a cited reference publication date. Dates can be blocked out of laboratory notebook pages that are introduced into the patent prosecution record. In contrast, interference proceedings and litigation may require disclosure of dates relating to inventorship.

*What if the data entries are not in English?*

At present, there is no regulation in the United States Patent Office requiring that laboratory notebook pages be translated into English. It might be possible to submit the pages together with a sworn declaration by the inventor providing a summary of the data pages. At that time, the Patent Office may elect to prepare a translation. Alternatively, the Applicant may elect to submit a formal, certified translation of the laboratory pages. It is likely that Patent Office regulations will be promulgated in this area in the near future.

*How does the Patent Office determine whether documentary evidence is sufficient to antedate a reference?*

The standard of review for interference proceedings is a “preponderance of evidence” standard. This is a higher standard than what is required for routine patent prosecution; however, if the preponderance of evidence standard is used to maintain coherent, legible laboratory notebooks, the Patent Office will be convinced that a proper showing has been made. In general, the Applicant must demonstrate during patent examination that more likely than not the invention was conceived and either reduced to practice or was worked on diligently from the time of conception to the patent application filing date.

*If a laboratory notebook is preferred, what should it look like?*

Preferably, the laboratory notebook is a bound volume. The pages should not be removable. These volumes are commercially available. The research organization or individual orders a series of the volumes, each successively numbered. A numbered book is checked out to an individual scientist for their use and recorded in a central ledger. The notebook includes a designated place for the scientist’s name, together with the starting and the ending dates. The individual scientist writes his or her name in the book and enters a starting date. The notebook contains the name of the research organization, a statement regarding the confidentiality of the contents of the volume, an index and consecutively numbered pages. Each page should preferably contain a printed statement such as: “This notebook is consid-

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ered confidential material and is the sole property of Organization X.” There is a place for the scientist to sign and date each page. Also at the bottom of each page is a place for the signature of at least one witness along with printed words stating that the signature indicates that the witness has read and understood the contents of that page. An exemplary page from such a notebook is found at the end of this pamphlet.

*What should the laboratory notebook contain?*

The notebook should contain a legible account of each experiment that is performed. In addition, the notebook should record inventive ideas that may form the basis for proving conception. The recorded experiment should begin with a title or a statement of purpose. The methods should be provided in detail at least one time. Later, methods used in similar experiments can reference the original experiment and list changes that have been made to the methods. All preparatory calculations and formulations are listed in the notebook. This includes a record of each animal and what it received or each sample and how it was treated. When abbreviations are used that would be unfamiliar to the average scientist at another organization, a key should be maintained within the notebook to translate the abbreviations. Data results are also incorporated into the volume. A summary of the results should be provided with the data. The level of detail should be sufficient to permit someone to repeat the experiment using only the notebook or resources cited in the notebook.

*How should the scientists summarize their data in the notebooks?*

It is best if the scientists are educated regarding the need to summarize results factually. Where an experiment failed, a simple statement indicating that the experiment will be repeated is enough. When not needed, or not completely true, absolute statements in a laboratory notebook regarding failure, inconclusiveness or the obviousness of a result can be used by the Patent Examiner or, after issuance, by a competitor to argue against patentability.

*What should the scientist do with photographic evidence or data output from lab equipment?*

Photographs of animals, electrophoretic gel results and other photographs, together with printed data records including radionucleotide quantitations, and spectrophotometric measurements and readouts should be incorporated into the notebook. This information can be labelled and glued or taped onto a blank page. A writing, e.g., signature or detail of the data, can be written across both the insert and the page space to authenticate its placement in the notebook. Remaining blank regions should be blocked out. Dates should be entered next to the data and some explanation should be provided for these entries. Copies of graphical displays of data should also be incorporated into the notebook. In some cases, such as where large autoradiograms are used, the rough data will not fit within the confines of a notebook. In these cases data sheets can be cataloged, permanently labelled, signed and witnessed with reference made within the laboratory notebook regarding interpretations from the data and their location within the laboratory.

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***What if graphical displays are stored on the computer rather than in a notebook?***

While this is a trend in many laboratories, retrieval of data from long term computer storage without evidence of a duplicate hard copy created at a time the graphical display was made may create problems in the United States Patent Office. Some Patent Examiners recognize that there may be motivation to manipulate data that has been stored electronically and may reject such data. A hard copy stored in a laboratory notebook is the best defense against these allegations. Where computer storage is preferred, disks should be archived regularly to document that no change was made to the data. Again, in such a circumstance, the Patent Office may view the archive date as the date of conception or reduction to practice absent evidence to the contrary.

***What if the scientist is recording data for more than one experiment at a time?***

Many commercially purchased notebook volumes contain a space stating “continued on page \_\_\_\_” at the bottom of each page and a “continued from page \_\_\_\_” at the top of the page to provide continuity and clarity for experimental records that are performed over weeks or months. These can be used to track the progress of individual experiments. Alternatively, each scientist may employ multiple notebooks; each notebook following the course of a particular project. This is useful in proving that the scientists worked diligently to reduce the invention to practice. Notes should be made as to incubation times and dates when laboratory animals or reagents are ordered with expected arrival dates. These dates are aids for documenting diligence where, because of the nature of the invention, daily work on a particular invention is not possible.

***When are the laboratory notebooks signed and dated?***

Each entry should be dated and handwritten in pen. The notebook pages should be signed and dated by the scientist as each page is completed. Empty spaces on the pages should be crossed out in pen. The notebooks should be witnessed as soon as reasonably possible. Ideally, the notebook pages are signed by witnesses on the day when they are completed, after the blank spaces have been crossed out. Practically, the laboratory should initiate regular (preferably bi-monthly) notebook signing sessions to insure that each notebook is up to date. There is a danger that the Patent Office or a court may use the date that the witness has signed a particular page, rather than the date of the scientist’s signature. Therefore, prompt review by a witness is important.

***What if the scientists in my organization prefer to use pencil?***

They should stop. Experimental records should be permanent. Each page of a notebook should be written in the same ink to negate arguments that additions were made to the text at a later date. Mistakes should be crossed out in the same pen with the corrected text written next to, and not above, the mistaken entry.

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*What if a scientist wants to correct errors in the notebook at a later date?*

If a scientist identifies errors, for example, in the math associated with a particular calculation, the errors can be corrected by crossing out the necessary information and writing in the correct entry. Some explanation should be provided in the notebook to give guidance as to why these changes were made. The changes should be initialed and dated and the changes should be signed and dated by a witness as well.

*Who should sign a laboratory notebook as a witness?*

Individuals signing as witnesses cannot be inventors to the invention. Under United States law, the inventor is the individual who conceived of the invention. Those who reduced the invention to practice are not necessarily inventors. Therefore, a laboratory co-worker, one who is not considered an inventor, may sign each page of the laboratory notebook of another indicating that they have read and understood the contents of the notebook. To prevent arguments of bias, the witness is preferably a laboratory worker who is not working on the same project and still more preferably, the witness is from another research group within the organization, who is familiar with the work in that laboratory and who is under a duty of confidentiality to the organization.

*Who maintains possession of the laboratory notebooks?*

The notebooks are the sole property of the research organization. When a particular scientist leaves the organization, the notebook remains with the organization. Old laboratory notebooks that are no longer needed in the laboratory should be checked into a data storage repository. The individual organization may elect to keep the notebooks in one place and a microfilmed copy of the notebook at a different location.

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The following is an example of a page from a laboratory notebook.  
Comments provided in the margins note both the positive and negative attributes of this entry. This entry and the corporate name are purely fictitious.

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## *Legend for Notebook Diagram*

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1. Top of the page identifies the notebook number, the page the work continued from, the page number, date and project.
2. The entries are organized and legible.
3. Laboratory abbreviations and designations are defined and referenced.
4. Methods are provided in sufficient detail so that a third party could repeat the experiment using only the references and materials supplied in the notebook.
5. Methods are referenced to earlier notebooks. The term “nbk” should be spelled out in a designated place in each notebook.
6. The cell line is sufficiently identified by its supplier.
7. Well known abbreviations do not need to be defined further.
8. An initial correction is made with a single line. The corrected text is placed in line, next to the error.
9. A later correction is properly initialed, dated and explained.
10. The entry is in a single permanent ink.
11. Raw data is identified and entered into the notebook.
12. If the experiment did fail, a simple statement that the experiment will be repeated is sufficient. Here, it appears that the results may show that the blockers did work at higher doses. Results should be stated positively and repeated as necessary.
13. Blank regions are blocked out in pen.
14. New entries are re-dated.
15. We do not know who or what MLP is. If it is a supplier, it should be spelled out or referenced to an earlier page. If it is a person, the name should be spelled out or the initials provided in the abbreviations index.
16. “i.p.” is a well known scientific term of art for individuals in this field and need not be further identified. The test is whether an abbreviation could be reasonably interpreted by someone similarly skilled in the art.
17. This notebook page was timely signed and dated.
18. The signature is illegible. Where this is a problem, the name should be printed at least once, beneath the similar signature. Also, if MLP is Mark Peterson, then a question arises as to whether Mark is an inventor. Inventors must not witness notebooks reducing their invention to practice.
19. The witness date is much too late. Preferably the witnessing signature is provided within the same week or two week period.
20. Each page is labelled as confidential and the property of the particular research organization.

Title: Inhibition of MabTAT3 binding by test compounds ANTAT3-1 and ANTAT3-10

Purpose: To test compounds ANTAT3-1 and ANTAT3-10 for their ability to competitively block antibody binding to TAT3. As described (nbk. 425, p.1). We have isolated a cell surface molecule, TAT3, involved in spermatozoa maturation and development. Monoclonal antibody MabTAT3 binds TAT3 with high affinity. Testing and preparation is described in nbk. 426, pp. 67-92. TAT3 is characterized in nbk. 425, pp. 5-32. The preparation and initial screening of ANTAT3-1 and ANTAT3-10 is described in nbk. 432, pp. 1-22.

Methods: ATCC cell line 7456A was cultured and plated ( $10^5$  cells/well) in 35 mm<sup>2</sup> wells and grown to confluency. Culturing conditions are described in nbk. 425, p. 3. ANTAT3-1 and ANTAT3-10 were diluted in HBSS (GIBCO) in 10-fold dilutions ranging from  $4 \times 10^5$   $\mu$ g/ml to 40  $\mu$ g/ml. MabTAT3 was diluted from a stock solution of 25  $\mu$ g/ml and used at between 0.05  $\mu$ g/ml to ~~40  $\mu$ g/ml~~ ~~25  $\mu$ g/ml~~ obtained from MLP.

10  $\mu$ g/ml MabTAT3 JCL 1/4/96  
see end of report  
Samples were distributed in the cell samples as diagrammed on page 5. Cells were incubated for 2 hrs, 37 C and harvested and lysed as described (nbk. 426, p.140)  
 MabTAT3 bound to 7456A cells was quantitated by modified ELISA described in nbk. 432, p. 80.  
 Raw data are provided on p. 6.

Results: The experiment failed, no ANTAT3-1 or ANTAT3-10 binding was detected in any of the wells except at the highest doses, but I think this is an artifact.

1/3/96 Title: Ability of ANTAT3-1 ANTAT3-10 to inhibit spermatozoa maturation in mice.

Method: BalbC mice were injected i.p. with 0.5 ml of a 1mg/ml solution of

Work continued to page 5

SIGNATURE: Julie Lawson

READ AND UNDERSTOOD BY: Mark Folger

READ AND UNDERSTOOD BY:

DATE: January 3, 1996

DATE: March 10, 1996

DATE:

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**W**e hope that you have found this information helpful. Please feel free to contact us with your questions and comments related to this new legislation or related to other matters in intellectual property law.