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IN SCIENCE

■ FROM THE DIRECTOR'S OFFICE

Technology Transfer and the CCR Investigator

Technology transfer became a federal mission with passage of the Stevenson-Wydler Technology Innovation Act in 1980, which required federal laboratories to devote 0.5% of their budgets to technology transfer and those with budgets of more than \$20 million to establish an office of research technology applications. In 1986, this law was expanded by the Federal Technology Transfer Act, which empowered industry collaboration with federal employees through the use of Cooperative Research and Development Agreements (CRADAs). These laws were further extended in 1995 with the National Technology Transfer and Advancement Act and in 2000 with the Technology Transfer Commercialization Act, which established incentives for investigators, expedited CRADA negotiations, and allowed licensing of preexisting inventions.

The NCI has been actively working with many corporate partners who have successfully moved our research into products for patient use or use in health care facilities. Over the years, thousands of licensing agreements have been executed on NCI technologies, which transfer NCI inventions to the private sector for further research and development and potential commercialization that can lead to public health benefits. Licenses are granted in exchange for royalty payments and licensing fees. Biomedical research at the NIH is licensed through the Office of Technology Transfer (OTT). A report by the Department of Commerce states that the NIH's royalties accounted for nearly 70% of the total invention royalties received by the federal government, and 11 of the top 20 commercially successful inventions at NIH were based on NCI technologies. These include the HIV drugs Videx, Hivid, and Prezista, the cancer treatment drugs Taxol and Fludara, and the immunosuppressive drug Zenapax.

Understanding Patents

A patent gives the inventor an exclusive right to develop an invention for a number of years, usually 20, in exchange for publicly disclosing the invention. To qualify for a patent, an invention must demonstrate novelty, usefulness, and non-obviousness. Furthermore, an invention must be either a process, a machine, a manufacture, a composition of matter, or any new and useful improvement thereof. If an invention were publicly disclosed prior to filing a patent application, it would no longer be considered novel, and the public disclosure could prevent the invention from being patented. All foreign patent rights are also lost on the day the information is disclosed. Many times a company will choose not to license a product without foreign patent protection. Additionally, all rights within the United States will be lost if a patent application is not filed within 12 months of the disclosure. Common ways that researchers inadvertently forfeit their patent rights include presentations, abstracts, journal articles, methods detailed in grant applications, theses, e-mails,

Sometimes commercialization and technology transfer are best accomplished without patent protection. At times, technologies or “know-how” is most appropriately transferred to the private sector through publication. For some technologies, patenting and licensing are costly, unnecessary, and could hinder their dissemination and application. Surgical procedures are a good example of the sort of technology that doesn’t need patent protection. The vast majority of CCR’s new inventions may be classified as research tools, for example, mouse models, antibodies, and cell lines, best distributed broadly under biological materials licenses without patent protection. This strategy encourages the distribution of these technologies at nominal costs to the research community. However other technologies that have significant time and cost associated with their development, such as those with preventive, diagnostic, or therapeutic uses, may require patent protection for commercial product development.

and even certain conversations.

The CCR Office of Policy and Intellectual Property

The CCR Office of Policy and Intellectual Property provides advice and guidance to the Center’s Directors, senior staff, and others members of the CCR scientific and administrative community on issues relating to collaborative agreements, intellectual property, ethics, policy, and regulatory, judicial, and legislative issues. The goal of the office is to facilitate basic, translational, and clinical collaborations with the pharmaceutical industry and develop collaborative relationships with other agencies and organizations both nationally and internationally. The Office is the Center’s principal contact with the NCI Technology Transfer Center (TTC), NIH Office of Technology Transfer (OTT), NIH Office of General Counsel (OGC), and NCI Ethics Office. The Office works closely and partners with TTC and OTT on issues relating to the CCR intellectual property portfolio, reviews and approves all CCR patent filing decisions, promotes technology, supports key technology development initiatives, and facilitates industrial basic, clinical, and translational research collaborations. The Office is involved with outreach for the CCR by strategizing and promoting collaborations with industry, academia, and other government institutes and agencies, facilitating the technology transfer process and ensuring that regulatory and training requirements are met. The Office also plays a role in conflict investigation and resolution to ensure that CCR objectives are best met.

Investigators are encouraged to contact the Office if they need assistance or advice on how best to understand and navigate the

If you have an interesting invention, talk to your NCI technology transfer specialist early to see if a patent should be pursued. To avoid loss of patent rights, also notify the specialist before any talk or publication that would disclose the invention and obtain signed confidential disclosure agreements where appropriate. Note that proper record keeping is essential for the ability to obtain a patent. Preferably, experiments should be recorded in bound notebooks with consecutively numbered pages. The entries should be signed and dated by the researcher each day and periodically witnessed by at least one person who is not an inventor with a notation such as “disclosed to and understood by me this _____ day of _____, 2007.” With this type of record keeping, a patent application can seldom be challenged on the date an invention was developed.

The successful patenting and licensing of inventions not only contribute to the NCI mission by encouraging further development of promising new therapies, but also show the productivity and dedication of the CCR investigator to bring new therapies from the bench to the bedside. Patenting an invention begins with filing an Employee Invention Report

seemingly complex technology
development process at the NIH.

(EIR), which is reviewed by the NCI
Technology Transfer Center (TTC) technology
transfer specialist, the NIH OTT, and the NCI
Technology Review Group (TRG) for

patentability, marketing potential, and licensing interest. The combined recommendations are forwarded to the Center's Director for final filing decisions. After obtaining a filing date from the designated patent office, public disclosure of the invention can take place without jeopardizing its patentability.

The NCI receives royalties generated by licensing agreements on these government-owned patents and by biological material licenses. These funds can then be used to further stimulate promising research initiatives. Through licensure of inventions, individual investigators can directly receive a percentage of the royalties and may also be eligible for Federal Technology Transfer Awards. In 2006, the CCR filed 121 new EIRs, received 37 new patents, and executed 81 new licenses, representing 33%, 40%, and 32%, respectively, of the totals for the NIH.

For more information on patents or procedures please visit the following Web sites:

The NCI Technology Transfer Branch: <http://ttc.nci.nih.gov>

NIH Office of Technology Transfer: <http://www.ott.nih.gov>

The US Patent and Trademark office: <http://www.USPTO.gov>.

Eric Hale, JD, MBA, MS

Michael Gandolph, JD

Laura Hooper, PhD
