NIH OFFICE OF TECHNOLOGY TRANSFER
ANNUAL REPORT
FY-2004

The Office of Technology Transfer (OTT) is the central National Institutes of Health (NIH) office responsible for the management of inventions from NIH and Food and Drug Administration (FDA) intramural research activities and for the development of technology transfer policy for NIH intramural and extramural research activities. Implementation responsibilities are shared among the OTT, the Office of Extramural Research (OER/OPERA), and the Institutes and Centers (ICs). At the end of FY04, OTT was staffed by 58 Government full-time employees (FTEs), 11 contractors, six Intramural Research Training Award (IRTA) Fellows, two American Association for the Advancement of Science (AAAS) Fellows, and three interns.

This year, OTT underwent a complete reorganization resulting in the creation of three divisions: Division of Technology Development and Transfer (DTDT), Division of Policy (DOP), and Division of Administrative Management (DAM). The DTDT was formally divided into four branches entitled Cancer, Infectious Diseases, General Medicine, and Monitoring and Enforcement to reflect their functional portfolios. The groups handling royalties and patent prosecution payment and procurement services were moved to the DAM, while marketing was moved to the Office of the Director. The Cooperative Research and Development Agreement (CRADA) and invention extramural waiver responsibilities were moved to the DOP. In addition, a new position was created, Senior Advisor for International Technology Transfer.

Office of the Director

The Office of the Director provides advice to the NIH Director, other Department of Health and Human Services (HHS) agency heads, and Public Health Service (PHS) component ICs on general matters of technology transfer, including CRADAs, patenting, license agreements, Material Transfer Agreements (MTAs), and associated policies involving intramural and extramural activities. The Office is involved with numerous global, HHS, and NIH-wide issues involving intellectual property and technology transfer. These activities include agreements for the receipt of human embryonic stem cells, issues raised by members of Congress and public interest groups, CRADAs, and inter- and intra-governmental technology transfer issues. Additionally, the Office provides outreach to companies and non-profit institutions world-wide to facilitate public-private partnerships and provide information on NIH technology transfer activities and advice to Government and non-profit organizations on technology transfer infrastructure development.

In January 2004, HHS received two requests for the agency to consider using its Bayh-Dole march-in authority for two products on the market that utilized technologies developed under NIH grants: Abbott's drug Norvir and Pfizer's drug Xalatan. Both requests were related to the higher price of the drugs in the U.S. as compared to Canada and European countries. On May 25, 2004, the Office held an NIH Public Meeting in

response to advocacy requests relating to Norvir. The Office prepared the resulting NIH decisions that were released on July 29, 2004 and September 23, 2004 for Norvir and Xalatan, respectively.

In FY04, representatives from the Director's Office attended or presented at national and international meetings, including: World Health Organization (WHO); Council on Governmental Relations (COGR); United Nations Industrial Development Organization (UNIDO); Association of American Medical Colleges (AAMC); Organization for Economic Co-operation and Development (OECD); Biotechnology Industry Organization (BIO); Association of University Technology Managers (AUTM); Pan American Health Organization (PAHO); American Society for Microbiology (ASM); Center for Strategic and International Studies (CSIS); Federal Laboratory Consortium for Technology Transfer (FLC); American Association of Pharmaceutical Scientists (AAPS); Licensing Executives Society (LES); Global Forum of Health Research; American College of Neuropsychopharmacology (ACNP); and, Developing Countries Vaccine Manufacturers Network (DCVMN). The Office also hosted meetings at OTT, including: an international meeting of institutions holding SARS genomic patents pending; Enterprise Ireland; the Department of Homeland Security Science and Technology (DHS S&T); BIO; a meeting on technology transfer in Eastern Europe; the Serum Institute of India; and, the Department of Energy (DOE).

The Office received a multitude of international visitors and represented HHS and NIH at international conferences around the globe. International visitors to OTT included representatives from Australia, Austria, Brazil, China, France, Ireland, Italy, Japan, Korea, the Netherlands, Russia, Scotland, and Thailand.

The Office also represented NIH at foreign embassy receptions and sessions on technology transfer, including those held at the Embassies of Canada, Finland, Germany, Hungary, Ireland, the Netherlands, and the United Kingdom.

The Office works with institutions in developing countries by helping to identify their public health needs and facilitate the transfer of NIH technologies. This fiscal year, the international effort led to the identification of public health needs and opportunities for the transfer of NIH technologies in the areas of HIV/AIDS, tuberculosis, malaria, dengue, rotavirus, meningitis, cancer, and diabetes. Through this effort, NIH technologies have been made available in Brazil, China, India, and Mexico.

The marketing group coordinates and conducts marketing activities, including evaluating technologies for marketability, identifying potential markets for technologies, and conducting activities designed to disseminate current technology transfer information. The marketing group promotes NIH technology transfer and markets NIH technologies through the OTT web site, exhibits and presentations at technology shows, an e-mail newsletter, dissemination of promotional materials, and a targeted marketing program. The targeted marketing program, focusing on hard to place technologies, has resulted in the marketing of 15 technologies and the execution of four licenses. Examples of these technologies include: cancer diagnostics; method for coupling anti-cancer compounds to

intracellular delivery peptides; a gene-cassette for the enhancement of protein production; monoclonal antibodies that define human cytochrome P450 metabolism; food quality indicator strip antibodies that selectively detect human nestin protein; evaluative means for detecting inflammatory reactivity, avian adeno-associated virus and uses; N-acylphosphoramidites and their use in oligonucleotide synthesis; phytoestrogenic isoflavone compositions and uses for protection against treatment of radiation injury; and, thermolabile hydroxyl protecting groups and methods of use.

The marketing group initiated an integrated program of graphics, logos and taglines to solidify the image and recall of NIH and OTT in the corporate world. An interactive CD-ROM has been developed that will replace many of OTT's printed materials with an electronic medium that is richer in content and easier to navigate. Focused market research is also being carried out with an aim to refine and optimize the different marketing strategies currently being used.

This fiscal year, the Office initiated its Technology Transfer IRTA program designed for post-doctoral fellows wishing to begin a career in technology transfer. The Office recruited seven fellows in its inaugural year – two from within NIH, one from the FDA and four from outside NIH. The Office also recruited a second AAAS fellow to assist in international technology transfer issues. The Fellowship program has already had success with two of the Fellows finding permanent employment within their first year of Fellowship. OTT also trains a number of volunteers every year under its Internship/Detail program. These volunteer trainees also have been successful in parlaying their OTT training and experience into successful careers at technology transfer offices, law firms, and biomedical companies.

Division of Technology Development and Transfer (DTDT)

This Division has the primary responsibility for overseeing all OTT program activities related to the reporting of research inventions, assessing the commercial and patent potential of technologies, securing patent protection for commercially viable technologies, negotiating licenses as well as the monitoring and enforcement of those agreements. Included in these patent and licensing responsibilities are industrial outreach as well as inter- and intra-agency coordination activities, coordination and support of collaborative research activities, and coordination and resolution of national and international patent and licensing issues relating to NIH extra- and intramural programs. DTDT also provides CRADA administration support to the IC technology transfer offices as well as to the CRADA Subcommittee.

DTDT reported the following statistics for NIH technology transfer activities for fiscal year 2004 (the numbers include the FDA unless otherwise indicated):

Invention Disclosures Received	403
New U.S. Patent Applications Filed	199
Issued Patents	122
Executed Licenses	276
Royalties (in millions)	$56.3
Executed CRADAs (NIH Only)	87
Standard	43
Material	44

Of the 276 licenses executed during the fiscal year, 27 new licenses and five license amendments were finalized with foreign countries, including Australia, Austria, Belgium, Canada, England, France, Germany, India, Japan, Mexico, the Netherlands, and the United Kingdom

Some of the NIH technologies licensed this fiscal year included: ddI, human-bovine rotavirus vaccine, and biological materials for conjugated vaccine against typhoid fever. Three products licensed by NIH received FDA approval this year, including Didanosine delayed-release capsules, Kepivance, and Taxol Express Monorail cardiovascular stents.

OTT utilizes proprietary software named TechTracS (i.e. Technology Tracking System) to record, facilitate, and coordinate many Office functions (e.g. docketing, work-flow and records management). DTDT continues to manage substantial enhancements to TechTracS, which this fiscal year included: upgrading the system to a newer operating system; improving the handling of information related to patent infringements, royalties, license monitoring, patent prosecution contracts, and processing of license applications; and improvements to dissemination of information from TechTracS to the IC technology transfer offices. Also, as part of DTDT's ongoing efforts to utilize state-of-the-art records management (e.g. radio frequency identification tags to track file locations and innovative file labeling) over 900,000 pages were scanned into electronic form and attached to corresponding records in TechTracS, thereby reducing storage costs and greatly facilitating document retrieval.

The Monitoring and Enforcement Branch monitors the status of executed licenses; reviews, reports, and resolves potential infringement of NIH intellectual property; and resolves disputes with licensees regarding non-payment, infringement, and other issues that may result in amending licenses. During the fiscal year, 276 new licenses were executed while 91 licenses were terminated and 71 licenses expired, resulting in a net increase of 114 licenses to track and monitor, bringing the total to over 1,400. Branch activities resulted in the collection of $692,221 from audits, $2,121,411 from collections, and $220,057 from new licenses, for a total of $3,033,698.

OTT began the process of developing a Technology Service Center Branch which will provide a variety of services to the ICs, including review of Employee Invention Reports and patent annuity payments, and administration of TechTracS, the OTT proprietary database. Additionally, OTT agreed to enter into a Memorandum of Understanding (MOU) in FY05 with the National Institute of Mental Health (NIMH) to serve as its Competitive Service Center. The Competitive Service Center will provide a full range of technology transfer services that would otherwise be managed by the Institute.
DTDT hosted 15 technology transfer training lectures for the entire NIH technology transfer community, coordinated and taught a Foundation for Advanced Education in the Sciences (FAES) course entitled "Technology Transfer," served on both the PHS Technology Transfer Policy Board (TTPB) Training and Education Subcommittee and the Technology Development Coordinators (TDC) Training Working Group, and hosted the "NIH On-Line Technology Transfer Training" module on the OTT Web-site.

Division of Policy (DOP)

The Secretary of HHS has designated NIH as the lead agency for technology transfer and intellectual property policy matters for HHS. OTT represents HHS and NIH at interagency, intergovernmental, and international fora. Additionally, DOP is the focal point for NIH comment through the NIH Office of Legislative Policy and Analysis (OLPA) on legislative proposals regarding technology transfer and intellectual property policy and operational issues and has the lead responsibility for NIH extramural technology transfer and intellectual property policy matters. DOP also serves as the lead office for NIH in developing and implementing policies and procedures related to CRADAs.

This fiscal year, the Policy Division worked with the TDCs on the development of new model standard and clinical trial PHS CRADAs; developed and reviewed intellectual property plans for intramural scientists for the Gates Grand Challenge Grant; created case studies on three FDA-approved drugs (Velcade, Thyrogen, and Neutrexin) made using licensed NIH technology; developed and initiated a metrics program for evaluating products resulting from NIH technologies; designed a TechTracS module for evaluating and tracking extramural waiver requests; processed 91 extramural waivers; performed site visits to two universities to assess the impact of the Research Tools policy on university sharing practices; and presented at various meetings, including FLC, AUTM, National Council of University Research Administrators (NCURA), and First Forum on Intellectual Property of Chinese Universities and Colleges in Beijing, China.

Division of Administrative Management (DAM)

This Division is responsible for the internal policy development, guidance, and conduct of administrative and management functions within OTT, including financial management; human resource management; administrative training; travel; purchase and maintenance of equipment and supplies; acquisition and management of space; contracts and interagency agreements; data base management; and records and forms management. DAM is also responsible for the post license agreement administration tasks related to

royalty collection, recoupment of patent costs from licensees, receipt of annual progress reports, and assistance in audits of licensees. In FY04, NIH collected $56.3 million in royalty payments from 777 license agreements or amendments from a total of about 1,650 active licenses.

In June 2004, the HHS Office of Inspector General began a year long audit of the Royalties processes and collections reviewing all payments received in FY 2002, 2003 and 2004. As a result of their initial findings, the auditors determined they only needed to perform an in-depth review on a small sample of the payments and associated license agreements.

DAM oversaw the hiring of 10 new FTEs, 11 contractors, one AAAS fellow, and seven IRTA fellows. Additionally, DAM processed one AAAS fellow for an additional year, three personnel details, and nine interns from the ICs, educational institutions, and foreign countries. As a result of the reorganization of OTT, the Division wrote 10 new position descriptions and resulting EPMS plans. The office received more than 1,300 visitors, processed more than 500 non-patent prosecution invoices, 46 training requests, and 122 travel orders. The information technology personnel reviewed eight NIH-wide IT policies, provided IT and TechTracS support to 116 people, and created a website to assist TechTracS end-users.

DAM also supports the multi-award contract to law firms for patent prosecution of NIH and FDA inventions. In FY04, the group managed 14 law firm contracts and authorized 2,896 records of call resulting in over $19 million in work orders.

Articles authored by OTT personnel in FY04

Report to Congress on Affordability of Inventions and Products, June 2004.

Posters presented by OTT personnel in FY04

International Technology Transfer at NIH: Partnerships and Opportunities with Developing Countries, AUTM Annual Meeting, March 2004.

Science, Ideas and Breakthroughs: The Fruits of NIH Technology Transfer, AUTM Annual Meeting, March 2004.

New Measures of Technology Transfer Success, AUTM Annual Meeting, March 2004.

Technology License Monitoring Programs at NIH, AUTM Annual Meeting, March 2004 and NIH Research Festival, September 2004.

Avoiding the Avalanche: Using Records Management Techniques to Improve Workflow in Technology Transfer Offices, AUTM annual meeting, March 2004 and NIH Research Festival, September 2004.

CRADAs: Research Collaborations between NIH and Industry, NIH Research Festival, September 2004.

Linking Science to the Marketplace: Technology Transfer at NIH, NIH Research Festival, September 2004.

Select presentations by OTT personnel in FY04

Priming the Pipeline with PPPs, AUTM Annual Meeting, March 2004.

Best Practices for the Licensing of Genomic Inventions, AUTM Annual Meeting, March 2004.

Technology Transfer Fellowships at NIH, Career Opportunities Panel, Johns Hopkins University, April 2004.

Reducing Tolls along the Research Highway, AAMC, April 2004.

Improving Public Health through PPPs, UNIDO, April 2004 and WHO, Vaccines for Developing Countries, April 2004.

NIH TT: Improving Public Health through PPPs, Shanghai Institutes of Biological Sciences, China, April 2004.

Data Sharing and IP Issues in Large Scale Collaborative BioMedical Research Projects, Conference of the American Bar Association, April, 2004.

Partnerships for Health: NIH/OTT Activities in Developing Countries, American Society for Microbiology, May 2004.

Bench to Bedside: TT to Improve Public Health, University of Minnesota, May 2004.

U.S. Government IP Protection and Licensing Guidelines and Goals, National Academy of Sciences, June 2004.

Research Tools: Ensuring a Robust Research, BIO Annual Meeting, June 2004.

TT: 21st Century Challenges, BIO Annual Meeting, June 2004.

NIH Patenting and Licensing Policies, National Academy of Science, June 2004.

The Research Exemption in Non-Profit Research, BIO Annual Meeting, June 2004.

Exploring Practical Options Available for Companies to Obtain Antibodies, SRI's 3rd Annual Antibody World Summit, July 2004.

NIH Patenting and Licensing Policies, 4th International Antibody Deal-Making & Financing, July 2004.

Monitoring and Enforcement at OTT, NIMH TAC, August 2004.

Marketing IP and Biological Materials, Office of Technology Transfer, Harvard Medical School, August 2004.

Marketing Biomedical Inventions: An NIH Perspective, FLC Mid-Atlantic Regional Meeting, September 2004.

Challenges & Opportunities in Vaccines Development: NIH TT Activities in Developing Countries, Meeting of the Developing Countries Vaccine Manufacturers Network, September 2004.

NIH TT: Harnessing Innovation to Improve Public Health, CSIS: Hungary-US Scientific Collaboration, September 2004.

TT to Improve Public Health, University of Kansas, September 2004.

The NIH Roadmap, University of Kansas, September 2004.

Awards received by OTT personnel in FY04

Food Safety Indicator Strips: Is My Food Safe?, First Prize, Hot Technology Awards Competition, FLC Mid-Atlantic Region, September 2004.

Potent Small Molecule Therapeutics for Cancer, Second Prize, Hot Technology Awards Competition, FLC Mid-Atlantic Region, September 2004.

NIH Merit Awards (10)

NIH Technology Transfer Training Sessions in FY 2004

Federal Circuit Law Update, September 28, 2004

Inventorship and Laboratory Notebooks: Practical Tips, September 14, 2004

OTT License Administration: Royalties Collection & License Monitoring, July 27, 2004

Biotech Patent Protection in Israel, June 29, 2004

Restriction Practice for Biotech Applications, May 25, 2004

Basics of Foreign Patenting, May 10, 2004

Biotechnology and Technology Transfer in the Office of Science and Technology Policy, April 27, 2004

Strategies for Claiming Pharmaceutical Compositions and Patent Term Extensions-Strategies for Pharmaceutical Life Cycle Patent Protection, April 13, 2004

The OddzOn Dilemma – When Communications between Collaborators Can Become Prior Art, and What's Being Done about It, March 30, 2004

Overview of the PCT and New Procedures as of Jan 1 2004, March 16, 2004

Royalty Compliance, February 12, 2004

Strategies for Claiming Genes and Proteins, Including Anticipating Written Description and Enablement Issues, January 23, 2004

Research Exemptions to Patent Infringement, January 8, 2004

Protecting China and China's Emerging Biotech Industry, December 9, 2003

Patent Damages - Current Issues and Strategies, October 3, 2003