U.S. Department of Health & Human Services

National Institutes of Health
Office of Technology Transfer

Annual Report

Fiscal Year 2009

Message from the Director

Dear colleagues and partners:

The transfer of technologies from the NIH intramural research program provides a ray of sunshine in an otherwise gloomy economy of 2009. While there were some limited negative effects attributable to the economic downturn, the primary and long-term impact of our efforts to improve public health through the transfer of technology remains strong. In 2009, OTT managed 347 active licenses collectively reporting product sales of nearly $6B. The future looks promising as well with OTT licensees reporting 52 new products in the clinical development pipeline.

Preliminary new data released last October illustrates the significant NIH contribution to biomedical products available to the public (Ashley Stevens, Boston University). Considering all sources of funding over the last 30 years, public sector institutions in the US have licensed inventions that have given rise to 153 FDA approved drugs and biologics. The NIH contribution is 22 products, approximately 14% of the total. Based on estimates of the total annual sales revenues of the products, sales by NIH's licensees constitute 14% of the total sales.

Accounting for less than 10% of the total biomedical research funding to public sector institutions, the NIH intramural program has had a substantial and disproportionately large effect on the development of drugs and biologics in the US. Consistent with the Administration's innovation goals announced last September, these technologies have made and will continue to help improve public health, create jobs, and maintain US global competitiveness - a highly valuable return to the American taxpayers for their investment in NIH and FDA research.

Thanks to our highly creative and inventive scientists at NIH and FDA, we at OTT have the privilege to manage a valuable intellectual property portfolio for the benefit of the public. I also have the privilege of working with a talented and highly effective technology transfer staff that manage these inventive technologies and transfer them to the private sector. In addition, the technology transfer staff at the Institute and Center level effectively link their scientists with companies under collaborative agreements to advance scientific progress and commercialization of technologies. I personally am grateful for the opportunity to work with all these people.

OTT is committed to improving how we deliver value to the NIH and its external clients. We have developed new IT tools to make it easier to obtain information on technologies available for licensing and the products that result from these commercialization efforts. Rather than resting on our laurels, we expect ongoing improvements in how we conduct technology transfer. These text mining and visual analytics tools also open opportunities for federal labs to work together by sharing information about technology transfer opportunities and facilitating joint commercialization opportunities involving that otherwise would be hard to piece together.

Please let us know if you would like more information about licensing opportunities or have suggestions for innovations in how we manage NIH inventions.

Sincerely,

Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer

MISSION STATEMENT

The mission of the NIH Office of Technology Transfer (OTT) is to improve public health through the management of NIH and FDA inventions and in doing so serve a leading role in public sector biomedical technology transfer policy and practice.

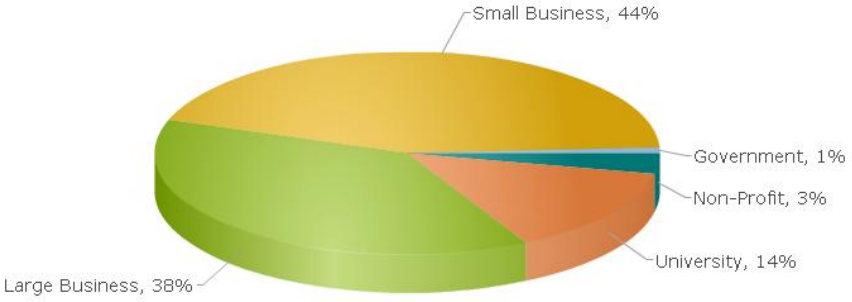
Purpose

OTT serves as the bridge that connects the inventive discoveries made in the NIH and FDA intramural research programs to commercial partners that develop these technologies into products and services to benefit public health. Without this bridge, the public would not benefit from the full potential of these biomedical discoveries. In carrying out its mission and purpose, OTT applies its policies and practices to the management of NIH's and FDA's inventions, including: the appropriate use of the patent system; marketing NIH and FDA technologies to identify appropriate commercial partners; negotiating licenses to ensure the timely development of technologies; and monitoring the progress of the development of the technology to ensure commercialization milestones are reached and royalties are paid.

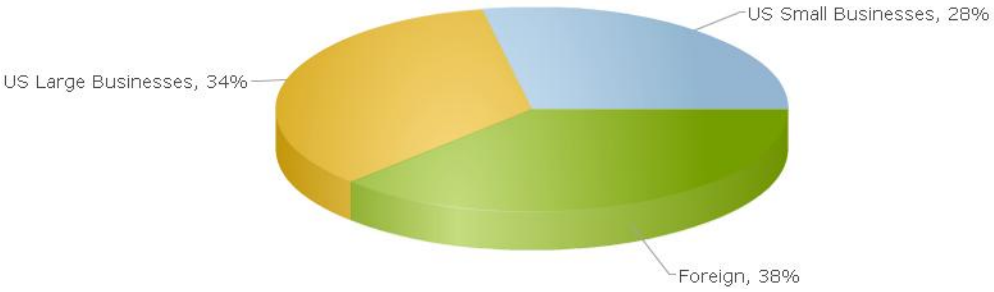
LICENSING AND PATENTING

The ultimate goal of any technology transfer office is effective and responsible licensing to ensure the development of technologies. NIH has maintained a strong patent and license portfolio, in an otherwise slow economy, and in doing so has made a positive impact on public health and jobs. Over the years, these efforts have helped stimulate the economy through small entrepreneurial companies created to commercialize a technology licensed from NIH as well as large companies developing high-growth technologies. In FY09, OTT executed 215 license agreements - 81% with US companies and 35% with small US businesses. Nearly 60% of the first-time licensees were US companies and about half of these were small businesses. Over one-third of the new licenses were to companies licensing from NIH and FDA for the first time.

Licensee by Business Type

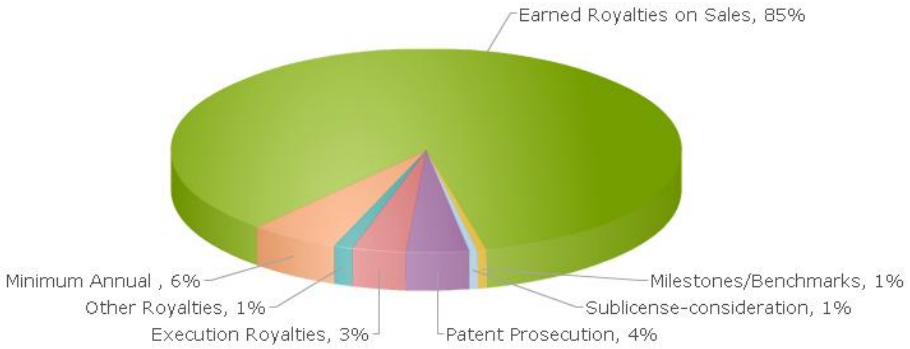


First Time Licensee by Business Type



Sales of products built around NIH and FDA licensed products remain strong with licensees reporting nearly $6B in sales of products licensed from the NIH. In FY09, OTT had 350 licenses reporting products on the market. Royalties on sales of these commercial products and services account for 85% of the $91.2M in royalties collected in FY09.

Royalty Income by Type

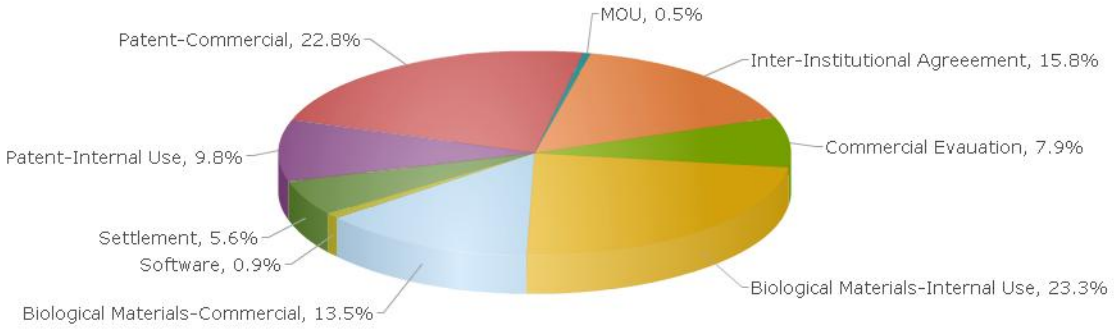


The top 20 products generating royalty income account for 83% of the total overall royalties. Thus, sales of a limited number of products generate a very large fraction of the royalties.

The FY09 technology transfer outcomes follow a long trend of successful licensing of biomedical inventions by the NIH and also reflect the NIH's dedication to technology transfer - the broader economic impact of which becomes especially important during difficult economic times. OTT has used novel and flexible licensing practices to mitigate economic stressors affecting the pharmaceutical and biotechnology industries. Through these efforts, OTT continues to build strong partnerships with both public and private entities to support the NIH mission of improving public health.

While most of the royalty income collected by OTT is based on sales of pharmaceutical and biotechnological products and services, most of the products on the market under OTT licenses are research tools and reagents. Although the sales of research tools cannot compete in volume or financial return with sales of FDA-approved products, they make a considerable impact in advancing both private and public sector research.

Licenses by Type of Agreement



Some of these best selling products include purified Transforming Growth Factor beta (TGF-β), Antibodies to human IL-8, and QuikChange® Site-Directed Mutagenesis Kits.

The success of OTT's licensing program and its overall mission of serving global public health is reflected in the following representative two agreements:

1. Dengue Vaccine

The global prevalence of dengue has grown dramatically in recent decades. Dengue is now endemic in more than one hundred countries in Africa, North and South America, the Eastern Mediterranean, Southeast Asia, and the Western Pacific. Some 2.5 billion people, two-fifths of the world's population, are now at risk from dengue. The research and development required to bring a vaccine to market for dengue is long and expensive, yet commercial development of such a vaccine is critically needed. To address this need, OTT executed two exclusive patent license agreements with institutions in Brazil and Vietnam. The licensed technologies originated in the laboratory of Dr. Brian Murphy, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), NIH. In structuring these licenses, a regional licensing approach was used, whereby institutions are given a nonexclusive license or exclusive rights only for their country or region. Just as NIH and FDA supports research to prevent, diagnose, and treat diseases that disproportionately impact developing countries, OTT's role is to develop creative licensing structures to transfer these technologies to institutions that will bring the fruits of the research to the people throughout the world who will benefit from them.

2. Prostate Cancer Immunotherapy

While the research and development required to bring a cancer treatment to market is long and expensive, the benefit for patients is incalculable. Dr. Jeffrey Schlom, Chief of the Laboratory of Tumor Immunology and Biology at the NIH National Cancer Institute, led the scientific team that developed PROSTVAC, a prostate cancer immunotherapy that triggers the patient's own immune system to attack prostate cancer cells. An exclusive patent license was granted to Bavarian Nordic to further develop the technology. The company recently released encouraging clinical data at the American Society for Clinical Oncology Annual Meeting. Phase 2 clinical trials demonstrated an improved survival of 8.5 months, on average. In contrast, the only approved treatment currently available for advanced prostate cancer is a form of chemotherapy, which extends survival by an average of only 2.4 months.

The management of a large and complex patent portfolio at times requires OTT to take novel approaches to resolve legal disputes in a manner that minimizes the expenditure of public funds while maximizing public benefit. In one example this year, OTT was able to effectively use a novel patent interference settlement monetization strategy that protected existing NIH intellectual property for a cancer therapy, as well as acquire additional patent properties to provide further incentives and protection of the technology in current or expected clinical development. This was an important development as interferences are expensive, adversarial proceedings before the U.S. Patent and Trademark Office to determine the first party to invent a specific technology. They tend to be lengthy in nature and often have unpredictable outcomes – creating risk and uncertainty for anyone seeking to invest in the clinical development of such inventions. Because of the urgent need for new cancer therapies and the potential commercial risk to the clinical investment made by both NCI and other parties, this case represented a significant accomplishment and cost-saving for OTT and NIH overall.

OTT manages inventions arising from 27 NIH Institutes and the FDA (ICs) on technology transfer matters. The management of a portfolio from such a diverse group of ICs with differing missions and a wide range of technology transfer activities presents a unique set of administrative challenges. During this last fiscal year, OTT streamlined its interactions with these ICs through a variety of mechanisms. Regular meetings and updates are

provided to the ICs regarding individual technology portfolios. In particular, OTT conducted broad technology audits to identify the most promising technologies and then made recommendations to the ICs for those technologies for which patent prosecution should be discontinued. Through such efforts, financial controls are strengthened and budgets can be better managed.

MARKETING

OTT reaches out to maintain close communication with its existing and potential licensees to better meet their needs. Meetings are held with interested parties to discuss scientific, business, and legal issues in support of the transfer of NIH/FDA technologies. During this last year, individual meetings held with a number of companies led to executed licenses.

One of the biggest challenges for any technology transfer office is to identify companies to approach for marketing purposes. To assist with this effort, a new market data mining system was developed in-house that allows OTT staff to quickly and easily find companies that have expressed prior interest in a similar disease area. This database also includes epidemiological and clinical trial information on various diseases to help OTT staff fine tune their positioning of a particular technology.

OTT initiated the creation of Real Simple Syndication (RSS) data feeds to include NIH/FDA technologies available for licensing. RSS feeds make information easily and quickly accessible to interested parties. In addition to the RSS feed, OTT also created a subscription-based automated email service. Using this method, subscribers will automatically receive emails with information about new technologies targeted to areas of interest specified by the user.

After a technology is marketed and licensed, some technologies become products that detect, treat or prevent disease or assist researchers as they continue to explore ways to develop newer and more effective health care products and procedures. OTT developed a Product Showcase to display those products developed by commercial partners from NIH and FDA intramural research program inventions. In FY09, the Showcase was vastly improved to include 49 products with the capability now to filter and display them by product type, market launch year, and approval date. More will be added in the coming year.

OTT continues to develop an electronic website for Research Materials (eRMa) that will serve as a marketplace for many hundreds of research materials available for licensing from the NIH and FDA intramural research programs. The objective in developing this website is to ensure the efficient transfer of research materials to the private sector. The interactive website will provide a marketing and licensing option that is designed to expedite the licensing process, decrease transaction costs, and facilitate greater dissemination of research materials to companies.

Synapse™, the OTT text mining tool, has been expanded to include available technologies from 23 non-profits worldwide that engage in biomedical research. These enhancements allow for the development of customized reports to industry in their search to acquire new technologies and increase the ability to identify a more valuable licensing package from multiple institutions.

Pipeline-to-Partnership (P2P) is a virtual space where NIH licensees and SBIR/STTR grantees can self publish a showcase of their technologies and product development for an audience of potential strategic partners and

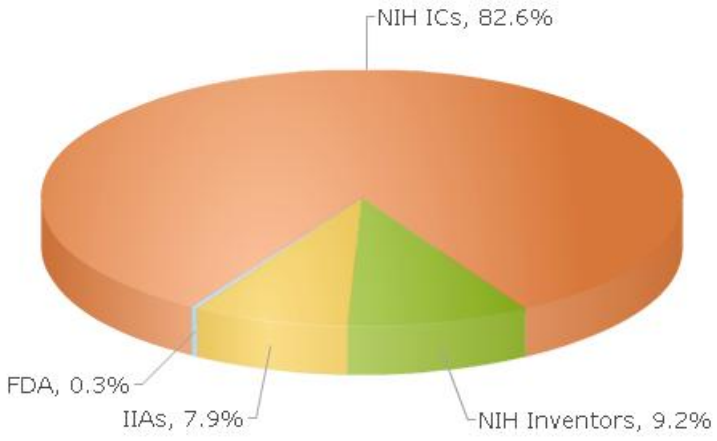
investors. P2P has been expanded to include over 150 unique technologies from 153 companies. By providing this web portal resource, NIH advances its own mission and supports small business activity based on technologies from intramural or extramural programs. OTT has heard from several companies that this site has facilitated new strategic relationships to advance the development of their technologies.

The Rare Diseases and Conditions Technologies website initiative, supported by OTT and the NIH Office of Rare Diseases Research, provides an added marketing push and opens up new possibilities for packaging various inventive components of these technologies for which there is great medical need but weaker market incentives for investment. The site currently offers more than 500 rare disease technologies from OTT and 26 other non-profit institutions worldwide. The technologies include drugs, biologics, and devices that are available to for licensing.

ROYALTY ADMINISTRATION

While the essential purpose of the technology transfer process is to improve public health, the collection of royalties is an important by-product. Royalties collected from licensees of NIH and FDA intramural program inventions are distributed to the ICs that developed the inventions, the inventors, and, when relevant, extramural institutional co-owners of the inventions. There are various fees paid as royalties under licenses, including upfront license fees, annual minimum payments to maintain a license, payments associated with the achievement of commercial development milestones and "running royalties" on sales of product. By far, the largest amount of royalty funds is received on sales of products. These products cover the spectrum of biomedical related products and include vaccines, therapeutics, devices, diagnostics, software, and research materials. Royalty collections fluctuate from year to year and are impacted by a variety of factors, including rise and fall in sales, FDA licensing approval, license termination when patents expire, etc. Royalty funds are an important source of funds for ICs to pursue activities that might otherwise remain unfunded. The ICs use the income to pay technology transfer expenses (such as patent expenses and OTT costs) and support research and training programs, including the purchase of expensive laboratory instrumentation or clinical agents.

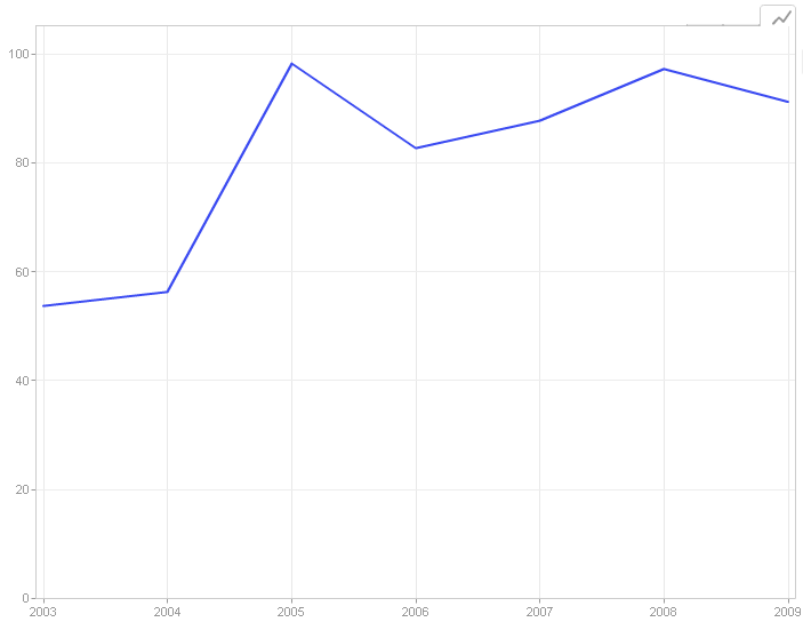
Royalty Distribution



The OTT administered $91.2M in royalties in FY09 with 83% of the total going to the ICs and 9% to the inventors. The remainder was distributed under Inter-Institutional Agreements (IIAs) to our extramural partners that are co-owners of licensed inventions.

This income was received from 499 companies, or their subsidiaries, under 870 license agreements, three-quarters of which are US based. Royalty levels remained relatively stable with only a 6% decrease from the previous fiscal year and a 4% increase over the year before last.

Royalty Income



The decline in FY09 royalties over FY08 was primarily due to the expiration of a patent license for one product and a sharp drop in the earned royalties received from sales of another. There were, however, significantly higher earned royalties from several products sales. (See for a complete list of the top 20 inventions for FY09.)

In accordance with statutory requirements, inventors under a given license receive annually the first $2,000 received by the NIH; 15 percent of royalties above $2,000 and up to $50,000; and 25 percent of royalties in excess of the first $50,000. In FY09, 1,144 inventors received royalty payments amounting to $8.4M. Of these, 78 were first-time recipients. In addition, 25 inventors received the statutory cap of $150,000 per year.

During this fiscal year, the Office set an operational goal to improve the process by which licenses which have a requirement to reimburse patent prosecution costs are identified. These costs are reimbursed through the royalty administration process directly to NIH IC and FDA intramural research programs. As a result of this effort, over $7.62M in patent prosecution costs were billed out to licensees. Of this amount, $3.62M was already recovered by the end of fiscal year 2009.

MONITORING AND ENFORCEMENT

To ensure compliance with license obligations and development of technologies licensed from NIH and the FDA, OTT maintains a monitoring and enforcement program for its portfolio of more than 1,200 active license agreements. During FY09, 79 licenses were terminated and 117 licenses expired. Twenty three cases of alleged infringement of NIH/FDA patents were investigated and closed either through licensing or by the company's voluntary withdrawal of the infringing product. At no time, however, did NIH ask for product to be withdrawn or seek an injunction. OTT conducted internal audits of all licenses for administration and royalty compliance, resulting in an overall collection rate of 93% of royalties due in fiscal year 2009. OTT terminated eight NIH licenses for non-compliance during the year. Additionally, three licensees with higher licensed product sales were audited by firms under contract to OTT to verify proper payment of earned royalties. OTT's enforcement activities resulted in the collection of over $6 million in overdue royalties during the year.

TRENDS

The current economic recession has, thus far, had only a minor impact on the amount of royalties received by OTT. The effects of the slowdown are evident in the smaller number of license applications received - 9% fewer in FY09 than in FY08. This downward trend began in FY08 when 10% fewer license applications were recorded than in FY07. The number of new licenses executed dropped by 15% in FY09 compared to FY08. Most of this decline is seen in the number of license applications and executed licenses for patent or biological materials for commercial product development as opposed to licenses for internal research use.

The impact of the current economic recession could also be seen in an increased number of licenses terminated in FY09. Compared to FY08, 33% more were terminated in FY09. Most of this increase was in the category of "internal use" licenses. Of these, most were biological materials licenses, but there was also an increase in the number of patent internal use licenses terminated. Internal use licenses are typically needed for research and development programs conducted by licensees. The termination of an internal use license generally reflects a decision by the licensee to terminate such a program. The increase in terminated licenses seen in FY09 was not due to more licenses terminated by OTT for non-compliance in paying royalties owed. The number of such terminations in FY09 was similar to FY08. The ability to keep this number steady reflects OTT's continuing efforts to assist licensees struggling to meet their financial commitments to NIH by developing payment plans or other means to defer payments until economic conditions improve, while maintaining license compliance. Because most of the licenses affected in this manner are still in the development stage, the effect to the overall level of royalties collected is minimal, as the license fees involved are small compared to most royalties on sales after product launch. In the course of time, of course, one could expect royalties to decline if the number of new product development licenses does not rebound.

POLICY ACTIVITIES

The scope of OTT's formal and informal policy activities is broad in that they include health related technology transfer and intellectual property matters, including support of legislative affairs. Using the experience of U.S. universities and the NIH in technology transfer as a reference, OTT provided advice on policies and procedures to enhance the translation of early-stage technologies into practical applications by companies, ultimately for the benefit of public health. OTT has led a variety of initiatives directed to NIH-wide technology transfer policies and procedures. OTT representatives serve as Vice-Chair and Executive Secretary of the Public Health Service (PHS) Technology Transfer Policy Board, the advisory board for technology transfer policies for the NIH, FDA, and Centers for Disease Control and Prevention (CDC). As such, OTT has led ongoing comprehensive review of policies and procedures related to patenting, licensing, Cooperative Research and Development Agreements (CRADAs), material transfer agreements, and extramural activities. Additionally, OTT spearheaded the revision of the CRADA Subcommittee Charter to provide for additional representation from the NIH Institute/Center technology transfer community.

Members of OTT actively participate in a wide array of NIH and U.S. Government-wide projects that address programmatic components of technology transfer. Examples include membership on the Trans-NIH Task Force on Nanotechnology, the Data/Resources Sharing Interest Groups, and the NIH Stem Cell Task Force. Members of OTT represent HHS and NIH in interagency and intergovernmental fora, such as the Global Issues in Nanotechnology working group supporting the National Nanotechnology Initiative, the Interagency Workgroup for Technology Transfer, the interagency working group for the Working Party on Biotechnology of the Organisation for Economic Cooperation and Development (OECD), the interagency working group on health and trade issues, the National Science and Technology Council (NSTC) Committee on Technology, and the Biomarkers Consortium.

Similarly, OTT has been asked to serve as advisors to NIH and HHS on many *ad hoc* issues related to technology transfer and intellectual property issues, including pandemic influenza, gene diagnostic technologies, and the transfer of materials from human subjects.

In support of coordinated technology transfer when NIH and outside university collaborators co-invent technologies, OTT has led efforts to enhance dialogue between NIH and university technology transfer offices. In April, OTT sponsored a presentation by the Association of American Universities on "Biomedical Research and Technology Transfer Policy Issues". This presentation was followed by an in-depth roundtable discussion bringing together extramural institutions receiving NIH funding, the Council on Governmental Relations, and the NIH IC technology transfer offices.

In its role as the focal point for technology transfer policy within the PHS, OTT spearheaded a major overhaul of the PHS Technology Transfer Policy Manual, the first in many years. Technology transfer professionals throughout the NIH and FDA have assisted with this effort. This ongoing revision process is directed to updating practices and procedures for the full range of activities that promote the transfer of technologies and, in turn, spur biomedical innovation.

During FY09, OTT continued to serve as a technical advisor to the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS), focusing on the area of gene patents and licensing. SACGHS, through a task force, initiated a study in 2006 to assess the positive and negative effects of gene patenting and licensing practices on

patients' clinical access to genetic tests and on the public's health and quality of life. OTT has provided technical support to the task force as it worked through legal and policy issues related to gene patenting and licensing. Additionally, in March 2009, SACGHS released its Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, which included an appendix, co-authored by OTT, presenting a preliminary analysis from a study of DNA patenting and licensing practices. Following public comment in October, SACGHS is expected to issue its final report and recommendations early in 2010.

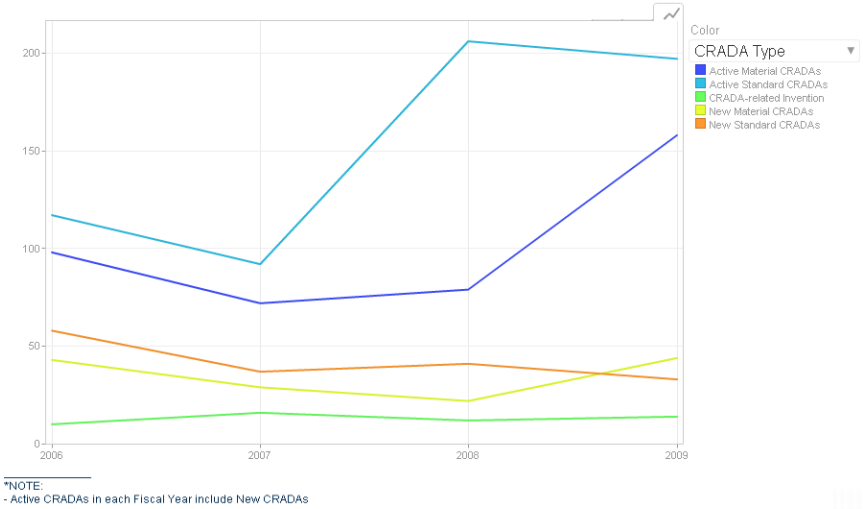
An important role for NIH is to ensure that universities receiving NIH funds comply with their statutory responsibilities to make NIH funded inventions available to the public and research community. To this end, OTT has delegated authority to make the final agency determination on grantees' and OTT licensees' requests to assign their rights in an invention to a third party; requests to substantially manufacture the technology outside of the US; and requests to waive title to an invention to the inventor. In FY09, OTT reviewed and provided recommendations on two intramural inventor waiver requests, fifty requests to waive title to extramural inventors, and eight requests to waive the U.S. manufacturing requirement.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADAs)

Cooperative Research and Development Agreements (CRADAs) provide an opportunity for NIH investigators to join with their colleagues from industry and academia in the joint pursuit of common research goals. CRADAs are negotiated by technology transfer staff in the ICs while OTT collates and administers CRADA data and serves as a member of the NIH CRADA Subcommittee.

In FY09, there were 355 active CRADAs; 197 were standard CRADAs and 158 were Materials-CRADAs. During the year, NIH executed 77 new CRADAs; 33 of which were standard and 44 were Material-CRADAs. Three-quarters of these were with US companies, and about one-third of US companies are small businesses. The number of active CRADAs in FY09 is similar to the statistics from FY08, but about 75% higher than those in FY07.

Multi-year CRADA Metrics



In addition, OTT supported NCI in its work to implement a new CRADA mechanism termed an "Umbrella CRADA" which increases NCI's access to proprietary agents and improves processing time. The Umbrella CRADA, while focused on specified proprietary agents or classes of agents, encompasses broad research topics which accommodate a large number of individual research projects of NCI intramural investigators. Since NCI began using this mechanism in early 2008, ten NCI Umbrella CRADAs have been executed and approximately 30 internal MTAs have been put into place to connect the individual research projects to the corresponding Umbrella CRADA. Four of these NCI Umbrella CRADAs were executed in FY09; one with Amplimmune, one with Genentech and two with AstraZeneca AB.

THE GREEN INITIATIVE

Through the increased the use of digital media, OTT has made significant strides to facilitate communication with outside entities. OTT has initiated paperless license execution and implemented new software to transfer and process license agreements and patent prosecution expense reports throughout the office as well as exchange and reconcile royalty income reports between the OTT and the NIH Office of Financial Management. This new process eliminated the need to print out more than 2,500 income documents per year, decreased processing time, and significantly reduced out-of-pocket costs.

OTHER ACCOMPLISHMENTS

The NIH along with Hope Pharmaceuticals and Aires Pharmaceuticals received the 2009 Deal of Distinction Award™ from the Licensing Executives Society, Inc. The award recognizes efforts to promote creative and innovative solutions to licensing issues. This award acknowledged the innovative licenses for the development of sodium nitrite as a repurposed pharmaceutical agent for treatments for conditions not well-managed by existing therapies. The agreements, negotiated by OTT, were based on the discovery by scientists at four NIH Institutes (National Institute of Neurological Disorders and Stroke, National Heart Lung and Blood Institute, Clinical Center, and National Institute of Diabetes and Digestive and Kidney Diseases) and four universities (Loma Linda University, Louisiana State University, University of Alabama, and Wake Forest University) that low, physiological and non-toxic concentrations of sodium nitrite could be used to treat a variety of diseases. The Inter-Agency Agreements and the final license agreements are a testament to the willingness of all sides to work together to transfer new technologies for the treatment of important chronic diseases.

An invention by NIH scientists Arnold S. Kirshenbaum, M.D., Dean D. Metcalfe, M.D., and Cem Akin, M.D., Ph.D. of the National Institute of Allergy and Infectious Diseases (NIAID) was selected to receive a 2009 Federal Laboratory Consortium (FLC) "Excellence In Technology Transfer Award". At NIAID, Dr. Kirshenbaum and co-investigators derived the LAD2 cell line from a mast cell sarcoma/leukemia sample. The cell line has become the gold standard for allergy and inflammation studies and has been transferred to many non-profit and academic institutions, resulting in many peer-reviewed publications from laboratories around the world. This technology has also been a licensing success with broad international interest from biotechnology and pharmaceutical

companies; thirty biological materials licenses have been executed since the cell line was made available in 2001.

Members of the Office were recognized with awards for their significant contributions to technology transfer as well as the overall mission of NIH. These included eight group NIH Office of the Director Merit Awards, two individual NIH Office of the Director Merit Awards, and five National Cancer Institute CCR Federal Technology Transfer Awards.

OTT staff was invited to give presentations at many domestic and international meetings. These outreach efforts help communicate NIH's technology transfer policies, increase opportunities for licensing technologies, learn from others engaged in technology transfer, engage in cooperative technology transfer with governmental and non-profit institutions, and provide training to institutions implementing technology transfer mechanisms. These presentations included: BIO Korea; the Asian Pacific Economic Cooperation - Intellectual Property Experts Group Meeting on Technology; BHLSI 4th Annual Haifa BioSeminar in Israel; University Startups Conference 2008; NIH Post-Doc Conference and Career Fair; Licensing Executive Society Annual Meeting; Georgetown University Biotechnology Program; National Eye Institute Post-Doc Retreat; FITCI Business Incubator Seminar Series; NIAID International Coordination Meeting; Association of University Technology Managers Annual Meeting; Montgomery County Maryland Business Incubator Seminar Program; Johns Hopkins Biotechnology Network Conference; Maryland TEDCO Small Business Training Series; Wales/Washington Life Sciences Day. OTT staff also presented posters at several scientific and technology transfer conferences that highlighted the research efforts of OTT members as well as featured "hot" technologies for licensing based upon the research efforts of intramural scientists.

Additionally, OTT staff published several articles:

- Two licensing case studies on Typhoid Vaccine and Rotavirus Vaccine published in the MIHR handbook.
- A two part article entitled "Intellectual Property and Other Contractual Issues in Cooperative Research and Development Agreements (CRADAs)", published in *les Nouvelles, Volume XIV No.1 pp. 41-48 (March 2009) and Volume XIV, No.2 pp. 79-86 (June 2009)*.
- An article on "Technology Transfer at the National Institutes of Health" by M.L. Rohrbaugh and B.R. Stanton, in *Technology Transfer in Biotechnology: A Global Perspective*, P. Ganguli, R. Khanna and B. Prickril, eds., Wiley-VCH, pp. 35-57 (2009).

OTT hosted a delegation of foreign patent examiners from South Korea, Germany, Egypt, and China at the request of the United States Patent and Trademark Office. This initiative was designed to expose foreign examiners to US patent prosecution practices and policies as well as a variety of other related technology transfer activities. Additionally, as part of the International Training Opportunities in Federal Technology Transfer Program, OTT provided training for a representative from the Korea Health Industry Development Institute in South Korea.

In FY09, OTT staff members served as organizers, instructors, and speakers for several local technology transfer educational programs. These programs allow OTT to share its experience and expertise in technology transfer and provide training opportunities in the field for scientists, other members of the NIH, and the regional community.

Summary

Overall, the transfer of inventions from NIH and FDA intramural laboratories and the role of OTT in informing technology transfer policy considerations remain strong. With 347 products on the market in FY09 and combined reported sales of nearly $6B, the program is having a substantial public health and economic impact. From the technology transfer perspective, the American public is receiving a strong return on its investment in the NIH intramural biomedical research program. While the economic slowdown, in most cases, has not affected the sales of biomedical products licensed from OTT, it appears to have affected the ability of companies to license new technologies for commercial development. OTT has responded, when necessary, by being more flexible in financial terms or delaying payments until a company is in a stronger financial position. The pipeline for licensed technologies is healthy enough to expect no retrenchment in the number of new products that will reach the market in the coming years. By partnering with ICs, other offices in the NIH Office of the Director, and university technology transfer offices, OTT has introduced new IT tools and procedures to improve operational efficiencies and increase the number of technologies transferred for commercialization to the private sector. OTT is committed to utilizing new IT tools and developing new strategies for federal laboratory technology transfer to enhance the impact of NIH research on public health. The future is bright in this regard.