

## **Information and Guidelines Concerning the Patent and Copyright Process at East Tennessee State University**

### **I. Steps in the Process of Declaration of Your Invention or Creation.**

**A.** It is the policy of East Tennessee State University to: 1) encourage inventions, discoveries, and the production of copyrightable and trademarkable materials by members of the institution; 2) facilitate the utilization of such discoveries and materials to the benefit of the public, the University, and members of the University community through dissemination of results; and 3) provide for the equitable sharing of any proceeds derived from the commercial exploitation of inventions, discoveries, copyrightable and trademarkable materials in which, pursuant to the ETSU policy on Patents and Copyrights, the University is determined to have an interest.

**B.** If you have an invention that you might want to patent, or something you have created that you want to register with the U.S. Copyright Office, or for which you wish to seek trademark protection, and have used ETSU resources to produce this invention or creation, you may be legally obligated to declare the invention or creation to the University. Also, if ETSU determines that it does have a legal right to the invention, discovery, or creation, the University will provide financial and personnel support to obtain the necessary protection and will assist in finding commercial outlets for your invention, discovery or creation.

◆ **Remember, if the results of your research have led to a device, process or application that you might want to patent and you publish a paper, present information about your invention, or even discuss the possibility of commercializing it with an industry or business, you are in jeopardy of losing your rights to obtain a patent.**

**C.** Steps to Take to Declare Your Invention or Creation and Ask ETSU to Support Your Application for Protection

1. The first step in the process of declaring your invention or creation to the University is to read the ETSU Policy on Patents and Copyrights. This can be found in the print and Web-based versions of the *Faculty Handbook* and on the Website for the Office of the Vice Provost for Research.

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**2.** The second step in the process is to discuss your invention or creation with the Vice Provost for Research. The person holding that position is the Technology Transfer Officer for the University and can advise you in the steps to take to both comply with University and Tennessee Board of Regents policy **and** obtain University support in obtaining protection for your intellectual property (the thing you have discovered, invented, or created).

**3.** The third step in the process is to complete the Invention Disclosure or Copyright Disclosure Form and submit it to the Vice Provost who, following the University Patent and Copyright Policy, may arrange for its review. For inventions, completing the Declaration can be a significant effort and the information under item 4 below and in Section II is intended to assist you to produce a substantive and convincing declaration.

**4.** The fourth step is a review of your Disclosure by the University Patent and Copyright Committee. This Committee is charged with determining whether the material in the Disclosure meets the requirements for obtaining a patent, a trademark, or being registered with the Copyright Office. All reviews of your intellectual property by the committee are done in complete confidence.

If you have declared an invention that you wish to have patented, the process is more complex than the decision to register a copyright or seek trademark protection. This is because of the cost of obtaining a patent. If you are seeking to have the University support a patent application, the Committee will seek to answer two basic questions:

- a.** Is the invention patentable? That is, is it novel, useful, and obvious to someone knowledgeable in the field of endeavor?
- b.** If it is patentable, will it be commercially attractive so that someone will want to license it or it can be made profitable through some other mechanism?

In addressing these issues the Committee will ask the following questions:

- a.** How does this invention differ from present means of solving the same problem? Is it not only different, but better? In what way is it better? How much better?
- b.** What need in the market might this invention fill? Is it a minor need or a major one?
- c.** Is the market large or small?
- d.** How is this market need being filled now?
- e.** Is this market need recognized now, or will it have to be developed?

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- f. Is anyone investing in that market? Is it a dying field, an unprofitable one, or one that is otherwise out of fashion?
- g. How sure are you that this invention will work for the purpose intended? How difficult will that be to demonstrate?
- i. Is this invention so early in its R & D cycle that any patents obtained will expire before products can be marketed?
- j. Are the inventors recognized in their fields? Are they leaders?

5. The fifth step is a written recommendation by the Committee to the Vice Provost for Research. If that recommendation is to pursue the patent the Vice Provost will so indicate to the President of the University who will either approve pursuit of the patent or decline to pursue it. If the recommendation of the Committee to the Vice Provost is to decline the patent, the Associate Vice President will so recommend to the President. If the President concurs with the recommendation to decline the patent, the University will release all rights to the invention to the inventor.

6. The sixth step is development of the application for a patent, copyright registration, or trademark.

## II. Overview of a Patent Application\*

**A. Background.** Article I, Section 8 of the Constitution of the United States grants to Congress the right "To promote the Progress of Science and useful Arts, by securing for a limited Time to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." However, this grant was not made solely to protect the author or inventor. Rather, it is part of a bargain with authors and inventors. The bargain is clearly stated in the Constitution which goes on to state that the patent will "Teach the public how to make and use your invention, rather than keeping it a trade secret, and you will be allowed to exclude all others for the term of the patent."

This Article of the Constitution is the basis of all patent law in the United States, however, the exact form of current patent law comes from laws passed by Congress and contained in the United States Code (U.S.C.), court rulings, and opinions of the Board of Patent and Interference Appeals of the United States Patent and Trademark Office (USPTO). It is the USPTO that will decide whether or not your invention is indeed patentable.

The patent application will be prepared by an attorney specially trained in patent law and who has passed the bar in patent law. However, the more you can do to provide information about your invention, the stronger the patent application will be.

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- ◆ At a minimum a patent application must include 1) a written specification in English with at least one claim, 2) drawings if necessary to understand the invention and 3) an oath by the inventor(s) indicating that he/she/they did originate the invention, giving the date of invention. The proper fees and power of attorney to the lawyer working on the patent must accompany the application. An assignment of rights to ETSU must be executed before issuance of the patent.

**B. Patent Filing and Prosecution.** When completed, the patent application will be sent to the USPTO and, if it contains at least the minimum contents indicated in the bulleted paragraph above, it will be given a filing date and serial number. The filing date is very important because it indicates the primacy of your invention if other similar patents are filed at a later date.

- ◆ **No “new matter” can be added to the application once the filing date and serial number are assigned.**

Your application will be assigned to an Examining Group by the USPTO. The Examiner-In-Chief for the group will assign the case to an Examiner who has a relevant technical degree and training in patent law. In many ways the Examiner is the audience for which the application is written, although because the patent is to teach the public how to produce the invention, the public is also part of the audience; if the claims of the patent are infringed, judges and juries may also become a part of the audience.

Applications are reviewed in the order received and the timeline for the examination process will be from 1 to 30 months.

**C. Specification.** 35 USC Section 112 indicates “the specification shall contain a written description of the invention and of the manner and process of making and using it.” The description must be written in such full, clear, concise and exact terms as to enable any person “skilled in the art to which it pertains ..... to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”

1. Part 1 of the Specification begins with a **description of the background of the invention** and of the field or discipline to which it pertains. This is a good point at which to begin to explain how the existing public information (e.g. other patents, devices, journal articles, etc. - collectively “prior art”) does not defeat patentability of the claimed invention.

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- ◆ **You are the expert in your field and, although the patent attorney will write the patent for you and do an Art search to strengthen the argument that your invention is different from prior art, it is imperative that you provide as much information as possible.**

2. The next section of Part 1 of the Specification will contain a summary of the invention in broad terms and a general description of the drawings<sup>1</sup> (or other figures), followed by a detailed description of the invention and drawings or figures. For biotech inventions, specific examples may include the experiments to identify, purify, characterize, and use the material. For mechanical inventions, this would be a detailed, step-by-step description of the diagrams and drawings, with enough text to instruct the reader in appropriate materials and instructions for use.

- ◆ **This part of the Specification is a “teaching” section. It must be complete and so clearly written that anyone “skilled in the art to which it pertains” could make or use the invention “without undue experimentation.”**

3. Part 2 of the Specification will contain the claims. 35 U.S.C. Section 112 directs that:

- ◆ **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

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<sup>1</sup>Drawings must conform to the very strict rules of the patent office. Generally, drawings are filed informally, that is not conforming to rules. Hand-drawn diagrams, photocopies of gels, photos and the like, are sufficient for examination purposes. Formal drawings can be created after the patent is allowed and this is often good practice since the examiner who reviews the drawings may have his/her own opinion as to how they should be done.

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The claims are the heart of the patent. The claims define the scope of the invention. For this reason, the claims create the barrier to the use of your invention by others without your permission (generally granted by a license). An infringer of your rights to your patented invention will not infringe the patent - **the infringer will infringe individual claims.**

- ◆ **Claims have two qualities - breadth and strength.**

- a. Breadth means that you should claim every possible use for your invention that does not infringe on prior art.
- b. Strength means specificity, i.e. a complete description of the your invention including such things as the details concerning how it is made, what it is made of, what it does, etc.

- ◆ **Claim all patentable subject matter - e.g. apparatus and method of use, composition of matter, and method of making it.**

The patent attorney has experience in writing claims and will be responsible for developing them, but you must provide all of the details of your invention and as much prior art as possible in order to produce the best claims section.

### D. What Will the Examiner be Looking For?

1. The basic definition of what is patentable is given by the following statement in 35 U.S.C. Section 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The "requirements" are **Subject Matter, Utility, Novelty** and **Non-obviousness**. Your invention must meet each of these for the patent to be allowed. You should consider how to respond to challenges to each of these requirements and address each of these in your declaration to the Vice Provost for Research.

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### **2. Subject Matter**

**a. Unallowable Subject Matter.** Most subject matter can be patented, but there are some exceptions. If the subject matter is illegal or contrary to public policy, it cannot be patented. For example, a new use for heroin would likely be denied a patent on the basis that that drug is illegal in the United States. Currently humans and parts of humans cannot be patented as this is held as being against public policy.

\*Section II is adapted from "A Patent Filing in the United States" by Kathleen R. Terry published in AUTM Technology Transfer Practice Manual, Volume I, Part IV, Chapter 2, 1993.

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Products of nature cannot be patented, as such things are assumed to belong to everyone. Therefore, a microorganism existing only in nature could not be patented by its discoverer. However, if taken from its natural environment, cultured and induced to secrete useful products, it might be patentable.

There is also a category of inventions that can be seized and kept secret by the government for reasons of national security.

### b. What Subject Matter is patentable?

- ◆ **Process** - Examples: diagnostic method, transforming bacteria, new use of an existing legal substance, computer software<sup>2</sup>, synthesis of a drug.
- ◆ **Machine** - Examples: PET scanner, robotic device, circuit board.
- ◆ **Manufacture/composition of matter** - Examples: DNA probes, pure enzyme, pharmaceutical formulation of old drug suitable for infusion where the original formulation was not, computer housing made by computer assisted design.

**Note that in most of the examples above, the same inventive act can be described as a process, machine, or manufacture. It is absolutely vital that all aspects of the subject matter be included in the claims.** The Vice Provost for Research as Technology Transfer Officer and especially the patent attorney will assist you in defining your patentable subject matter as broadly as possible.

**3. Utility.** To be patentable, an invention must be useful. How to use the invention and the best mode for doing so must be included in the specification. The use does not have to be claimed. Utility is not a high bar to patentability. The invention needs only to have one use and that use need not be particularly valuable.

It is important to avoid unbelievable claims which can lead to an “incredible claims” rejection. Wording in this section can be very important. For example, it is probably not wise to claim a universal cure for cancer, but rather that treatment x reduces the size of tumors.

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<sup>2</sup>Although software can be patented, it is highly unlikely that ETSU will elect to pursue a patent on software. There are several reasons for this, e.g. difficulty in achieving an adequate prior art search and rapid developments in software development that could easily render the software commercially non-viable by the time the patent is issued. Software can be protected by Copyright and that is the recommended route for protection for most software developed at universities.



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- ◆ **Research utility alone is not sufficient utility. The use must be commercial, but it is not necessary from the view of the USPTO that the invention be commercially valuable.**

### 4. Novelty.

- ◆ **35 U.S.C. Section 102. Conditions for patentability; novelty and loss of right to patent.**

A person shall be entitled to a patent unless --- the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for a patent in the United States...

The critical date against which the one year time period is measured is the date of filing of the application.

- ◆ **The one year grace period applies only in the United States, Canada, and the Philippines. In all other countries, publication even one day before filing defeats the patent.**

For novelty to be compromised under '102 it must be both printed and published. A handwritten letter or information displayed in a poster session is not printed. However, if someone photocopies the note and distributes it, or if a picture or videotape of the poster is made and distributed, this can be considered publication.

- ◆ **Abstracts for talks are printed publications if distributed and may defeat patentability.**

Something offered for sale for more than a year is not considered novel for patent purposes in the United States. It is not necessary to complete a sale or transfer the product. An offer to sell is sufficient to start the one year clock running.

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### 5. Non-Obviousness.

- ◆ **U.S.C. '103 Conditions for Patentability: non-obvious subject matter.**

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

The question at issue is the importance of the contribution to the technology made by the inventor, or in terms used in European patent law, the existence of a significant “inventive step”. If the “invention” is only a trivial variant of an existing invention, or a combination of old inventions, or something anyone skilled in the art could put together, a patent may not be allowed. **Obviousness is often the first and foremost challenge made by the Examiner.** The following guidelines have been established by Supreme Court decision for an obviousness determination:

- ◆ Determine the scope and content of prior art.
- ◆ Ascertain the differences between the prior art and the claims at issue.
- ◆ Resolve the level of ordinary skill in the pertinent art at the time of invention.
- ◆ Against this background, determine whether one of ordinary skill in the pertinent art could make the invention without undue experimentation.

Non-obviousness is likely to be the most difficult part of the patent to defend. You will need to provide as much information as possible in this area, as overcoming this barrier to patentability may be the most severe test faced by you and the patent attorney.