

**NIH OFFICE OF TECHNOLOGY TRANSFER
ANNUAL REPORT
FISCAL YEAR 2007**

The Office of Technology Transfer (OTT) is the National Institutes of Health (NIH) office responsible for the patenting and licensing of inventions from NIH and the Food and Drug Administration (FDA) intramural research activities and the lead office 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), and the Institutes and Centers (ICs). At the end of Fiscal Year 2007 (FY07), OTT was staffed by 64 Government full-time employees (FTEs) (a 10% over all increase from FY06), three contractors, and three Intramural Research Training Award (IRTA) Fellows.

OTT technology transfer activities for FY07 (the numbers include FDA technologies unless otherwise indicated) include:

Invention Disclosures Received	419
New U.S. Patent Applications Filed	178
Total U.S. Patent Applications Filed	354
Total PCT & Foreign Applications Filed	325
Issued Patents	117
Executed Licenses	264
Royalties (in millions)	\$87.7 (from 902 licenses)
Executed CRADAs (NIH Only)	44
Standard	23
Material	21

There was an increase in production from the previous fiscal year in all categories except for CRADAs.

Some of the year's transactional highlights include:

- Working with NCI to find a new commercial partner for the ProsVac® cancer vaccine program previously in clinical development.
- Obtaining assignments to the remaining CC49 cancer antibody portfolio from a former CRADA collaborator who had discontinued product development.
- Executing agreements with two global non-governmental organizations (NGOs) – the International AIDS Vaccine Initiative (IAVI) for a specialized HIV assay and Program for Appropriate Technology in Health (PATH) for a rotavirus vaccine.
- Entering into a major collaboration and patent collaboration agreement for HIV-1 diagnostics with Institut Pasteur.

- Finishing a new licensing agreement for several important therapeutic indications (stroke, heart attack and sickle-cell disease) for sodium nitrite. This represents new commercial investment and development of a previously-known, simple compound that is already on the market for other uses.

Continuing its strong role in the development and utilization of the NIH Research Tools Policy, OTT non-exclusively licensed research tools for broad distribution and utilization, including mouse models implicated in a wide range of diseases, such as diabetes, cancer, and cardiovascular disease, LAD2 cell line, and P450 monoclonal antibodies and cell lines that impact drug metabolism R&D.

OTT also executed licenses for genetic diagnostic tests for Niemann-Pick Type C disease and improved oligonucleotides for PCR and PCR-based research kits.

The Office has continued its active role in the international arena both in licensing and training -- including new licenses with institutions in India, Brazil, Spain, and Nigeria and supporting visitors from developing countries participating in the Internship Opportunities in Federal Technology Transfer program. Scientists and technology transfer administrative personnel from Mexico, Brazil, China, Chile, Hungary, India, and Kenya received in-house practical training. The training also included rotations at OTT, NIH Institutes, other federal agencies (such as the FDA and USPTO), and technology transfer offices at several universities. All the trainees were sponsored and funded by institutions in their home countries. OTT also maintained strong collaborative ties with research and technology transfer organizations in Japan. This included ongoing support for the Japanese/English language version of "Research Tool Web" (www.research-tool.info). (Updated Sept 2013: Research Tool Web link removed -- no longer available.)

OTT has an active program for marketing NIH and FDA intramural technologies through one-on-one interaction with potential licensees, the OTT web site, exhibits, and presentations at technology shows, an e-mail newsletter, dissemination of promotional materials, and a targeted marketing program. In order to provide more up-to-date information to potential licensees, OTT further streamlined data flow from its transactional database to the website and beyond.

Companies benefited from the enhancement of information about available technologies through the use of Synapse™, a text mining tool to quickly provide individualized and targeted technology matching. Synapse™ itself has been upgraded and now allows for multiple databases to be searched simultaneously as well as live links to available technologies. These enhancements allow for the development of customized reports to industry. Overall, OTT tracks the licensing needs of over 250 companies, ranging from large pharmaceutical giants to small start-ups, as well as about 15 venture capitalist companies, technology brokers, and alliance seeking companies.

OTT joined with the NIH SBIR/STTR Program Office to create a virtual space where NIH licensees and SBIR/STTR grantees can showcase their technologies and product

development for an audience of potential strategic partners and investors. A pipeline of technologies available for partnering is on the OTT website at <http://www.ott.nih.gov/p2p> as an index searchable by category of technology and stage of development. By providing this resource, NIH is advancing its own mission to further the development of its licensed technologies or those for which it has provided SBIR/STTR funding. This fiscal year, 116 unique technologies developed through either SBIR/STTR funding or an NIH license has been published by 96 companies at the site. (Updated Sept 2013: P2P link removed -- no longer available.)

Less than a year since its launch, the Rare Diseases and Conditions Technologies website initiative by the OTT and the NIH Office of Rare Diseases (ORD) has seen phenomenal growth. OTT has contributed 237 rare disease technologies to the site and 22 external non-profit institutions added their 295 rare disease related technologies.

OTT has the critical job of monitoring compliance by NIH licensees, settling license disputes, and investigating potential infringement of NIH patents. The Office actively reviews licensee's reports of commercial development progress, licensed product sales, and earned royalties as well as manages third-party (outside auditing firm) audits of licensees' sales records and enforces collection of royalty payment obligations. By the end of FY07, the Office had reviewed more than 2,000 active licenses (an increase of 46% from FY06) and completed third-party royalty audits for two licensees.

One of the Office's top policy priorities this last fiscal year was managing and facilitating the review and revision of existing technology transfer and intellectual property (IP) policies as well as crafting new policies that reflect current NIH and Public Health Service (PHS) technology transfer practices. For example, in the past year, OTT began a five-year project to overhaul the entire PHS Technology Transfer Policy Manual.

OTT also provides review and recommendations for requests for waivers by the NIH extramural community (to inventor, of the U.S. manufacturing requirement, and for assignment to third parties). In FY07, OTT received 72 extramural waiver requests (an 8% improvement) through the NIH Office of Extramural Research, of which 52 were requests to waive title to inventors, 18 regarded U.S. manufacturing, and three were requests for permission to assign to third parties.

Philip S. Chen, Jr. Distinguished Lecture on Technology Transfer

OTT co-sponsored the second lecture titled "Innovation and Collaboration: The Science, Technology and Promise of Prevention HPV Vaccines" presented by Douglas R. Lowy, M.D.

Articles authored by OTT Personnel

Rohrbaugh, M., NIH Offers Licensing Agreements to Commercialize Technologies: *BioPharm International*, March 2007

Spiegel, J., Technology Transfer, *Principles and Practices of Clinical Research*, 2007

Spiegel, J., Knowledge and Technology Mobilization to Advance Public Health: An NIH Perspective, *Intellectual Property at the Edge: New Approaches to IP in a Transsystemic World*, A Compendium of the 2006 Meredith Lectures at the Faculty of Law McGill University, 2007

Sanhai, W.R., Spiegel, J., Ferrari, M., A Critical Path Approach to Advance Nanoengineered Medical Products, *Drug Discovery Today: Technologies*, Vol 4, No.2, 2007

Spiegel, J. (contributor), The International HapMap Consortium A Second Generation Human Haplotype Map of Over 3.1 Million SNPs, *Nature*, Vol. 449, 2007

Posters presented by OTT personnel

Carson, S. and Kirby, T., “Tools of Our Trade: Licensing Research Tools at the NIH,” NIH Research Festival, Bethesda, MD, September 2007

Select presentations by OTT personnel

OTT staff was invited to give presentations at many meetings domestic and international including:

13th European Congress on Biotechnology; Tech Transfer Summit, Barcelona, September 2007

ACI Conference on Pharma/Biotech Industry – Academia Tech Transfer, January 2007

Alliance Management Conference, April 2007

American Intellectual Property Lawyers Association – China Delegation Seminar, June 2007

American Intellectual Property Lawyers Association, August 2007

Asian Pacific Legal Institute (APLI) 2007 Intellectual Property Training Program

Association of University Technology Managers (AUTM) 2007 Eastern Region Meeting, June 2007

FITCI Business Incubator Education Program, October, 2006

Fudan University Conference on Pharmaceutical Regulation, IP, Licensing and Partnerships, Shanghai, April 2007

Genetic Alliance Summit, September 2007

IEDC 2007 Federal Economic Development Forum, March 2007

Third International Conference on Rare and Orphan Diseases, Brussels, September 2007

Investing In Technology Transfer Conference, October, 2006

Keizai Doyukai Conference and RIKEN Technology Transfer Seminar, Japan, August 2007

National Meeting of Federal Consortium for Technology Transfer (FLC), May 2007

National Graduate Institute for Policy Studies (GRIPS) Seminar, Tokyo, August 2007.

NEOS Technologies & Mercado 2006 IP Tour, October 2006

Technology Development Corporation (TEDCO) Preventing, Diagnosing and Treating Cancer, September 2007

Trade Shows

Federal Laboratory Consortium for Technology Transfer (FLC) (National and Regional)

American Intellectual Property Lawyers Association

BIO 2007 Annual Meeting

Association of University Technology Managers (AUTM) Eastern Region Meeting

Licensing Executive Society

Federal Post Doc Conference & Career Expo

NIH Job Fair

NIH Research Festival

NCI-TEDCO Showcase

Dean's Summit for Technology Transfer

Mid-Atlantic BIO