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Prior Art: Silent Time Bombs That Can Blow Away Your Licensing Deals

by Grace P. Malilay
Ann M. Mueting
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Association of University Technology Managers, Inc.

No. 2

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The *AUTM Educational Series* publishes articles on important aspects of technology transfer. The information contained in these publications is intended as background educational material that may be of assistance to the technology transfer professional and the inventor; it is not, however, offered as legal advice and does not take the place of legal counsel.

Prior Art: Silent Time Bombs That Can Blow Away Your Licensing Deals

Contents **Page**

EDITOR'S PREFACE

In keeping with the purpose of the *AUTM Educational Series*—to publish informative articles on topics of interest to technology transfer practitioners and inventors—this second volume of the *Series* presents a discussion of an important topic: prior art. The authors set forth a compilation of the issues that can threaten the ability to obtain a patent, and provide helpful advice on how to recognize and avoid these difficulties. The article is written for technology transfer professionals and inventors in a university or research setting, where publications, presentations, poster sessions, student theses, experimental use or testing, and grant and contract applications are everyday occurrences. Raising the inventors' awareness of these pitfalls and providing ways to avoid them can enhance the ability of the technology transfer office to protect intellectual property.

This article first appeared in the 1996 *Journal of the Association of University Technology Managers*, Volume VIII. The authors have since updated this paper to include an authors' summary of the main topics, and discussions on electronic mail, oral presentations, thesis defenses, and contract proposals. We thank them for their efforts on behalf of the technology transfer community.

Those contemplating submitting a paper to the *AUTM Educational Series* are encouraged to do so and may contact the Managing Editor for content and review procedures.

Jean A. Mahoney, Editor
September 1997

AUTHORS' SUMMARY

Any information or disclosure that is available to the public before the filing of a patent application is called "prior art." A patent may not be obtained on anything that is already available to the public. In the United States, there is an exception: an inventor has up to one year (referred to as "grace period") to file a U.S. patent application after a publication or public disclosure is made by the inventor anywhere in the world, or after a public use, sale, or offer for sale of the invention in the United States. In contrast, the patent laws in most foreign countries are more strict. Patent rights are forfeited if any public disclosure is made at any time, in any manner, before a patent application is filed.

Examples of prior art may include articles, abstracts, slides, posters, theses, electronic information, grant and contract proposals, 35 U.S.C. § 102(e) references, and experiments such as clinical and field trials. These instances of prior art could bar the patentability of inventions throughout the world, except in the United States where inventors and technology transfer managers have up to one year after the prior art occurrence to file a U.S. patent application. The bulleted items below and the full-text article that follows suggest ways in which inventors and technology transfer managers can defuse these "prior art time bombs."

I. WHAT IS A PRINTED PUBLICATION AND WHEN DOES IT CREATE A TIME BOMB?

- Printed Publication: An invention is not patentable in the United States if it was "patented or described in a printed publication in this or a foreign country...more than one year prior to the date of the application for patent in the United States."

- How to determine a printed publication

  - The disclosure must be publicly available and accessible, at least to those skilled in the art to which the invention relates.

  - The degree of public accessibility and dissemination required to qualify as a "publication" depends on the type of

disclosure in question and the circumstances of its distribution.

A. When Does an Article Become a Publication?

- An abstract or an article becomes a printed publication as of the date it reaches the addressee and not the date it was placed in the mail.
- However, to be safe, file a patent application before the journal or book containing the abstract or article is mailed from the publisher. Otherwise,
  - The publication of the article can be delayed by holding onto the galley proofs until the patent application is filed.
  - Write an abstract without fully disclosing the invention so that other persons skilled in the art cannot make and use the invention.
  - Consider not submitting an abstract at all.

B. Is Electronically Available Information a Publication?

- There is no case law that has categorized information that is transmitted electronically as a printed publication. However, access to information, regardless of the form in which it may have been recorded, is an important factor in determining what is a publication.
- Electronic subscriber services
  - An abstract or the entire article may be put online several weeks or months before the book or journal is mailed to subscribers and, therefore, be publicly available before subscribers receive a hard copy of the book or journal.
  - Verify not only the mailing date of the book or journal from the publisher, but also ask if and when

an electronic version of the article or parts of the article will be available online.

- Remember that new chemical compounds having a registry number and new gene sequences assigned an accession number are automatically posted online.

◆ Electronic mail or e-mail sent over the Internet

- Unlike postal mail, electronic mail sent over the Internet is not sealed or secure, and can be accessed or viewed on intermediate computers between the sender and recipient, unless the message is encrypted.

- Use caution when transmitting messages over the Internet.

- When transmitting sensitive material, such as drafts of manuscripts or proprietary information, encrypt or protect the information by password or other generally accepted equivalent security system.

C. Are Poster Presentations and Slides Used During Oral Presentations Publications?

◆ There is no case law that deals with whether or not poster presentations are printed publications. Unlike slides, posters are not transitory. It may be wise to consider a poster presentation as a potential publication.

◆ Slides used during oral presentations are not printed publications *per se*, even when the slides describe the invention in detail.

- If printed copies of the slides are available and disseminated to those who attend the lecture, then the slides can serve as a bar to obtaining a patent.

◆ Remember that abstracts of lectures and poster presentations may become publicly available close to the

day a meeting starts, or in a journal, conference proceeding, or on the Internet several weeks or months prior to the meeting.

D. When Does a Thesis Become a Publication?

- A thesis placed in a college or university library is deemed publicly accessible only after it has been catalogued and shelved.

- To prevent a thesis from being catalogued and shelved, place a "hold" on the thesis, if possible, to delay the shelving of the thesis in the college or university library.

- Theses are often submitted to University Microfilm, Inc. (UMI), in Ann Arbor, Michigan, for microfilming. UMI also publishes abstracts of all theses it has received in *Masters Abstract International* about twelve weeks after the thesis is received; however, abstracts typically go online in several databases one month before their appearance in *Masters Abstract International*.

  - Notify UMI to put an abstract and the on-line version of the abstract "on hold."

- An oral thesis defense may be considered a printed publication if printed copies of the thesis defense are distributed to the audience, where some individuals in the audience may be external to the university.

E. Is a Federal Grant or Contract Proposal a Publication?

- The law requires funding agencies within the federal government, such as the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Public Health Service (PHS), to make information about *funded* grants available to the public, including the title of the project, the grantee institution, the principal investigator or program director, and the amount of the award.

- The abstract (or the brief description of the project provided by the investigator) is typically available without disclosure restrictions to the public from the agency and/or is available from the National Technical Information Service (NTIS), U.S. Department of Commerce, with respect to the information disclosed in the abstract. Depending on the agency, this may also be true for summaries, progress reports, final reports, etc.

◆ The *Commerce Business Daily (CBD)* publishes *funded* contracts, including the title of the project, the name of the federal contract officer, contract number, the amount of the award, and the institution awarded the contract. The on-line version of the *CBD* also publishes a synopsis of the project, though this frequently resembles the title of the project.

◆ The text of any *funded* grant or contract proposal may be available to the public through the Freedom of Information Act (FOIA). But, proprietary information can be withheld because Exemption 4 of FOIA permits withholding of "trade secrets and commercial or financial information."

II. WHAT IS A 102(e) REFERENCE?

◆ 35 U.S.C. § 102(e): If a patent application is filed in the United States and a second application is subsequently filed on related technology by "another" in the United States, the first application can be a reference against the second application once the first one issues as a patent, and may prevent the issuance of a patent on the second application.

- Applies only if the inventors on the two applications are different.

- The fact that the two applications have one or more inventors in common is immaterial; the applications would still have different inventive entities.

- If there are related technologies with different inventors from the same institution, and one could be used as a reference against the other, either a single application should be prepared for both inventions, or two separate applications should be filed on the same day.

III. IS EXPERIMENTAL USE OR TESTING, SUCH AS A CLINICAL TRIAL OR FIELD TRIAL, A PUBLIC USE OR SALE OF AN INVENTION?

- A person may not obtain a United States patent if the invention was in public use or on sale in the United States more than one year prior to the date the U.S. patent application was filed.

- Factors that determine whether an invention was in public use or on sale:

  - The amount of control retained by the inventor over the invention.
  - The extent of public testing required in relation to the nature of the invention.
  - The necessity for the public testing.
  - The length of the test period.
  - Whether any payment was made.
  - Whether there was a secrecy agreement or obligation.
  - Who conducted the experiments.
  - Whether records were kept.
  - The degree of commercial exploitation during the tests in relation to the purpose of the experimentation.

- A single use may be sufficient to establish public use of an invention.
  - However, if the circumstances indicate that the uses were truly for experimental purposes, then even multiple uses will not trigger the "public use" bar.
- A single sale or offer for sale can be sufficient to establish an on-sale bar; for example, a free distribution of a prototype may raise the on-sale bar if it is done to solicit sales, or an on-sale bar can be created despite *losing* money on a sale.
  - However, a genuine experimental purpose to perfect the invention rather than for commercial exploitation does not trigger the "on-sale" bar.
- If an inventor needs to perform an experiment or needs to have a third party perform an experiment, it is critically important to make sure that the inventor or the inventor's assignee retains control over the invention.
  - Keep the outside testing to a minimum.
  - Involve only the number of people necessary.
  - Make sure research notes are recorded.
  - Keep strict controls over the research notes.
  - Get secrecy agreements in place before the testing begins.
  - Do not begin any commercial exploitation until after the patent application is filed.
  - If compensation for the experimental use of the invention will be paid from an outside source, be sure that it is merely to cover costs and not for profit.

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INTRODUCTION

It is very important to understand what the U.S. Patent Office considers to be a "publication" or "public disclosure." For example, some inventors may still think that "publication" refers to the publication of an article in a magazine or scientific journal, or to a chapter in a book. However, inventors and technology transfer managers must be aware of prior public disclosures, especially those that are less obvious or "hidden," that could invalidate patents and thereby blow away licensing deals.

Any information or disclosure that is available to the public before the filing of a patent application is called "prior art." A patent may not be obtained on anything that is already available to the public. In the United States, there is an exception: an inventor has up to one year to file a U.S. patent application (referred to as "grace period") after a publication or public disclosure is made by the inventor anywhere in the world, or after a public use, sale, or offer for sale of the invention in the United States.[1] In contrast, the patent laws in most foreign countries are more strict. Patent rights are often forfeited if any public disclosure is made at any time, in any manner, before a patent application is filed.

An article entitled "What Counts: A Publication Guide for the Inventor Seeking a Patent" appeared in the *Journal of the Association of University Technology Managers*, Vol. VI, 1994. That article focused on what constitutes a "printed publication." This paper discusses additional examples of prior art that could bar the patentability of inventions throughout the world,

and thereby create a time bomb. It also goes one step further by suggesting ways in which inventors and technology transfer managers can defuse prior art time bombs. If any of the activities discussed below occurs before the filing of a patent application, then inventors and technology transfer managers can still file a patent application in the United States, provided that it is filed within one year after the prior art occurrence. The prior art reviewed in this article includes articles, abstracts, slides, posters, theses, electronic information, grant proposals, 35 U.S.C. § 102(e) references, and experimental use or testing.

I

WHAT IS A PRINTED PUBLICATION AND WHEN DOES IT CREATE A TIME BOMB?

An invention is not patentable if it was "patented or described in a printed publication in this or a foreign country...more than one year prior to the date of the application for patent in the United States." [2] 35 U.S.C. § 102(b) is sometimes referred to as the "printed publication bar." In analyzing whether or not an invention can be patented *in the United States* under the "printed publication bar," one must first determine whether or not a disclosure is a "printed publication," and, if so, whether it was available to the public more than one year before filing a patent application. Whether or not the content of a publication is sufficient to constitute an "enabling" disclosure is beyond the scope of this article.

There are a number of court cases that analyze whether or not a disclosure is a "printed publication." These disclosures include, for example, articles, slides and drawings, microfilm, photographs, theses, intra-company distributions, and grant proposals. The underlying theme to all of these cases is that the disclosure must be publicly available and accessible, at least to those skilled in the art to which the invention relates.[3] The degree of public accessibility and dissemination required to qualify as a "publication" depends on the type of disclosure in question and the circumstances of its distribution.

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A. When Does an Article Become a Publication?

An abstract or an article becomes a printed publication as of the date it reaches the addressee and not the date it was placed in the mail.[4] In practice, however, inventors and technology transfer managers should file a patent application before the book or journal containing the abstract or article is mailed from the publisher. By doing so, one will be sure that the application is filed prior to the book or journal reaching the addressee. The anticipated mailing date can be obtained from the publisher of the book or journal; however, that date can change, so make certain to check with the publisher frequently, particularly as the mailing date approaches, to ensure that the publisher does not mail early. Remember, the publication of the article can also be delayed. One of the easiest ways to do this is to advise the publisher that you will hold onto the galley proofs until the patent application is filed. Alternatively, one should write an abstract without fully disclosing the invention so that other persons skilled in the art cannot make and use the invention. Also consider not submitting an abstract at all.

B. Is Electronically Available Information a Publication?

To promote rapid exchange of scientific information, some scientific journals now post abstracts of accepted articles on electronic subscriber services, weeks or months before publication of the paper version in the scientific journal. There are other services that post the entire manuscript online before or on the day the journal is mailed to subscribers. Also jumping on the "electronic format" bandwagon are scientific societies or organizations that post abstracts on the Internet along with information about upcoming meetings. Furthermore, if the manuscript includes a new chemical compound, once the manuscript is accepted by any of the twenty-two journals published by the American Chemical Society (ACS), the new chemical compound receives a registry number. The chemical name, molecular formula, and structure of the compound are then put online in the Registry database produced by Chemical Abstracts Service®. New chemical compounds receive registry numbers not only in journals published by the ACS but in any journal in which the manuscript is published. Also, if the manuscript includes a gene sequence, once a gene gets

assigned an accession number, GenBank® posts the sequence online automatically.[5] Thus, it is no longer sufficient for technology transfer managers to be concerned only with the appearance of a paper or parts of a paper in a scientific journal.

Complicating the issue is the fact that electronic information services vary in sensitivity to an inventor's or to a university's pursuit to perfecting patent rights. ACS, for example, modified its procedures in late 1993 for publishing abstracts of articles in *Advance ACS Abstracts*. This publication contains abstracts and bibliographic information for articles that have been accepted for publication in many of the ACS journals. The information can appear up to twelve weeks in advance of publication of the articles in their respective journals, and is available online in the CApreviews® database. Articles that are published in the ACS journals now contain a footnote that reveals the date on which the abstract was published in *Advance ACS Abstracts*. In addition, abstracts and references appear in the CApreviews® database only after they are published in *Advance ACS Abstracts*. This practice eliminates any ambiguity as to the earliest publication date. These procedures by ACS unfortunately are not the norm.

While there is no definitive case law that has clearly categorized information that is transmitted electronically as a printed publication, inventors and technology transfer managers should nonetheless assume that information appearing online would be considered a public disclosure. The Federal District Court in Delaware has suggested that a reference does not have to be actually printed or published.[6] Access to the information by those skilled in the art, regardless of the form in which it may have been recorded, is an important factor in determining what is a publication.[7] Inventors and technology transfer managers must now verify not only the mailing date of the book or journal from the publisher, but also ask if and when an electronic version of the article or parts of the article will be available online. Again, check with the publisher frequently, especially as the posting date approaches, to verify that the date of the electronic version does not change.

What should you do about communicating via electronic mail or e-mail? If communicating over a closed, private network, i.e., a

company's internal e-mail system also known as a "LAN" or "local area network," there is a reasonable expectation of privacy in transmissions that are sent over such a private network[8] and, therefore, these transmissions should not be considered printed publications. However, many inventors send informal letters or drafts of articles to colleagues over the Internet. Sending an Internet e-mail is like sending a postcard: the message is not sealed or secure and can be accessed or viewed on intermediate computers between the sender and recipient, unless the message is encrypted.[9] Use caution when transmitting messages over the Internet. If you are transmitting sensitive material such as drafts of articles, encrypt or protect the information by password or other generally accepted equivalent security system to prevent or deter access to information by unintended recipients skilled in the art.

C. Are Poster Presentations and Slides Used During Oral Presentations Publications?

Slides used during oral presentations[10] are not considered printed publications *per se*, even when the slides describe the invention in detail.[11] The rationale behind this rule is that the projection of the slides on a screen is transient. Such a projection does not make the content of the slides available in such a manner that persons who are interested in the information could locate it and put it to use.[12] However, if printed copies of the slides are available and disseminated to those who attend the lecture, then the slides can serve as a bar to obtaining a patent.[13] It makes no difference as to how many printed copies are distributed; even one distributed copy is one too many. When inventors make oral presentations using slides, handouts of the lecture or printed copies of the slides must not be disseminated to the audience.[14] Also, keep in mind that in foreign countries where absolute novelty is required, the slides themselves shown during a lecture as well as the lecture itself may be considered prior art.

There is no case law that deals with whether or not poster presentations are printed publications. Unlike slides, posters are fixed, not transitory. Those attending the poster sessions can walk around and take photographs of the posters. Photographs can be considered printed publications.[15] However, they do have to be sufficiently

accessible to the public so that persons concerned with the art could have the opportunity to inspect, digest, and understand the information contained in the photographs.[16] Nevertheless, it is wise to consider a poster presentation as a potential publication. Use caution and file the patent application in the United States within one year of the date of a poster session.

Remember also that talks and poster presentations typically are preceded by submission of an abstract to the conference organizers. The availability of the abstract depends on the organization. Some organizations do not make abstracts available until close to the day the meeting starts. Others send out the entire set of abstracts, or portions thereof, prior to the meeting.[17] Also, certain organizations publish their abstracts in a book or journal or on the Internet several weeks or months prior to the meeting. When calling an organization to determine what its policies are, one cannot ask enough questions. Find out what information participants will receive prior to a meeting and whether the organization publishes abstracts prior to a meeting.

D. When Does a Thesis Become a Publication?

There are a handful of cases that address the issue of theses.[18] The rule is that a thesis placed in a college or university library is accessible only after it has been catalogued and shelved.[19] Cataloguing and shelving make the thesis accessible to the public.[20] The nature of the cataloguing, however, also must be scrutinized to determine if it makes the thesis sufficiently accessible to the public.[21]

To prevent a thesis from being catalogued and shelved, the inventor or technology transfer office may be able to request the graduate school (or other department that receives theses) to place a "hold" on the thesis so that the information contained in the thesis can be included in a patent application. At institutions where such a "hold" is permitted, it likely will not prevent the student from graduating. For example, a Ph.D. candidate at the University of Minnesota must submit two copies of her thesis to the Graduate School on or prior to the date of graduation. At the time the thesis is submitted, a request can be made to put the thesis "on hold." A "hold" can also be placed on the thesis *after* it is submitted. A typical holding period is three to six months, though this can be extended, at least at the University of

Minnesota.[22] This simple act of putting a thesis "on hold" delays the cataloguing and/or shelving of the thesis in the library.

If confronted with a situation where the thesis was in fact catalogued and shelved before the patent application was filed, determine when the thesis was accessible to the public. In a court of law, accessibility does not have to be shown by evidence of the specific date of cataloguing and shelving.[23] Instead, competent evidence of the general library practice or evidence of routine business practice may be relied upon to prove that the reference was not available more than one year prior to the filing of a U.S. patent application.[24]

Routine business practice at the University of Minnesota is that upon receipt of two copies of any Ph.D. or Masters thesis, the Graduate School sends one copy to the University's Library Archives. Archives functions as a repository for each and every thesis written by University of Minnesota students. These theses are noncirculating. They may not be checked out from Archives, although they are accessible for viewing and copying.[25] The other copy is sent to University Microfilm, Inc. (UMI), in Ann Arbor, Michigan, for microfilming. Once microfilming is completed, this copy of the thesis eventually is sent to the appropriate campus library (for example, the medical school library). This copy is shelved for circulation to the public. UMI publishes abstracts of all theses it has received in *Masters Abstract International* about twelve weeks after it receives the thesis; however, it typically places abstracts online in several databases one month before their appearance in *Masters Abstract International*. When a "hold" has been requested, the Graduate School informs Archives and UMI.[26] Archives and the appropriate campus library sequester their copies of the thesis, and UMI delays publication of the abstract in both the journal and the electronic database for the required period.

Remember also that the nature of the cataloguing is a factor in determining the public's accessibility to a thesis on the shelf.[27] Take, for example, a thesis that was catalogued by title and name of the author only, and not by subject matter. One can argue that the public would have a difficult time gaining access to the thesis if the title was obscure and the author was unknown in the field.

On a related matter, would an oral thesis defense be considered a printed publication? There are no court cases that have addressed this issue. It would be impossible to predict how a court would decide the issue, but an oral thesis defense might be considered analogous to giving an oral presentation. If printed copies of the thesis defense are distributed to the audience, where some individuals in the audience may be external to the university, then the thesis defense may serve as a "printed publication." If unsure about who the audience is, do not hand out material at a thesis defense. Also, remember that foreign patent rights are often forfeited if any lecture, including a thesis defense, is heard by people external to the university who are not bound by the terms of a confidentiality or non-disclosure agreement.

E. Is a Federal Grant or Contract Proposal a Publication?[28]

Funding agencies within the federal government, such as the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Public Health Service (PHS), make information about funded grants[29] available to the public, including the title of the project, the grantee institution, the principal investigator or program director, and the amount of the award. The abstract (or the brief description of the project provided by the investigator) is typically available without disclosure restrictions to the public from the agency and/or is available from the National Technical Information Service (NTIS), U.S. Department of Commerce. Typically, the abstract is placed in a printed publication listing federally funded research and is placed in the NTIS on-line database (and maintained there for about three years). Depending on the agency, this may also be true for project summaries, progress reports, final reports, etc.[30] Thus, inventors and technology transfer managers need to learn about the procedures used by each of the federal agencies that is funding the research. This may be cumbersome, but it is vital to ensuring that the university's patent rights are protected.[31]

In addition to abstracts, the text of a grant proposal may qualify as a printed publication. In 1990, a district court in California held that NSF and NIH grant proposals were printed publications.[32] The court based its determination on the fact that the funding agency catalogues and indexes the proposals by author, title, institution, and grant number, and that the grant proposals were publicly available through

the Freedom of Information Act (FOIA).[33] Therefore, the court felt that these documents were sufficiently accessible to a researcher who exercised reasonable diligence. This is not the end of the story, however.

The court ignored one very important section of the Freedom of Information Act. The court assumed that all information contained in grant proposals is freely accessible to inquirers under the Freedom of Information Act. Generally, this is not true. Exemption 4 of the Freedom of Information Act permits withholding of "trade secrets and commercial or financial information,"[34] and therefore certain materials submitted by the institution and/or principal investigator may be entitled to protection under this exemption. Thus, the entirety of a funded grant proposal may not be sufficiently accessible or available to the public.

When a request is made under FOIA for a funded grant or contract proposal, the Freedom of Information Officer for the funding agency must contact the institution and/or principal investigator to give the principal investigator an opportunity to redact (i.e., withhold) any information considered proprietary.[35] Generally, the agency will only send out to the requesting party that which the principal investigator recommends can be distributed. However, certain information cannot ordinarily be redacted, such as that which is known through custom or usage in a trade, business, or profession, or information that is generally known to any reasonably educated person, as well as self-evident statements or reviews of the general state of the art. Thus, the funding agency can overrule the withholding recommendations made by the principal investigator.

So, what should be done when an inventor's grant or contract proposal is cited by a Patent Examiner as prior art during prosecution of your application? Do not despair. If the inventor does not remember whether he/she has received any requests or not, contact the Freedom of Information Officer for the funding agency and ask if there have ever been any FOIA requests for the grant or contract proposal. The agency must keep records of these requests. A declaration that no FOIA requests have been received may be sufficient for the Patent Examiner to withdraw the rejection.

Alternatively, to provide evidence of what portions of the grant or contract proposal would have been available under FOIA had there been a request, have someone request the grant or contract proposal. The agency must then contact the institution and/or principal investigator for identification of proprietary information pursuant to Exemption 4. If the principal investigator does not have a copy of the requested years of the grant or contract proposal, a copy may be requested from the funding agency. Information that could adversely affect the pending application and any issued patents can then be redacted and the redacted version sent back to the agency. Once this is approved, the agency will then send out to the requesting party that which the agency considered to have been properly redacted. This version of the funded grant or contract proposal can then be sent to the Patent Examiner, in order to overcome the rejection.

In summary, it is extremely important to know when disclosures may become available to the public. In many cases, measures can be taken to protect the information in an article, thesis, or grant or contract application from becoming a silent time bomb.

II

WHAT IS A 102(e) REFERENCE?

35 U.S.C. § 102(e) states that if a patent application is filed *in the United States* and a second application is subsequently filed on related technology by "another" *in the United States*, the first application can be a prior art reference against the second application once the first one issues as a patent, and may prevent the issuance of a patent on the second application. Although patent applications that are filed in the United States are secret, once a patent issues, the effective date for prior art purposes is its filing date, not its issue date. Thus, there is a presumption that what is in the application is publicly known as of the date it is filed, even though in reality it is kept secret until the patent issues. Prior art is an issue only if the inventors on the two applications are different. The fact that the two applications have one or more inventors in common is immaterial; the applications would still have different inventive entities.[36] Be aware that if the second application naming different inventors is a Continuation-In-Part of the first application, then a §102(e) time bomb can exist.[37]

It is common in university and industry settings to have related technologies come out of one laboratory with the principal investigator as the person common to the different, though related, technologies. Make sure that you will not be confronted with a § 102(e) time bomb. For example, if there are related technologies with different inventors (Principal Investigator and Technician-1 compared to Principal Investigator and Technician-2), and one could be a reference against the other, either one application should be prepared for both inventions, or two separate applications should be filed on the same day.[38]

III

IS EXPERIMENTAL USE OR TESTING, SUCH AS A CLINICAL TRIAL OR FIELD TRIAL, A PUBLIC USE OR SALE OF AN INVENTION?

Another potential time bomb to a licensing deal is an experiment such as a clinical or field trial. A person may not obtain a United States patent if the invention was in *public* use or on sale in the United States more than one year prior to the date of the patent application (i.e., the "critical date").[39] If either of these two activities has occurred prior to the critical date, then the inventor will be barred from having a patent issue on the invention.

In looking at an experimental use or testing situation, two issues must be addressed to determine if patent rights may still be available. First, it must be determined if the clinical or field trial could be considered a "public use" of the invention. Second, it must be determined if any payments made in conjunction with the clinical or field trial would mean that the invention could be considered to be "on sale." [40] Unfortunately, these legal terms are not clearly defined in the case law, making it difficult to perform an accurate predictive assessment. Another complicating factor is that the determination of whether an experiment would legally be considered a "public use" or "on sale" depends on the specific facts in each case. Therefore, it is difficult to predict what a court's finding would be in these types of cases. It is important, however, at least to be aware that experimental uses may create patenting difficulties.

A patentee can escape the statutory bar where a use or sale was primarily for a genuine experimental purpose to perfect the invention (referred to as the "experimental use exception") rather than for commercial exploitation.[41, 42] For example, experimental use does not include market testing where the

inventor is attempting to gauge consumer demand for his or her claimed invention.[43] Courts have recognized that an inventor may need to test an invention in order to make certain that the invention is complete or to determine if further changes need to be made.[44] The courts have also recognized that the testing of an invention may require disclosing the invention to the public or having a third party perform the testing on behalf of the inventor to determine that the invention works as intended.[45]

Several factors weigh in the determination of whether an invention was in public use or on sale.[46] These factors include the amount of control retained by the inventor over the invention, the extent of public testing required in relation to the nature of the invention, the necessity for the public testing, the length of the test period, whether any payment was made (e.g., for the product produced by the invention or for the inventive process itself), whether there was a secrecy agreement or obligation, who conducted the experiments, whether records were kept, and the degree of commercial exploitation during the tests in relation to the purpose of the experimentation.[47]

One of the most important factors to consider is whether the inventor retained control of the invention.[48] For example, did someone other than the inventor conduct the experiments? Further, did the inventor keep or require records of progress? The lack of written progress records is circumstantial evidence of a non-experimental purpose.[49] The experimental use exception does not apply when the inventor or the inventor's assignee fails to keep control over the invention while others test it.[50] In other words, the experimental use exception is personal to the inventor or the inventor's assignee. The Supreme Court has indicated that for an assertion of experimental use to have merit, it must be clear that the inventor kept control over the invention in the course of its testing.[51]

A related issue is the length of the test period. In some situations, a test needs to run for a considerable time and under differing circumstances before the inventor can know whether the invention would answer the purpose intended. A test can run for several years and still be considered "experimental."[52] Also, the nature of the invention can be important in determining if the length of the test period is appropriate. Some products require minimal testing, while others must be tested by prolonged, open use by the public.[53]

Another factor to consider is whether the experimental user agrees to use the invention secretly.[54] A lack of secrecy in use is not fatal to an inventor's claim

of experimental use, but steps taken to keep an invention from more than a few necessary testers may support a claim of experimentation.[55] The fact that an invention was not hidden from view may make the use "not secret," but non-secret use is not in itself "public use" activity.[56] Conversely, the use of an invention in a setting not open to the public, such as a hospital operating room, can still mean that the use was a "public use" within the meaning of the statute.[57]

A single use may be sufficient to establish public use of an invention.[58] It should be noted, however, that more than one use prior to the critical date may not trigger the bar. If the totality of the circumstances indicates that the uses were truly for experimental purposes, then even multiple uses will not be a bar. It is not surprising that the more uses prior to the critical date, the more likely a court will find that the use was not for experimental purposes.[59]

As mentioned above, if an invention is placed on sale or is offered for sale, the §102(b) bar will arise. A single sale or offer for sale outside the grace period can be sufficient.[60] Limiting the extent of sales may not negate the bar. A free distribution of a prototype may raise the on-sale bar if it is done to solicit sales.[61] Further, even though a patent holder did not make a profit on the invention, but was only reimbursed for its costs, a sale still may have occurred.[62] A patent holder may have created an on-sale bar despite ***losing*** money on a sale.[63] Also, even a rejected offer may create an on-sale bar.[64] Furthermore, the offer need not actually be received by a prospective purchaser.[65] If any sale or offer for sale (i.e., commercial exploitation) does occur, it must be merely incidental to the primary purpose of experimentation to perfect the invention.[66]

Thus, if an inventor needs to perform an experiment or needs to have a third party perform an experiment outside the inventor's laboratory, be sure that the experiment really needs to be done to perfect the invention or to ascertain whether it will answer its intended purpose. If it is not necessary, have the experiment done after the patent application is filed. If the experiment is necessary, it is critically important to make sure that the inventor or the inventor's assignee retains control over the invention: keep the outside testing to a minimum; involve only the necessary number of people; make sure research notes are recorded; keep strict controls over the research notes; and get any secrecy agreements in place before the testing begins. Further, do not begin any commercial exploitation until after the patent application is filed. If

compensation for the experimental use of the invention will be paid from an outside source, be sure that it is merely to cover costs and there is no profit.

CLOSING

Inventors and technology transfer managers must be aware of "prior art time bombs" that can blow away licensing deals. It is very important to consider both traditional and nontraditional "publications" and "public disclosures." Be aware of the publication dates of articles, of when electronic information is placed online, of when poster or slide presentations are made, of theses being catalogued and shelved, and of information in federally funded grant or contract applications. Also, be aware of multiple inventions coming out of the same laboratory where not all of the inventors are the same for the different inventions. Be careful of having experiments performed on the invention outside the inventor's laboratory. If the experiment must be done either by the inventor or by a third party on behalf of the inventor, make sure the inventor or the inventor's-assignee retains control over the invention. Because the law is not clear in all cases of experimental use, judge each situation in light of the facts of the case.

In conclusion, while prior art can be a danger to licensing deals, careful and close management throughout the process of technology transfer can make a difference.

NOTES

1. 35 U.S.C. § 102(b).

2 *Id.*

3. A disclosure is not available to the public if a confidentiality agreement has been signed by the disclosing party (e.g., the university) and the receiving party (e.g., a company). For example, without a confidentiality agreement, papers or reports distributed at meetings with industrial sponsors are considered printed publications. However, materials distributed at meetings within a company are not disseminated to the public, and therefore the distributed materials do not constitute a publication (*In re Kratz*, 592 F.2d 1169 (C.C.P.A. 1979)).

4. *Protein Foundation, Inc. v. Brenner*, 260 F. Supp. 519, 521, 151 USPQ 561, 562 (D.D.C. 1966).

5. The author of the article submits the sequence to GenBank®. The sequence is then assigned an accession number, and this number appears in the article. An inventor should request that a "hold" be placed on the sequence so it is not posted online until the publication of the article in a journal.

6. *Mobil Oil Corp. v. Amoco Chemicals Corp.*, 779 F. Supp. 1429, 1488-89 (D. Del. 1991), *aff'd on other grounds* 980 F.2d 742 (Fed. Cir. 1992).

7. *Philips Electronic & Pharmaceutical Indus. v. Thermal & Electronics Indus.*, 450 F.2d 1164, 171 USPQ 641 (3d Cir. 1971); *In re Wyer*, 665 F.2d 221, 226, 210 USPQ 790 (C.C.P.A. 1981).

8. *See National Emp. Serv. Corp. v. Liberty Mut. Ins. Co.*, 3 Mass. L. Rptr. 221 (Mass. Super. Ct. 1994) (internal e-mail generated by in-house lawyers subject to attorney-client privilege); *see also U.S. v. Keystone Sanitation Co.*, 903 F. Supp. 803, 808 (M.D. Pa. 1995) (attorney-client privilege waived as to inadvertently produced e-mail messages).

9. *American Civil Liberties Union, et al., v. Janet Reno, Attorney General of the United States*, No. 96-963 and *American Library Association v. United States Department of Justice, et al.*, 929 F. Supp 824 (E.D. Pa., July 11, 1996).

10. This discussion focuses on inventors giving presentations or lectures to an audience that is composed of individuals external to a university or company, who are not bound by the terms of a confidentiality agreement.

    An oral presentation by itself presumably does not create a bar for obtaining a patent in the United States because 35 U.S.C. § 102(b) requires a "printed publication." Courts that have decided cases regarding the printed publication issue have examined "printed publication" in terms of a *document or other tangible material*, and whether it was disseminated, accessible, or made available to the public. The term "document" can be construed broadly.

    If inventors and technology transfer managers want to protect an invention in the United States that was described in an oral presentation, it is advisable to file a patent application within one year of the presentation because the inventor-lecturer may have effectively communicated the invention to one skilled in the art. Remember that oral presentations may bar patentability in foreign countries that require "absolute novelty."

11. *Regents of the University of California v. Howmedica, Inc.*, 530 F. Supp. 846, 210 USPQ 727 (D.N.J. 1981), aff'd, 676 F.2d 687 (3d Cir. 1982).

12. *Regents of the University of California*, 530 F. Supp. at 860, 210 USPQ at 739.

13. *Id.*

14. *Massachusetts Institute of Technology v. AB Fortia*, 774 F.2d 1104, 1108 (1985) (paper orally presented at conference and copies distributed, without any restriction, to as many as six persons is "printed publication"); *Deep Welding, Inc. v. Sciaky Bros., Inc.*, 417 F.2d 1227, 1235 (1969) (papers distributed at various conferences in Europe or read at the conference with detailed summaries distributed are prior art).

15. *See, e.g., Vetco Offshore Industries v. Rucker Co.*, 448 F. Supp. 1203, 200 USPQ 525 (N.D. Cal. 1978) (drawings with written descriptions were made available to companies involved in the art), *Tyler Refrigeration Corp. v. Kysor Indus.*, 601 F. Supp. 590, 593-594, 601-604, 225 USPQ 490, 494, 500-502 (D. Del.), aff'd, 777 F.2d 687, 227 USPQ 845 (Fed. Cir. 1985); *see also Tyler Refrigeration Corp. v. Kysor Indus.*, 533 F. Supp. 279, 220 USPQ 1033 (D. Del. 1982) (brochures of display panels shown at trade show held printed publications), *Torin Corp. v. Phillips Indus.*, 625 F. Supp. 1077, 228 USPQ 465 (S.D. Ohio 1985) (photographs of device were distributed to sales representatives in order to promote the device to customers), and *Bros. Inc. v. Browning Mfg. Co.*, 317 F.2d 413 (8th Cir. 1963) (device described in pamphlet containing photographs with detailed specifications).

16. *Tyler Refrigeration Corp.*, 601 F. Supp. at 601, 225 USPQ at 500.

17. Although the American Chemical Society does not send out the entire set of abstracts prior to a national meeting, certain subgroups of the organization, such as the Inorganic Division, send out books of abstracts for their presentations.

18. *In re Bayer*, 568 F.2d 1357, 196 USPQ 670 (C.C.P.A. 1978), *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986), *In re Cronyn*, 890 F.2d 1158, 13 USPQ 1070 (Fed. Cir. 1989).

19. *In re Bayer*, 568 F.2d at 1359, 196 USPQ at 672.

20. *Id.*

21. *In re Cronyn*, 890 F.2d at 1160, 13 USPQ at 1072 (index consisting of 450 cards of chemistry theses stored in shoe box was not a "publication," i.e., not sufficiently accessible to the public).

22. Holds typically come off automatically, so it is wise to docket the date on which the hold expires.

23. *American Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86, 113, 14 USPQ2d 1673, 1695 (D. Del. 1989).

24. *Id.*

25. At the University of Minnesota, Ph.D. candidates can graduate on the last day of any month of the year. About one month after a student's graduation date, a copy of the thesis is catalogued electronically by thesis title and name of the author. A permanent record of date of entry into the electronic card catalog system is documented in a notebook. This hard copy record is retained by the librarian, and serves as evidence as to when a thesis is accessible to the public. Key words describing the topic of interest can be used to search for a thesis. If a "hold" has been requested, it is keyed electronically into the system to indicate that it is not available for public viewing. When the holding period lapses, the notation is deleted from the system. Except for the hard copy record, one would never have known that a thesis was on hold just by looking at the electronic card catalog after the holding period lapses.

26. It may be unwise to rely solely on the Graduate School to inform UMI of a "hold." Preferably, the inventor should contact UMI directly to confirm that UMI is indeed notified of putting an abstract "on hold." Make certain that the inventor requests that a hold gets placed on the on-line version of the abstract as well.

27. *In re Cronyn*, 890 F.2d at 1160, 13 USPQ at 1072.

28. This discussion is limited to grants and contracts funded by the federal government. For purposes of this discussion, a grant is a pledge of support where the sponsor has little involvement in the scope and design of the research proposal, while a contract is an agreement where the sponsor has some involvement and uses the research project to achieve a specific outcome or deliverable. State agencies or private foundations funding grants and contracts have their own policies and procedures regarding the availability of information to the public, and these policies and procedures can vary considerably. Therefore, proposals, abstracts, etc., provided to state agencies and private foundations should also be considered as potential "prior art time bombs."

29. Grant proposals are maintained in confidence by federal agencies during the review process. They are not available to the public until they are actually funded. Thus, even if a grant proposal is approved, until the institution receives the money, i.e., the grant proposal is "funded," it is not available to the public under the Freedom of Information Act.

30. Sponsored Projects Administration at the University of Minnesota, the office responsible for the administration and management of grants and contracts, recommends to faculty at the University to mark sections of a grant or contract CONFIDENTIAL at the time the proposal is submitted to a federal agency, and on any subsequent reports that are submitted, in order to prevent inadvertent publication.

31. Likewise, funding agencies within the federal government make information about awarded contracts available to the public (an "awarded" contract is effectively a "funded" contract because, although the federal agency does not distribute funds to the institution except as stipulated under the terms of the contract, the funds have been set aside for the awarded project). Like grant proposals, contract proposals are maintained in confidence by federal agencies during the review process, and are not available to the public until they are actually awarded.

The *Commerce Business Daily (CBD)* publishes the title of the project, the name of the federal contract officer, contract number, the amount of the award, and the institution awarded the contract. In addition to this information, the on-line version of the *CBD* also publishes a synopsis of the project, though this frequently resembles the title of the project.

32. *E. I. Dupont de Nemours & Co. v. Cetus Corp.*, 19 USPQ2d 1175 (N.D. Cal. 1990).

33. *Id.* at 1185.

34. 5 U.S.C. § 552(b)(4). Further protection is provided by the Trade Secrets Act, 18 U.S.C. § 1905, which makes it a crime for government officials to disclose trade secrets.

35. Executive Order 12600, 52 Fed. Reg. 23781 (1987), issued by President Reagan, instructs agencies that when they are considering granting a FOIA request for information that arguably could be withheld under Exemption 4, they must notify the company that supplied the information and permit it to present objections.

36. *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992).

37. *Id.*

38. If two applications have already been filed, and the earlier filed one is a § 102(e) reference against the second, consider combining the two applications and filing a jumbo application claiming priority from both, and abandoning both parent applications. *See, Manual of Patent Examining Procedure*, § 706.02(k).

39. 35 U.S.C. § 102(b).

40. A sale is a contract between parties wherein the seller agrees "to give and to pass rights of property in return for the buyer's payment or promise" to pay the seller for the things bought or sold. *See, Manual of Patent Examining Procedure,* § 2133.03(b), *citing In re Caveney,* 226 USPQ 1, 4 (Fed. Cir. 1985). An assignment or sale of the patent rights or potential patent rights in an invention is not a sale of the invention within the meaning of § 102(b). *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986).

41. *Paragon Podiatry Laboratory v. KLM Laboratories,* 984 F.2d 1185, 25 USPQ2d 1561, 1563 (Fed. Cir. 1993); *accord, Sinskey v. Pharmacia Ophthalmics,* 982 F.2d 494, 498 (Fed. Cir. 1992) (To avoid statutory bar, "it must be shown that the activity was 'substantially for purposes of experiment.'"); *Baker Oil Tools, Inc., v. Geo Vann, Inc.*, 828 F.2d at 1558, 1563 (Fed. Cir. 1987); *TP Laboratories v. Professional Positioners, Inc.*, 724 F.2d 965 , 970 (Fed. Cir. 1984).

42. The following activities indicate "commercial exploitation": (1) preparation of "commercial" documents, e.g., orders, invoices, receipts, delivery schedules, etc.; (2) preparation of price lists; (3) display of samples to prospective customers; (4) demonstration of models or prototypes, especially at trade conventions, and even though no orders are actually obtained; (5) use of an invention where an admission fee is charged; and (6) advertising in publicity releases, brochures, and various periodicals. *See, Manual of Patent Examining Procedure,* § 2133.03(e)(1).

43. *In re Smith,* 218 USPQ 976, 983 (Fed. Cir. 1983).

44. *Baker Oil Tools, Inc.*, 828 F.2d at 1563.

45. *Id.; U.S. Environmental Products v. Westall,* 911 F.2d 713, 15 USPQ2d 1898, 1901 (Fed. Cir. 1990).

46. *Baxter International, Inc. v. Cobe Laboratories, Inc.*, 88 F.3d 1054, 39 USPQ2d 1437, 1440 (Fed. Cir. 1996); *Western Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 844 (Fed. Cir. 1985); *TP Laboratories,* 724 F.2d at 971-72; *U.S. Environmental Products,* 15 USPQ2d at 1901; *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 549-550 (Fed. Cir. 1990); *see also, Envirotech Corp. v. Westech Engineering, Inc.*, 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990).

47. *Lough v. Brunswick Corp.*, 103 F.3d 1517, 41 USPQ2d 1385 (Fed. Cir. 1996); *Sinskey,* 982 F.2d at 498, 25 USPQ2d at 1294; *U.S. Environmental Products,* 15 USPQ2d at 1901; *Baker Oil Tools, Inc.*, 828 F.2d at 1564; *see also Continental Can Co. U.S.A., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1750 (Fed. Cir. 1991). It should be noted that after-the-fact affidavit testimony from the inventor stating that a sale or use was merely experimental will not be sufficient to overcome the bar in the absence of additional objective evidence to support the inventor's statements. *Sinskey,* 982 F.2d at 499.

48. *U.S. Environmental Products,* 911 F.2d at 717, 15 USPQ2d at 1902.

49. *Id.*

50. *In re Hamilton,* 882 F.2d 1576, 11 USPQ2d 1890 (Fed. Cir. 1989); *but see, Moleculon Research Co.*, 793 F.2d at 1265-66 (inventor of puzzle allegedly infringed by Rubik's Cube did not expose puzzle to public use because he at all times retained control over puzzle's use by close friends and colleagues. There is no public use when inventor restricted use to locations where there was a reasonable expectation of privacy, e.g., at home, and the use was for his or her own enjoyment).

51. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877).

52. *See, e.g., TP Laboratories,* 724 F.2d at 972 (experimental testing of orthodontic device occurred over six years because dental follow-up treatment of patients takes time).

53. *James L. Taylor Manufacturing Co. v. Doucet Machineries Inc.*, 24 USPQ2d 1868, 1870-71 (W.D. Pa. 1992).

54. *Baxter International, Inc.*, 39 USPQ2d at 1440; *TP Laboratories*, 724 F.2d at 972.

55. *Continental Can*, 20 USPQ2d at 1750; *James L. Taylor Manufacturing Co.*, 24 USPQ2d at 1870-71.

56. *City of Elizabeth*, 97 U.S. at 136 (even though non-secret use, testing the durability of new and improved wooden pavement on a public road that was used for six years prior to the filing date of the patent application was experimental because the inventor put the pavement to the test of public wear to determine what improvements he might make. The court held that the invention was being perfected or it was being ascertained whether the invention would answer the intended purpose).

57. *See, Minnesota Mining and Mfg. Co. v. Research Medical*, 679 F. Supp. 1037, 1048-50 (D. Utah 1987); *Marrese v. Richard's Medical Equip, Inc.*, 504 F.2d 479, 482-83 (7th Cir. 1974).

58. *McGuire v. Acufex Microsurgical Inc.*, 34 USPQ2d 1749, 1755-1756 (D. Mass. 1994) (the single use of a surgical screw implanted under the control of the inventor-surgeon was found to be an experimental use. Even though the patient paid the regular surgical fee and did not sign a waiver or release indicating the experimental nature of the operation, the court found that the inventor did not commercially exploit the operation through advertising or initiate a sales campaign prior to the one year grace period. Further, the Court found that the inventor's assistants were bound to confidentiality through the patient-physician relationship. Therefore, despite the absence of a confidentiality agreement or the awareness by the patient of the experimental nature of the operation, the court held that the inventor did not place his invention outside his control).

59. *TP Laboratories*, 724 F.2d at 972 (three tests of an orthodontic device in patients were held to be experimental in nature. Again, the patients were charged the regular professional fees that patients were charged for other devices. Also, the patients did not sign a confidentiality agreement. The court found, however, that because there is a certain amount of variability in the treatment schedules of different dental patients, it was not unreasonable for the inventor to test the device in more than one patient. An additional factor in the inventor's favor was that during the testing period he had readily available the means to commercially exploit the device, yet he did not. The court held that the inventor was testing the device, not the market); *In re Hamilton*, 882 F.2d at 1578-79 (a "test order" of 309,000 forms after a successful bona fide manufacturing test run of 20,000 forms was held not to be experimental. In this case, the inventor did not retain sufficient control over the manufacturing run. During the run of 20,000 forms, the inventor observed the run and obtained samples. However, there was no evidence presented that during subsequent runs the inventor knew or cared what, if anything, the manufacturer was doing in terms of selling or testing the forms. Therefore, the court held that the subsequent runs were not experimental); *James L. Taylor Manufacturing Co.*, 24 USPQ2d at 1870-71 ("[A]lthough one use may be sufficient to establish public use, ... the more instances of production of an invention, the more likely it is that the invention is being commercially exploited.").

60. *Paragon Podiatry Laboratory, Inc.*, 984 F.2d at 1188, 25 USPQ2d at 1565; *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 830, 20 USPQ2d 1161, 1169 (Fed. Cir. 1991).

61. *Intel Corp.*, 946 F.2d at 830, 20 USPQ2d at 1169.

62. *U.S. Environmental Products*, 911 F.2d at 717, 15 USPQ2d at 1902.

63. *Id.*

64. *UMC Elecs. v. United States*, 2 USPQ2d 1465, 1469 (Fed. Cir. 1987).

65. *Wende v. Horine*, 225 F. 501 (7th Cir. 1915).

66. *U.S. Environmental Products*, 911 F.2d at 717, 15 USPQ2d at 1902; *see also, Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 23 USPQ2d 1481, 1483 (Fed. Cir. 1992), *hearing in banc denied*, 974 F.2d 1279, 23 USPQ2d 1801, 974 F.2d 1299, 24 USPQ2d 1138 (Fed. Cir. 1992) ("If a patent owner seeks to avoid the on-sale bar on the basis that a sale or offer was experimental,... a trial court must determine whether the patent owner sought the sale primarily for profit rather than as part of a testing program. To determine whether profit motivated a transaction, a court must examine the claimed features,... the offeror's objective intent, and the totality of the circumstances...."); *KeyStone Retaining Wall Systems, Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1451, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993) ("An on sale bar determination requires that the claimed invention asserted to be on sale was operable, the complete invention claimed was embodied in or obvious in view of the device offered for sale, and the sale or offer was primarily for profit rather than for experimental purposes.").