Technology Transfer at the National Cancer Institute:
Priming the Innovation Pump

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My presentation attempts to point out some of the significant features defining technology transfer at the National Cancer Institute (NCI), which is one of the 27 Institutes and Centers comprising the National Institutes of Health (NIH).

The overarching goal of the NCI is to transmit the fruits of the public's investment in cancer-related healthcare back to the public. This goal is perhaps best defined in the words of NCI's Director, Dr. Andrew C. von Eschenbach, who states the following:

> **"Critical to [NCI's] ultimate success will be the collaborations and partnerships necessary to further scientific discovery, to translate that discovery into the development of better prevention, detection and treatment methods, and to deliver that progress to all who are in need."**

Technology transfer at NCI is governed by this vision, but depends as well on working definitions which help define how this vision is being implemented. Two of the most important of these definitions are:

1. Implementation of the terms of the Bayh-Dole and Stevenson-Wydler Acts of 1980 and the Federal Technology Transfer Act of 1986 to *further the public good by appropriate transfer and commercialization of technologies created with government resources*.

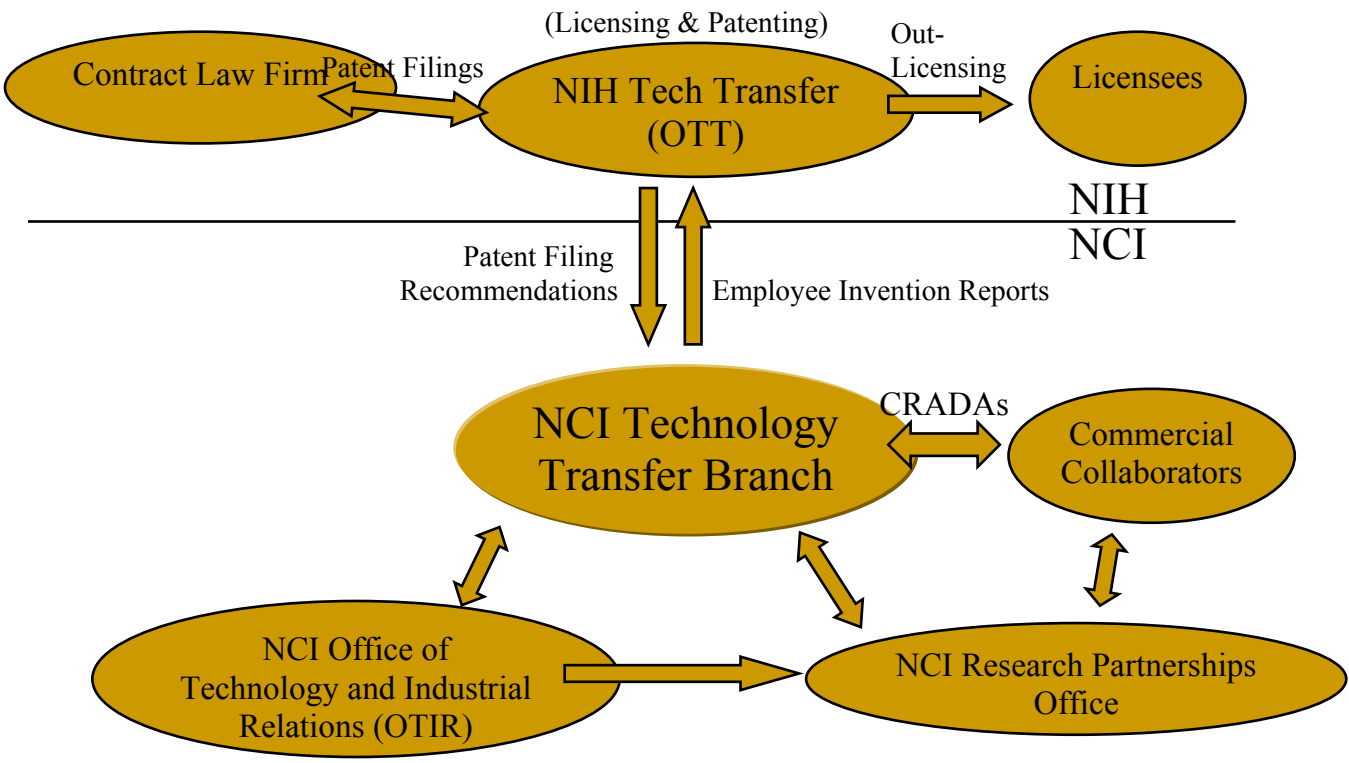
2. Transfer knowledge in the form of intellectual property to public companies, universities and nonprofit institutions in ways which ultimately benefit the public.

NCI is the largest of the NIH Institutes, and the number of staff dedicated to technology transfer reflects this. NCI's Technology Transfer Branch (TTB) is comprised of nearly 50 scientists, attorneys, former PTO examiners, business administrators, marketing specialists, and support staff. TTB manages ~250 active CRADAs and a wide range of other "transactional" agreements with industrial and academic partners, including Material Transfer Agreements (MTAs) and Confidential Disclosure Agreements (CDAs). NCI also houses a "Competitive Service Center" for nine other NIH institutes, essentially acting as an internal contractor within NIH to serve the technology transfer needs of these Institutes. TTB also ensures that NCI's technology development activities agree with Federal statutes and regulations, and NIH policy.

Since the work of the TTB staff is paid for by NCI, it is TTB that reviews new inventions submitted by NCI scientists, i.e., "Employee Invention Reports" (EIRs)., generate patentability reports and make recommendations to NIH's Office of Technology Transfer (OTT) concerning filing of domestic and foreign patent applications. Much of

the intra- and inter-office communication and responsibilities are summarized in the following graphic:

Technology Transfer: Communicating Within NIH



Perhaps the most important distinction to make regarding this diagram is the separate duties carried out at the NIH level by the NIH Office of Technology Transfer (OTT), and the NCI level by TTB. OTT carries out the following four basic functions:

1) Oversees NIH technology transfer policy;
2) Administers CRADAs for all NIH Institutes,
3) Carries out licensing of all NIH technologies, and
4) Administers all NIH patent prosecution using contract law firms

In carrying out its policy mission, OTT is guided by three basic tenets: to minimize publication barriers and delays, to avoid patenting of 'research tools' such as cell lines, reagents, and animal models and to facilitate transfer of government technologies to the public. It is important to note as well that funding flows from NCI (and other Institutes) to OTT. Because the Institutes

fund their own intellectual property (IP) filings, NCI must decide how and whether to file patent applications for new technologies developed by its scientists. NCI commits substantial resources in order to insure that appropriate inventions are filed. In order to do so TTB calls on the resources of other NCI offices as well as the NIH OTT. We are constantly reassessing these procedures in order to maximize the effectiveness of these decisions.

NIH CRADAs are negotiated and crafted at the Institute level, and therefore TTB plays the crucial role of finding commercial partners to help in developing NCI inventions. TTB staff also explain to both the commercial partner and the NCI scientists the options available in developing a CRADA relationship, and follow the evolution of the collaboration once the CRADA has been fully implemented.

As alluded to above, TTB also implements "transactional agreements", most of which comprise Material Transfer Agreements (MTAs), Confidential Disclosure Agreements (CDAs) and Clinical Trial Agreements (CTAs). These agreements allow for the efficient flow of ideas and materials between Government scientists and outside parties, and insure that these will be transferred within an appropriate legal and ethical framework.

Cooperative Research and Development Agreements at NCI

The **C**ooperative **R**esearch **A**nd **D**evelopment **A**greement, or **CRADA**, is central to the role of technology transfer at NIH. Authorized by the Federal Technology Transfer Act of 1986 ("FTTA") and National Technology Transfer & Advancement Act of 1995 ("Morella Bill"), CRADAs require *intellectual collaboration* between the Government scientist and commercial collaborator. Through the CRADA mechanism collaborators gain *access* to technology, data and expertise, as well as to an *option to future IP rights.*
CRADAs also provide a means by which funding can flow from the commercial partner to the government laboratory in order to further the development of the technology.

The process by which CRADAs are implemented at NCI consists of four steps:

1. Finding or selecting a partner;
2. Drafting a research plan ("**RP**") to define the nature and scope of the proposed research;
3. Negotiation of the legal and scientific aspects of the Agreement; and

4. Obtaining approvals and carrying out the RP.

CRADAs have proven successful in attracting commercial collaborators for some very good reasons. Among these are the availability of options to the IP rights to new inventions arising under the Agreement and the ability to hold proprietary information confidential. From the public policy perspective CRADAs are also a "bargain" in that the Government retains a right to use CRADA technologies for its own purposes, and maintains the ability to publish research results. Outside of the IP provisions however, the CRADA provides a means of collaboration by which both parties have a large freedom to operate by means which serve the interests of both commercial development and the public good. The success of the CRADA program can be gauged by the fact that over 40 CRADAs were implemented by NCI in FY '02, and that in FY03 NCI scientists collaborated with industry and other partners under 185 active CRADAs.