PATENT LAW BASICS FOR UNIVERSITY RESEARCHERS

I. INTRODUCTION

This booklet has been prepared to provide Baylor University researchers with an overview of U.S. and foreign patent law. It is written in plain, "non-legalese" language, intended to communicate the basics in an understandable, easy-to-read fashion. After an initial reading, the booklet should be retained for reference to answer questions that may arise later. For any detailed question, please contact the Office of the Vice Provost for Research at (254) 710-3763; if we are unable to help you directly, we can contact local patent attorneys for an authoritative response.

This booklet should be read in conjunction with a companion booklet entitled *Inventions* and *Technology Transfer:* Together, these booklets cover the full spectrum of inventions, patenting, and commercialization of inventions through technology transfer. Copies of the companion booklet are available on request from the Office of the Vice Provost for Research.

II. WHY IS PATENT LAW IMPORTANT TO A UNIVERSITY RESEARCHER?

University researchers thrive on free interchange of ideas and discoveries with scientific peers throughout the world. Why, in such an environment, would a university seek to patent the discoveries of its researchers, since a patent may be perceived as a restriction on the use of the discovery that is patented? There are four important reasons, among others:

- Traditionally, a "research exception" has been recognized as a limit on a patent's effectiveness. Generally, patents covering a technology do not limit academic research on that technology. Thus, patenting has been assumed not to prevent academic research by the inventor or by anyone else in the academic research community.
- Historical experience has shown that ideas which are not patented—which are instead "dedicated to the public"—tend not to be developed commercially. This is because few commercial businesses will invest the millions of dollars frequently required to develop a university-originated idea into a commercial product unless there is a sufficiently long period in which that investment can be recovered from a "protected"

market.

- Commercial development of practical ideas has become more essential to the economic well being of the nation and the state; the economic dominance once enjoyed by American companies continues to be eroded by nations more adept at commercializing new ideas—in many cases, new ideas which originated in the U.S. but were not protected through patenting.
- Keen competition for federal research grants has increased the importance of industrial research funding, which usually requires the resulting technology to be patent protected.

Since much state-of-the-art research is done at university laboratories, researchers within the university setting play an extremely crucial role in the technology commercialization process. However, if researchers act without regard to the patent implications of their activities, the value of this cutting-edge technology can be lost; and U.S. opportunities to commercialize such technology can be severely compromised.

III. DOES PATENTING CONFLICT WITH RESEARCHERS' ACADEMIC FREEDOMS?

<u>NO!</u>

In the first place, enforcement of a patent is always at the discretion of its owner, and the university, by policy, permits access to researchers' technologies for non-commercial research purposes.

Also, the "research exception" mentioned previously ensures that scientists around the world will still be able to conduct research, even on a patented technology.

What this booklet hopes to do is convince researchers that patenting and publication are not mutually exclusive; that it is easy to "have your cake and eat it, too," and that simply knowing something of patent fundamentals and university procedures will encourage investigators to secure patent protection with the understanding that unrestricted publishing is still permitted. Such protection can then contribute to U.S. economic competitiveness, to additional funding for research, and to supplemental income for individual inventors.

IV. THE NATURE OF AN INVENTION

A. WHAT IS AN INVENTION?

A broad definition of an invention is "anything that's new." A patentable invention, however, is "the discovery or creation of a new material, a new process, a new use for an existing material, or any *improvement* of any of these." Each of these categories can be the subject of a patent. Typical examples might be the following:

i. New Material

A new material can be a device or manufactured product, such as the light bulb or gasoline engine, or it can be a new composition of matter, such as a chemical compound (e.g., aspirin) or a genetically engineered substance (e.g., a cloned protein).

ii. New Process

A new process is a sequence or methodology with usable results. The process of making something is independent of the product which is made; thus, even though a product is known (e.g., aspirin), the inventor of a novel process for making aspirin may also be entitled to a patent.

iii. New Use

A new use is the application of a known material to a previously unknown use. For example, aspirin is known to relieve pain, but if someone were to establish that it also increases lifting thrust when added to rocket fuel, then a patent on that new use would be possible.

iv. Improvements

Improvements to either materials or processes are also patentable. For example, if the current process for making aspirin produces 1 million tablets/hour, an inventor could get a patent on improving that process (say by increasing the temperature and pressure at a particular step) so that 2 million tablets/hour could be produced. As another example, if irradiating an aspirin tablet with laser light increases its pain-killing ability, then laser-irradiated aspirin would be an improved form of aspirin, and this improved form could also be patentable.

Whenever you find yourself questioning whether an invention is patentable or not, it is best to treat the invention as potentially patentable and to contact the Office of the Vice Provost for Research for an authoritative determination.

B. WHEN DOES AN INVENTION OCCUR?

- i. Under patent law, two important steps must be realized before there is said to be an invention: the invention must be conceived, and the invention must be reduced to practice. In other words, an idea alone is insufficient to constitute a patentable invention; there must also be a demonstration that the concept actually works. This demonstration is called a reduction to practice.
- ii. Reduction to practice does not necessarily require a working model or system. It merely demands that the concept can be shown to work, which can be accomplished through detailed drawings, formulas, and the like. When it is clear from the patent application that the invention will work as described, this is called "constructive reduction to practice," and a patent can be issued without actual reduction to practice.

C. WHO ARE THE INVENTORS OF AN INVENTION?

- i. It is very important to realize that co-authors are not necessarily co-inventors. Authorship is frequently based on overall contribution to the work (and occasionally on political or courtesy considerations). Inventorship is strictly based on identifiable contributions to the patentable elements of an invention; thus, even someone who participated in the research project on an active basis might not be a co-inventor for patent purposes. Inventorship is also very important legally: naming the wrong inventors (either adding someone who was not truly an inventor or omitting someone who was) is grounds for invalidation of a patent.
- **ii.** Because of the importance of naming the correct inventors on a patent application, universities may refer these matters to a patent attorney. When submitting an Invention Disclosure to the Office of the Vice Provost for Research, all contributors should be indicated. When the patent is actually filed, however, the named inventors on the patent may be different from those originally indicated on the Invention Disclosure.

V. ELEMENTS OF PATENTABILITY

Not all inventions are patentable. Some of the most successful commercial innovations—from pet rocks and "Ninja Turtles" to McDonalds and Federal Express—are based on concepts that would not make it through the Patent Office. In order to be patentable, an invention must have the following elements:

- it must be new (the novelty requirement)
- it must be useful (the utility requirement) and
- it must be non-obvious (the non-obviousness requirement).

A. NOVELTY REQUIREMENT

To receive a patent, an invention must be new and cannot have been publicly known before. The novelty requirement means that the invention

- cannot have been made public, through publication, display, or other form of description; or
- cannot have been sold or offered for sale; or
- cannot have been used commercially: or
- cannot have been the subject of a patent issuing elsewhere more than one year prior to a U.S. patent application being filed.

The novelty requirement is tested for each patent application by an examiner in the U.S. Patent Office. The examiner conducts a search for similar inventive work in issued patents or in published literature. These patents, along with any other source of public knowledge, are termed "prior art." The challenge faced by the applicant is to distinguish the submitted invention from all these examples of prior art.

The important implication of the novelty requirement for university researchers is that their normal activities can have a profound effect on patentability of their inventions. Such routine activities as giving presentations, colloquia, and poster sessions; submitting grant proposals to potential research sponsors; and publishing books and articles can affect patentability. They can, in fact, completely preclude patentability if not done in accordance with patent laws. Coordination with the Office of the Vice Provost for Research is strongly recommended to avoid inadvertent loss of patent rights.

B. UTILITY REQUIREMENT

In addition to being new, an invention must also be useful; at least one specific use for the invention must be stated in the patent application. By public policy, some types of inventions are not patentable because society does not approve of the use to which they might be put -- instruments of torture or slavery, for example, are not patentable. However, it is relatively easy to claim an appropriate use for most inventions.

C. NON-OBVIOUSNESS REQUIREMENT

One of the most difficult concepts in patent law is that of nonobviousness. Nonobviousness means that a person "with ordinary skill in the art" would not be likely to develop the same invention, even knowing all there was to know in the prior art. Non-obviousness is different from novelty, even though both refer to prior art.

In most cases, if the invention is novel, it is relatively easy to distinguish it from the prior art. On the other hand, an objection that an invention is obvious requires only that the Patent Office show that the invention would have been apparent if someone skilled in the art had combined elements of prior art. This is easier for the Patent Office to show and thus a much tougher barrier to patentability.

To understand the obviousness objection, assume a person invents and patents a pair of scissors designed for a right-handed person. Later, someone else files a patent for the same scissors redesigned for left-handers. Even if no left-handed scissors patent had existed and even if no one had ever thought of making left-handed scissors before, the Patent Office could well conclude that "knowing it was possible to make right-handed scissors, it would be obvious to one skilled in the art (e.g., a scissors-maker) that it would also be possible to make left-handed scissors." Hence, no patent.

And this example was simple; reality is much more complex. The Patent Office is not limited to saying "if one knew about 'A,' one could arrive at 'X'"; the Patent Office can combine any number of separate elements of prior art and conclude "if one knew about 'A,' 'B,' 'C,' and 'D,' one could arrive at 'X'."

Furthermore, "obviousness" is a theoretical standard. It's not necessary that any particular human being ever really knew about 'A,' 'B,' 'C,' and 'D,' (maybe 'A' was a chapter in an out-of-print textbook, 'B' was an article published in a

German-language periodical, 'C' was a poster presentation by a graduate student at a small college, and 'D' was a patent which expired in 1812). All that is necessary is showing that someone could have combined all these elements of prior art and arrived at the same invention.

A key concept in the non-obviousness requirement is this theoretical person having "ordinary skill in the art." That does not mean someone with exceptional skill at the cutting edge of a technology (else it would be difficult to get anything patented). Nor is it a novice or graduate student who is just beginning to understand a technical discipline. The standard has been taken to mean a "journeyman researcher": someone with a fair level of experience, but not one recognized as a leader in the field.

This "journeyman researcher" standard is important, as it provides a way of overcoming a Patent Office rejection based on obviousness. If the Patent Office says that an invention would be obvious to a journeyman researcher, the applicant can then submit affidavits from recognized leaders in the field, attesting that the invention was not obvious to them. If it's not obvious to recognized leaders in the field, then it wouldn't be obvious to a journeyman researcher. There are other ways of overcoming obviousness objections, as well, and these are among the skills for which one employs a patent attorney.

D. MISCELLANEOUS REQUIREMENTS

i. Enablement

The purpose of a patent is to "teach" the invention to the public. In exchange for this teaching, the public grants the inventor the monopoly which a patent represents. In order to serve this function, the patent must be explicit and detailed enough to permit or "enable" one with ordinary skill in the art to reproduce the invention without undue experimentation. If a patent is not clear enough to permit replication of the invention, then it can be invalidated.

ii. Best Configuration

Related to enablement, patent law also requires that the best configuration and use of the technology be disclosed. This prevents a patent being granted to someone who might wish to "hide" an optimum design: telling the world about the overall nature of the invention, but revealing only inferior embodiments of the design so as to minimize competition. This is not to say that improvements, better configurations, and better uses might not be developed later; but the best configuration known at the time of applying for a patent must be disclosed.

iii. Non-Abandonment

A patent may also be denied to someone who has "abandoned" his or her invention for a period of time. What constitutes abandonment depends on the facts of a given situation, but it has generally been held to mean that a

"substantially unbroken effort" was not made to finalize the invention. A significant period of dormancy between beginning and finishing the invention, or between finishing the invention and filing for a patent, may operate to defeat patentability. However, active testing or design refinement taking place during a particular period is normally considered reasonable and not grounds for denying a patent.

E. INVENTIONS THAT ARE NOT PATENTABLE

Some inventions are not patentable even if they are new, useful, and non-obvious: theories, ideas, plans of action, laws of nature, mental processes, mathematical formulas (algorithms incorporated in software may be patentable methods of doing business), and naturally occurring substances (although the isolation, concentration, and application of naturally occurring substances may be patentable). Also, as mentioned before, immoral or injurious inventions are not patentable.

VI. PUBLIC DISCLOSURE OF INVENTIONS

A. WHAT IS A PUBLIC DISCLOSURE?

As discussed above, prior art is very important in patent law: it can either show that an invention is not new or render it obvious, either of which defeats patentability. And anything disclosed to the public constitutes prior art. A critical element in patentability thus becomes: What is a public disclosure?

Generally defined, public disclosure is any communication to someone not obliged to keep the communication confidential. In patent law, such public disclosure can defeat patentability if it contains sufficient detail about the invention to enable that person with "ordinary skill in the art" to duplicate it. Thus, there are two key elements to public disclosure in patent law:

- it must be public, and
- it must be enabling.

Whenever you find yourself questioning whether your actions may constitute a public disclosure, contact the Office of the Vice Provost for Research for an authoritative determination. If you have presented or published your results within the past year and fear that you may have disclosed an invention, contact the Office of the Vice Provost for Research.

B. WHAT DOES "PUBLIC" MEAN?

Volumes have been written on what constitutes a "public" disclosure. As with any complex area of law, there are a number of nuances and details; however, basic guidelines focus on the following as forms of public disclosure:

i. Written Publications

The publishing of a manuscript, book chapter, journal article, proceedings, thesis, pre-print, and the like is a form of publication. The publication has to actually be available to the public; thus, a thesis before it is in a library and accessible (indexed) or a journal article, which has been read by reviewers or editors before the journal, is published does not count as a "public disclosure" or "publication." On the other hand, it is the date of actual mailing of a journal which counts not the date which may be printed on the journal (for example, if Science magazine carries a date of October 1, but was actually mailed on September 28, the date of mailing controls).

ii. Oral Presentations

Oral presentations may also constitute public disclosures, but are frequently held not to be public disclosures for two reasons: it's harder to communicate the essence of an invention orally, and it's harder afterward to establish exactly what was communicated. Still, the basic rules apply. If someone in the audience takes careful notes and the notes reveal how to make an invention, then publication has occurred. The rules regarding oral disclosures are fairly "gray"; for that reason, researchers should regard oral presentations with the same caution as written publications.

iii. Prototypes and Samples

Providing prototypes and samples of an invention can be a public disclosure, depending on the circumstances. If they are provided in order to be used for their intended purpose (or if *they are so used despite the intent*), then publication has occurred. If they are provided only for testing or evaluation, then public disclosure has probably not occurred. It's a question of fact and may hinge on whether written restrictions cover the use of the prototype or sample and whether these restrictions are communicated at the time of transmittal.

iv. Sale or Public Use

It has also been held that offering a product for sale (whether or not anyone buys) or public use of an invention is a public disclosure. Sales for experimental purposes are an exception as long as some strict rules are adhered to. Anyone contemplating a sale (e.g., of reagents or biological materials), even to researchers at other universities, should contact the Office of the Vice Provost for Research beforehand.

v. Meetings and Other Communications

Talking about an invention to an audience as small as one person is sufficient to constitute public disclosure. A meeting with a single representative from a corporate sponsor, for example, can invalidate patent rights. Meetings with peers employed by the same organization are generally not publications, but the same meetings are publications if peers from other institutions are involved.

vi. Grant Proposal Submittals

Technical details are commonly included in proposals to potential research sponsors. In the past, all such details sent to agencies of the Federal Government were publications since they were accessible by the public under Freedom of Information laws. Recent changes have eliminated that problem. However, affirmative action by grant proposers is still necessary to protect patentable details revealed in a grant proposal. The first page of the proposal should carry the caption:

CONFIDENTIAL THIS PROPOSAL CONTAINS POSSIBLY PATENTABLE SUBJECT MATTER ON PAGES XX – YY

Only those pages containing technical details should be listed; then the word "CONFIDENTIAL" should be written on the top of each such page (but only on those with technical details).

C. WHAT ARE "ENABLING" PUBLIC DISCLOSURES?

Not all publications defeat patentability. In order to defeat patentability, a publication must also "enable" the duplication of the invention by one with ordinary skill in the art.

Therefore, it is possible to have any manner of written or oral communications without defeating patentability, just so long as the details conveyed are insufficient to enable duplication of the invention.

D. HOW CAN RESEARCHERS PROTECT PATENTABILITY AND STILL PUBLISH? OR HOW CAN I HAVE MY CAKE AND EAT IT T00?

With so many ways to lose patentability, researchers may infer that they cannot have both patents and publication. THIS IS NOT THE CASE. Patentability can be protected in a number of ways, while still allowing researchers to publish and collaborate. The following steps are recommended.

i. File a Patent Application Before Publication

Publication defeats patentability only if it occurs before filing for patent protection. Hence, one easy way of protecting patentability is to have a patent application on file before the publication, the poster session, the discussion at a scientific meeting, etc.

Invention Disclosure is the first step to filing a patent application. The proper Invention Disclosure form for Baylor University inventions are filed by the Office of the Vice Provost for Research. Thus, simply communicating with us prior to publication can make a significant difference. It is essential that researchers think of patentability before they publish. Given a modicum of

advance notice, the Office of the Vice Provost for Research can make sure that all patent right are protected and that publication can go forward without problem or delay.

ii. Use Confidential Disclosure Agreements

Publication means communication to persons with no obligation to hold the communication confidential. Thus, another way to protect patentability is to place such an obligation of confidentiality on the audience. This is unworkable with any large audience, but it is very easy with a small group — for example, a meeting with industry scientists interested in a researcher's work. Whether these scientists visit the university lab or the researcher travels to the company's labs. A simple one-page Confidential Disclosure Agreement can make the difference between retention and loss of patent rights.

Again, the Office of the Vice Provost for Research can provide these forms and assist in their use. Industrial people seldom object to the forms, since patentability ultimately helps them the most. So if a researcher is scheduling a technical meeting with people outside Baylor University, a quick call to the Office of the Vice Provost for Research is all that's needed to help protect any potential patent rights.

iii. Don't Give "Enabling" Information

Since a communication must be enabling to defeat patentability, a researcher can also protect patent rights merely by giving a "tantalizing glimpse" of the technology without revealing technical details. This is not always appropriate, since a presenter at a scientific meeting is expected to answer technical questions from the audience. However, smaller or less formal meetings can easily show the results or benefits of a technology without revealing the details of how they are achieved.

As a general rule, complete technical information should not be volunteered. Abstracts or oral presentations can be "sanitized" to reveal only the general objectives and results of the work, without revealing significant, patentable details.

iv. When in Doubt, Mark "CONFIDENTIAL"

As discussed in conjunction with research proposals to Federal agencies, it never hurts to mark something as CONFIDENTIAL. It's not a guarantee, but it can help if the recipient of the information could be expected to hold information confidential on the basis of it bearing that message.

E. IMPORTANCE OF FOREIGN PATENT PROTECTION

i. Why Patent Outside the U.S.?

The U.S. market used to account for such a large percentage of the world

economy—especially in the high-tech products most amenable to patenting—that foreign patents were obtained in only a minority of situations. But times have changed, and now countries outside the U.S. account for over two-thirds of the total world market—particularly in high technology products.

In order to recover its investment, any company wanting to commercialize university technology will want to sell that technology in as many national markets as it can. When only the U.S. market is being considered, lack of patent protection outside the U.S. may invite "pirates" to set up business in other countries and illegally import these goods into the U.S. The bottom line is that most companies prefer to obtain patent protection in the U.S. as well as in foreign countries. Some firms even go so far as to say that if foreign patent rights are not available, they're simply not interested in the technology. However, foreign patents can be complex, very expensive, and difficult to obtain. Careful analyses, including market and cost/benefit analysis, must be performed when contemplating foreign patent protection.

ii. Why Are Foreign Patents More Difficult to Obtain?

Virtually all foreign governments have patent laws which are different from those of the U.S. in one key area. Whereas the U.S. grants a grace period of one year between first public disclosure of an invention and filing of a patent application, almost no other country does so. Most nations follow what is called the requirement of Absolute Novelty. This means that if an invention is publicly disclosed without a patent application's already having been filed, all meaningful foreign disclosed patent rights are lost at the instant of public disclosure.

This is a very heavy penalty. If a researcher publishes an invention on March 1 and tells the Office of the Vice Provost for Research about it on March 2, the Office would have until February 28 of the next year to file for an U.S. patent. However, the ability to file foreign patents would be lost forever. Without foreign patents, the commercial appeal of the technology may be significantly less.

However, by treaty with many (but not all) industrial countries, there is a small loophole. Under these treaties, publication does not cause loss of foreign patent rights IF a U.S. application has been filed prior to publication. If a patent application is filed in the U.S. before publication, and if a patent application is then filed in the foreign country within one year of filing in the U.S., then foreign patents may still be granted. But there are no loopholes if a U.S. patent application isn't on file prior to public disclosure of the invention, or if more than one year passes between the U.S. filing and the foreign filing.

Therefore, it is critical that researchers contact the Office of the Vice Provost for Research prior to making a public disclosure of any invention so that proper measures may be taken to protect your invention.

iii. Recent Changes to Patent Law

Some key changes to parts of the patent law have resulted from the General Agreement on Trade and Tariff (GATT). On January 1, 1995, federal legislation was enacted to bring the U.S. into compliance with the standards of intellectual property protection in World Trade Organization member countries. The provisions impacting the patent term and provisional applications went into effect on June 8, 1995.

1. New Patent Terms

The term of a patent is no longer 17 years from the date that a patent was granted. Under the new law, the patent term is 20 years from the date on which the patent application was filed. The new patent terms apply to all patents issuing from applications filed on or after June 8, 1995. The patent term for continuation, continuation-in-part, and divisional applications consequently becomes 20 years from the date on which the "parent" application was filed. However, this 20-year patent term can be extended if the patent recipient encounters certain procedural or regulatory delays through the Patent and Trademark Office.

2. Provisional Patent Applications

This change to the patent law concerns the introduction of a new type of patent application entitled "provisional applications." The provisional application permits inventors to file for patent protection and allows the petitioner one year from the date of filing to perfect the patent rights thereby reducing, up front, the time and expense required to file a patent application. Some important features of provisional applications are the following:

- A provisional application should provide an enabling description of the invention and identify the inventors.
- ◆ A provisional application is considered as an U.S. national filing and establishes a filing date.
- No patent can issue on a provisional application, and no claims are required.
- ◆ A provisional application must be converted to a regular U.S. patent application within one year in order for the regular application to claim priority from the filing date of the provisional application.
- The 20-year patent term does not include the period of time between filing a provisional application and a regular application.

VII. THE NATURE OF RIGHTS GRANTED BY A PATENT

A. THE "NEGATIVE RIGHT" GRANTED BY PATENTS

It is commonly believed that a patent grants to the inventor the right to use the technology covered by the patent. This is not the case. A patent actually grants the inventor the right to exclude others from practicing the invention. Thus, the right granted by a patent is not a positive right: it is a "negative right." This may seem a

small distinction, but it is essential in understanding what patents are and how multiple patents can interact.

As discussed previously, a patent can be obtained on an improvement to an existing invention. This is the case even if an unexpired patent covers the invention which is being improved; in such a case, the earlier patent may "dominate" the subsequent patent. So if two patents can cover the same product, which patent owner has the right to practice the improved invention? The answer is neither; each has the right to prevent the other from practicing the invention, but neither has the right to practice the whole invention alone. They would need to work out a legal arrangement between them to practice the whole invention.

VIII. MECHANICS OE OBTAINING A PATENT

A. HOW IS A PATENT INITIATED?

Any natural person, whether a U.S. citizen or not, may file a paten application in the U.S. A person may file without the assistance of a patent attorney, but only about 1 % of patents granted are to people who did not use the services of an attorney. In the case of Baylor University employees, patents are filed by patent attorneys retained or approved by the Office of the Vice Provost for Research.

Even though organizations (such as corporations or universities) are heavily involved in the patent process, all patents are filed on behalf of people (usually employees); the organization's interest is normally as assignee of the true inventor(s). Patent applications are filed with the U.S. Patent and Trademark Office in Washington D.C., and must contain the following elements in order to qualify for a patent (in addition to meeting the other requirements of being a patentable invention):

i. Specification

The specification typically describes the background of the invention, the details of the invention, and a description of its use or uses. It may include examples or experimental results showing application of the technology.

ii. Drawings

When necessary for a complete understanding of an invention the patent will include drawings and a description of how the drawings are to be understood and interpreted. Drawings are especially typical in patents of devices or machines.

iii. Claims

A patent's claims are the "heart" of the protection offered by a patent. After describing the invention, its background, and its utility, the inventor claims what is new in the invention. The *claims are the enforceable part of a patent:*

an inventor may exclude others from practicing that which is embodied in the patent's claims, but only that which is embodied in the claims.

iv. Miscellaneous

A patent application must also include the oaths of the inventors declaring that they created what they believe to be a new, useful, and non-obvious invention, and that the application is complete and accurate (even if it was actually prepared by another). The application must also be accompanied by the appropriate fees.

B. WHAT HAPPENS TO AN APPLICATION?

i. Filing Procedure:

When an application is received by the U.S. Patent Office, it is assigned a serial number and a date (the date of application); they are formally communicated to the inventor through a filing receipt issued by the Patent Office. Next, the patent is assigned to a specific Patent Examiner within the Patent Office who deals exclusively with the technical area encompassed in the invention. This Examiner reads the application, reviews the proposed claims, and evaluates the invention vis-à-vis the standards of patentability discussed earlier.

ii. First Office Action

After the Examiner's review, which can take anywhere from 6 months to 2 years (depending on backlogs in that technical area), the Patent Office issues its First Office Action. This is the Examiner's conclusion about the patentability of the invention. In rare instances, this First Office Action will conclude that the invention is patentable; far more frequently, the First Office Action may be a rejection based on the novelty, utility, or non-obviousness criteria discussed earlier.

iii. First Applicant's Response

The applicant has the right to require the Patent Office to reconsider its conclusions based on a response to the objections to patentability which were cited by the Examiner in the First Office Action. The applicant tries to overcome the objections by distinguishing the subject invention from the prior art, demonstrating that it was not obvious, or modifying the application's claims to avoid the objections.

iv. Second Office Action / Final Rejection

The Patent Examiner responds to the first applicant's response by accepting the applicant's arguments, rejecting them, or providing some mixture of acceptance/rejection. When the decision is a full rejection, the Second Office Action is called a "Final Rejection" because the applicant does not have an

automatic right to additional reconsideration.

v. Second Applicant's Response

However, as a practical matter, the door is frequently still open for further argument with the Examiner or further refinement of the patent's claims to work around the Examiner's objections. A lot can depend at this stage on the seriousness of the Examiner's objections, the strength of the invention, and the skill of the attorney representing the applicant.

vi. Final Rejection or Notice of Allowance

Ultimately, the Examiner will accept or reject the arguments of the applicant. If accepted, the Patent Office will issue a Notice of Allowance; after payment of the required fees, the patent will issue in due course. If rejected, a notice of Final Rejection will be issued.

Final Rejection is not necessarily final! If no further action is taken by an applicant, then a Final Rejection will result in no patents being issued. However, the applicant still has two courses of action open which may yet result in issuance of a patent. These are filing a Continuation-in-Part application or appealing the rejection.

vii. Continuation-in-part Application

The applicant may file a Continuation-in-Part, or "CIP," application. This is essentially a new application, giving the applicant an opportunity to restructure the application, to redefine the invention, to bring in new data or claims, and generally to make a fresh attempt to describe an invention so as to overcome the Examiner's rejections. A CIP application can be filed so long as

- the original application has not lapsed because of a Final Rejection,
- the CIP is filed within the time allowed for response to the Examiner's Second Office Action,
- the CIP specifically refers back to the original application, and
- at least one inventor on the CIP was also an inventor on the original application.

viii. Appealing the Rejection

There are two avenues of appeal from a Final Rejection. The applicant may appeal to the U.S. Patent Office's own Board of Appeals. This Board reviews the Examiner's objections and the arguments of the applicant and may overrule the Examiner's decision. The applicant may also appeal to Federal court, either directly or after an adverse decision from the Patent Office's Board of Appeals.

IX. IMPORTANCE OF DOCUMENTATION

Careful record-keeping is an important element in any researcher's methodology. Such records provide comprehensive history of the experiments, results, and overall development of a new technology. But while detailed record-keeping is good methodology in general, it is essential to effective patenting.

In the U.S., patents are awarded to the person who first invents something. Thus, the dates on which an invention is conceived and reduced to practice can be of critical importance in determining the first inventor. Such matters seldom become important unless there is a dispute over the validity of a patent or over whom, among competing inventors, is the one entitled to the patent. But when challenges are made, a patent can be lost if record-keeping has not been methodical.

A number of principles have been established invention-related record keeping. Some of the most important of these are outlined below:

- Maintain an ongoing record of experimental activities and thoughts in a bound notebook, preferably with numbered pages.
- Make all entries in ink in colors that reproduce well on photocopy machines. Date and sign all entries.
- Make entries as work proceeds; if work is suspended for a period of time due to vacation, unavailability of supplies, or the like. Make an entry explaining the delay.
- Write coherently and legibly; label charts and graphs; enter conclusions as factual statements, quoting the information leading to the conclusions.
- Firmly glue additional materials relevant to the research (such as photos. graphs, charts, etc.) to pages in the notebook, making written reference to the inserted materials in your comments. Sign and date each of these pieces.
- If not already pre-printed in the notebook, rubber stamp or hand ink on the bottom of each page the legend "Witnessed and Understood" with a place for two signatures and two dates.
- Have the notes periodically witnessed by people with a fair understanding of the subject matter of your research but who are not directly involved in it. Witnesses' signatures should be obtained immediately if you feel something important or new has been described and should be obtained within a 2- to 4-week cycle in any event.
- If portions of a page are left blank after an entry, draw a diagonal line through the blank portions.
- NEVER erase any portion of an entry once made. If later information changes or qualifies a previous entry, either draw a single line through the changed information (leaving it clearly readable) and enter and date the new information, or make an entry referring to the superseding information and where in the notebook it can be found.
- For the same reason, never remove any materials glued into the notebook.

• A final point, not strictly relevant to notebook keeping, is that date of conception and reduction to practice can be authoritatively established by following Baylor University guidelines disclosing the Invention to the Office of the vice Provost for Research.

In general, these guidelines are designed to establish credibility in the researcher and the records the researcher maintains. Although tedious at times, methodical record-keeping is the easiest and most conclusive means of establishing ownership and priority for an invention.

X. OTHER FORMS OF PROTECTION

This booklet has dealt almost exclusively with how inventions are patented and what this means. Although central to the type of research normally carried out in university laboratories, it is important to recognize that a number of other forms of proprietary protection exist. Collectively, these protections are called intellectual property rights. The chief intellectual property rights, other than those already discussed, are briefly described below.

A. OTHER FORMS OF PATENT RIGHTS

In addition to the types of patents discussed in this booklet, which are called "utility" patents, there are two forms of patent which seldom involve Baylor University researchers.

- i. Design Patents, as the name implies, are patents granted for a particular "artistic" design. They cover only that expression of the design and do not grant any rights to basic or underlying technology; for example, one could get a design patent on a shape for a stapler, but the patent would only cover that particular shape and someone who made a stapler with a different shape would not infringe on the design patent.
- **ii.** Plant Variety Patents are a special type of patent granted to breeders of asexually reproduced plants for example, a specific variety of strawberry, seedless grape, or tulip.
- **iii.** Laws of nature cannot be patented, and this applies to mathematical formulas as well. However, in some circumstances a mathematical algorithm can be the basis for issuance of a patent. Increasingly, software that meets the criteria of novelty, utility and non-obviousness is being patented.

B. TRADE SECRETS

Patents are a limited-term monopoly granted to an inventor in exchange for the inventor's teaching the invention to the public. After the patent expires, the public has unlimited access to the invention. But what if the inventor prefers not to teach the public?

Trade secrets are inventions (or other valuable business information, such as customer lists, internal procedures, etc.) which the inventor does not wish to share with the public. The inventor receives no monopoly in the form of a patent and thus has no protection against someone who independently comes up with the same thing. And the inventor must be vigilant in preserving the secrecy of the trade secret. But trade secrets do have some advantages, not the least of which is that they have an unlimited lifespan, so long as the secret is maintained.

One of the most classic examples of a trade secret is the formula for Coca Cola. Had the inventor decided to patent the formula, that patent would have expired more than half a century ago. The Coca Cola Company has preferred to maintain the formula as a trade secret, accepting the risks because of the benefit offered by unlimited life.

To be protected as a trade secret, the information or invention must be used in a business, and positive measures must be employed to keep it secret. Since a university's task is exactly the opposite the dissemination of technical information universities are seldom involved with trade secrets.

C. COPYRIGHT

Another form of intellectual property is the copyright. This is used largely for the "creative arts" such as books and other written works, plays, video performances, and the like. Copyrights also cover computer software, whether or not it is also patentable.

A copyright does not require a formal application process to become effective; it is automatically effective the moment the work is published (sent or presented to another). However, it is best to at least provide a notice to the public that the copyright holder does not wish the material copied. This is best done by placing a copyright notice at the beginning of the work, as follows

Copyright, [date]
[name]
All Rights Reserved

The [date] is the year in which the work was created; the [name] is the name of the author(s) for works not owned by an employer and the name of the employer when the employer asserts rights in the copyrightable works.

D. TRADEMARK

A trademark can also be protected by a relatively and simple procedure. Unlike patents, no utility, novelty, or non-obviousness need be shown. It is only necessary that the desired trademark be easily distinguishable from other trademarks in the same class of products.

XI. CONCLUSION

Patents are important, but patent law can be complex. This booklet has provided only an overview of how patent law can affect university researchers as they publish, collaborate, and share their research findings with people around the world. It has also shown how patenting and publication remain compatible.

But the most important message has been that EARLY DISCLOSURE OF INVENTIONS TO THE OFFICE OF THE VICE PROVOST FOR RESEARCH IS ESSENTIAL in enabling unrestricted publication while still protecting valuable patent rights. When considering publication, get in touch. Before setting up a meeting with industrial people, get in touch. When in doubt, get in touch. The Office of the Vice Provost for Research can be reached at (254) 710-3763.