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**NATIONAL
CANCER
INSTITUTE**

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What every
NCI scientist should
know about Employee
Invention Reports
(EIR) and patents



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INTRODUCTION

Your scientific research at the National Cancer Institute (NCI) may lead to exciting new discoveries. Part of the excitement of medical research is seeing a new discovery transformed into a commercially successful invention that will improve public health. One of your responsibilities as a Federal scientist is to notify NCI of your inventions so that NCI can seek patent protection for your discoveries. Patent protection is important in order to attract the commercial investment necessary for the development of your invention. This brochure is designed to provide you with general information on patents, walk you step-by-step through the patent application and filing process, and provide you with information on licensing and royalties.

SECTION I GENERAL INFORMATION

What is a patent and what does it provide?

Patents are property rights authorized by the U.S. Constitution. An issued patent gives the owner the right to exclude others from making, using, selling or importing the claimed invention.

What makes an invention patentable?

A patentable invention must be something new, it must be useful and it must be non-obvious, meaning that the invention should not be obvious to fellow scientists in the same field of study. Each requirement must be proven in very specific ways before a patent will be granted.

Why does the National Institutes of Health (NIH) patent inventions?



NIH helps lead the way toward important medical discoveries that improve people's health and save lives. One way this is accomplished is by the NIH seeking patent protection for some technologies so they can be transferred to the private sector through licensing for further development, commercialization and distribution to the public. Often, without patent protection, commercial entities are unwilling to develop a product. The government seeks commercial partners because it is not within the scope of the government's mission to turn a discovery into a useful commercial product for wide distribution. Generally a patent is most useful when significant resources from the private sector are needed for further research and development of the technology.

SECTION II

HOW TO GET A PATENT FOR YOUR INVENTION

STEP You have made a new discovery

1 You should immediately contact your laboratory or branch chief and inform him or her of your discovery. As the inventor, your next responsibility is to fill out an Employee Invention Report (EIR) form (See Steps 2 and 3 below) to report your discovery to the NCI Technology Transfer Center (TTC) before you publicly disclose the discovery. In general, a “public disclosure” is the release of information about the discovery in sufficient detail to allow a fellow scientist in the field to make, use, or apply the invention to their research. Public disclosures include but are not limited to: publications, seminars, presentations, posters, abstracts and Internet postings.

Please Note: Either failing to report your discovery prior to public disclosure, or submitting your EIR (see below) immediately before disclosure, may result in loss of important patent property rights and could prevent your invention from being developed.

STEP Completing an Employee Invention Report (EIR) Form

2 An Employee Invention Report (EIR) form is a standardized Public Health Service (PHS) form used to report your invention. The purpose of the EIR is to document the invention by asking you for specific information and to evaluate whether or not the government should seek patent protection for your invention. The EIR also serves as an aid in searching the technical and patent literature to determine if the invention is patentable. This form can be found on the TTC web page or by contacting TTC (see page 12 for links and contact information). TTC staff are available to assist you in completing the form.

STEP Submitting the Completed EIR

3 You should forward the completed EIR to TTC (see page 12 for links and contact information). In order to expedite the evaluation process, the entire form should be completed, including listing any and all participants in the discovery of the invention who you believe to be co-inventors. A person who merely carried out the inventor’s instructions, or acted only as a “pair of hands” does not qualify as a co-inventor. Omission of a legitimate inventor or inclusion of a non-inventor could invalidate a patent. The patent attorney who prepares the patent application will make the final inventorship determination. Copies of manuscripts, data sets, lab meeting reports or any other printed matter describing your research, should be attached to the EIR to assist TTC staff in evaluating your invention.

Please Note: Please submit the EIR at least 12 weeks prior to any planned public disclosure.

STEP The Beginning of the Review Process: Evaluation of the EIR by the NCI Technology Review Group (TRG)

4 Staff at TTC will assist and guide you throughout the patenting process. TTC will schedule your EIR for review by the NCI Technology Review Group (TRG). The TRG is made up of fellow NCI scientists who will evaluate your EIR in light of the PHS Patent Policy. It is the job of the TRG to review the EIR and make a recommendation to your Division Director as to whether or not a patent application should be filed. Your EIR will be forwarded to TRG members who have the appropriate scientific expertise to evaluate your discovery. At least two TRG reviewers will thoroughly review your EIR. The TRG reviewers will present their assessment and recommendations about your invention at the monthly TRG meeting. You will be informed by TTC of the TRG’s recommendation and you will be asked to comment on it before it goes to your Division Director.

STEP The End of the Review Process: The Final Decision

5 It is your Division Director's responsibility to decide if a patent application for your discovery will be filed. The decision is based upon the recommendation from the TRG. Should your Division Director agree to file a patent application, the TTC notifies the National Institutes of Health (NIH) Office of Technology Transfer (OTT). NIH OTT sends the EIR to a contract law firm for patent application preparation and filing with the U.S. Patent and Trademark Office (U.S. PTO). You will work closely with the patent attorney at the contract law firm on the preparation of the patent application.

How long is the review process and who is my contact?

The EIR review process, from submission of the EIR form to the filing of the patent application, takes approximately 3 months. You can help expedite the process by submitting your completed EIR to the TTC as soon as possible. The TTC staff member assigned to your laboratory is your contact person and s/he will assist you throughout



the review process.

SECTION III

REASONS WHY YOUR INVENTION MIGHT NOT GET PATENTED

■ NIH generally does not seek patent protection for commercially valuable research tools (e.g. knock-out mice, receptors, cell lines and antibodies) for which future therapeutic, diagnostic or preventive uses are not anticipated. However, the NIH has the authority to license nonpatented biological materials and substances through biological materials licenses, and inventors can still receive royalties. It is still important to complete the EIR form and let the review process take place. Staff at TTC will inform you if a decision is made not to patent your invention.

■ Past public disclosures by the inventor or other scientists in the field may limit or destroy the patentability of an invention. This situation can be avoided by submitting your EIR to the TTC well in advance of any contemplated public disclosures.

■ NIH policy requires certain inventions to remain in the public domain (e.g. methods of performing surgical procedures) in order to ensure that they are freely and widely available.

■ The invention is in such an early stage that a patent application would not result in the issuance of a patent by the U.S. PTO. You will be encouraged to contact the TTC when additional information is available for re-evaluation of the technology. TTC staff will assist you in such situations and will advise you as to when an EIR should be resubmitted.

■ Your Division Director decides against filing a patent application or subsequently decides to abandon your patent application. You may request a waiver to obtain rights to the invention. If you are interested in requesting a waiver, or learning more about the implications of a waiver, you should contact the staff at TTC.

SECTION IV

FILING A PATENT WITH THE U.S. PATENT AND TRADEMARK OFFICE (PTO)

STEP

1 Filing a Provisional Application with the U.S. PTO

If your Division Director agrees to file a patent application, a NIH contract law firm will work closely with you to prepare a patent application. Generally, a patent application will be filed at the U.S. PTO as a provisional application. The provisional application is not examined by the U.S. PTO but filing the application is important because it establishes a priority date for your invention against any similar applications. You should work closely with the contract attorney to make sure you fully disclose and describe all aspects of your invention and its uses in order to establish a strong foundation for patent protection.

STEP

2 One Year Later...Applying for Foreign Patent Rights under the Patent Cooperation Treaty (PCT)

One year after a provisional application is filed with the PTO, decisions must be made on whether or not to continue the application for U.S. patent protection and whether or not to preserve foreign patent rights for the invention under the Patent Cooperation Treaty (PCT). Staff from the NIH OTT will contact you and ask about any further developments to your invention during the year since the provisional application filing. Your comments and a recommendation from NIH OTT will be used by the TRG to make a recommendation to your Division Director regarding the above decisions. Your Division Director will make the final decisions.



STEP

3 Another 18 months go by.....The National Phase & the U.S. PTO Examination

Another decision must be made 18 months after the PCT filing as to whether or not to enter into the National Phase of filing. This involves continuing the application process in the United States and filing patent applications in Europe and individual foreign countries such as Canada, Australia and/or Japan. Filing patent applications in foreign countries is largely contingent on the international value of your invention and whether or not licensing the invention in foreign countries will assist in the overall development and commercialization of the invention. As with the PCT filing decision, you will be contacted again by NIH OTT for updated information about the development of your invention. The NIH OTT will also make an updated recommendation regarding your invention. The TRG will use both NIH OTT's recommendation and the information you provide to make a recommendation to your Division Director. As always, the Division Director makes the final decision on whether or not to proceed with the National Phase.

Following the National Phase filing in the United States, the actual examination of your patent application in the U.S. PTO takes place. During the examination in the United States, (also referred to as a "prosecution") the U.S. PTO will issue "Office Actions". The patent law firm and the NIH OTT are responsible for responding to these Office Actions, and will work closely with you to make important decisions concerning the prosecution of your patent application. During patent prosecution you may be contacted by lawyers from the patent law firm for more information concerning your invention. Similar examinations will take place in the patent offices of the selected foreign countries following National Phase filing. The patent law firm, along with the NIH OTT, will work with the foreign associates overseeing these examinations.

How long does the patent filing process take and who is my contact?

The patent filing process, from filing the provisional application to the National Phase entry, generally takes 2 ½ years. Although this may seem long, the time span benefits the NCI. Prosecuting patent applications in the U.S. and foreign countries is expensive. The additional developments to your technology during this time period helps the TRG and your Division Director make the best decision on whether or not to commit funds to prosecute your patent application and ultimately maintain your issued patent. During this time, NIH OTT may find a licensee for your invention who may assume the payments for patent prosecution and maintenance.

Who owns the patent rights now that a patent application has been filed?

The government owns the rights to any patent that stems from a discovery made by any government employee working at a government facility, or from a discovery that involves use of a government facility or use of government equipment. The inventor, however, gets recognition for the invention and upon assignment of his rights to the government receives a share of any royalties from licensing the patent (see Section V). If the government declines to file for a patent, the inventor can request a waiver of rights to the invention (see Section III).



SECTION V

LICENSING PATENTS AND RECEIVING ROYALTIES

Why does the NIH license its patents?

The NIH licenses its patents and patent applications to private sector organizations in order to give the licensees the rights and incentives to research and develop technologies into commercial products. The NIH attempts to license technologies to as many commercial organizations as possible in order to ensure that each technology is being fully developed for the benefit of public health. However, there are certain circumstances in which granting an exclusive license to just one organization is beneficial for the development and commercialization of a technology. For example, due to the high risks and costs associated with technologies involving new drugs and vaccines, the NIH will generally grant exclusive licenses to organizations as incentives to research and develop these types of technologies.

Licensing CRADA inventions

A Cooperative Research and Development Agreement (CRADA) is a collaborative agreement between a NIH laboratory and a non-Federal organization in which both parties contribute intellectual resources toward the goal of jointly developing a new technology. As a result of the partnership, the CRADA partner has the first option to choose an exclusive or nonexclusive license for any technologies developed under the CRADA.

Please Note: If your invention is a result of a CRADA partnership, please include that information in your EIR form since special procedures apply to licensing CRADA inventions.

How are royalties divided if my patent is licensed?

You will receive royalties on your patented invention or patent application when it is licensed to an outside organization.

The distribution of NIH license royalties is as follows:

Inventors share in:

- 100% of the first \$2,000 of royalties received under the license; and
- 15% of receipts between \$2,000 and \$50,000; and
- 25% of receipts over \$50,000.
- No NIH inventor may receive more than \$150,000 total in royalty income in a given year. Amounts in excess of this cap are distributed to co-inventors (unless they also cap, in which case the royalties flow back to the Institute or Center).
- Even if you leave government employment, you are still entitled to your royalty share (which will still be capped at \$150,000 per year). Please make sure that the staff at the NIH Office of Financial Management have your current address and banking information for royalty payments (see page 12 for links and contact information.)



Further Information:

Technology Transfer Center
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Facsimile: (301) 402-2117

Frederick Telephone: (301) 846-5465
Facsimile: (301) 846-6820

TTC Home Page:
<http://ttc.nci.nih.gov>

EIR Form:
<http://ttc.nci.nih.gov/forms>

Royalty FAQ:
http://www.ott.nih.gov/faqs/royalty_distrib_inventors_faq.aspx

