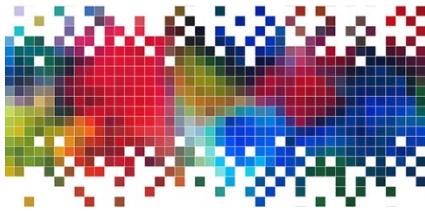
FY-2014 ANNUAL REPORT

NIH OFFICE OF TECHNOLOGY TRANSFER

National Institutes of Health
Office of Intramural Research

U.S. Department of Health & Human Services



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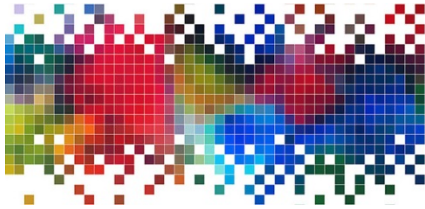


Message from the Director

Dear colleagues and partners in commercialization:

It's been a year of successful technology transfer as well as the beginning of an important transition in technology transfer at the NIH. In a year of significant changes the Office of Technology Transfer (OTT) staff worked hard to not only maintain but surpass the previous year's productivity. They are due a great deal of credit for their patience and dedication.

After passage of the Federal Technology Transfer Act in 1986, the NIH established, within the Office of Intramural Research (OIR), the OTT as a centralized group with primary responsibility for patent and license matters for all of the NIH Institutes and Centers as well as the FDA. Non-license transactional agreements have been handled in IC Tech Transfer Offices or serviced by NIH IC Tech Transfer "Servicing Centers".

Over the last 25 years, no significant changes have been made to the organizational structure of technology transfer between the agency level office and the IC offices, while there were significant changes at many of the ICs in the personnel and types of services offered by the IC tech transfer offices. This static process and organizational infrastructure showed the stress fractures as the rate of change in science, technologies, innovations and the marketplace continued at greater and greater speed. In 2013 an outside review panel of technology transfer experts was convened at the request of Dr. Michael Gottesman the NIH Director of the Division of Intramural Research and tasked with conducting a review of the OTT. A recommendation of this committee, and a subsequent recommendation from the NIH Tech Transfer Steering Committee, was to place the authority and responsibility for the implementation and execution of patenting and licensing throughout the NIH Institutes and Centers (ICs) — aligning Technology Transfer expertise with the science and the mission of the institutes and centers that generate the research materials and innovations with subsequent licensing and patenting.

The reorganization is underway and will be fully in effect as of October 1, 2015. The new structure is expected to result in less disruption in the flow of successive activities most often associated with the discovery and developmental path that occurs in life science research. The NIH ICs currently have multiple levels of tech transfer expertise and knowledge of their IC laboratories. By coupling this existing expertise with the responsibility and authority for patenting and licensing the NIH hopes to maximize the

outcomes of IC research and produce a more reliable technology transfer practice continuum.

The OTT will retain functions for the administration of royalties, the monitoring and enforcement of NIH patents, coordination of marketing activities, and the administration of legal services related to patent prosecution, employee invention reports and the support of the technology transfer IT system. It will manage the central website that includes a searchable database of all NIH technologies available for licensing. OTT's HHS customers are also planning changes for their technology transfer support. The FDA is considering standing up its own patenting and licensing functions, and the CDC patenting, licensing and remaining technology transfer activities will be reestablished within NIAID.

Senior staff within OTT have also made significant position changes. Mark Rohrbaugh moved from the office in October to be a Special Advisor for Technology Transfer in the OIR, and Richard Rodriguez became Acting Director, OTT. Ann Hammersla has moved from the position of Director, Division of Policy, OTT, to manage extramural policy matters in the Office of Policy for Extramural Research (OPERA), OER.

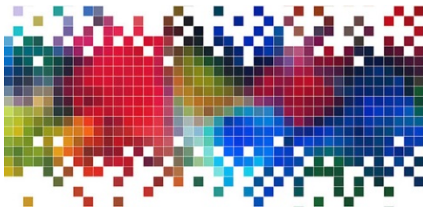
Technology Transfer policy functions will realign to the Office of Extramural Research (OER) for extramural matters, the OIR and the Office of Science Policy (OSP) for trans-NIH tech transfer matters, and the NIH ICs as appropriate.

With this reorganization, NIH will continue its efforts to enhance technology transfer of science-driven discoveries supported by services from transfer, to development to commercialization in a more cohesive manner. The overall goal is to support the technology transfer ecosystem at NIH as it continues to evolve into in readily adopting best practices and is an even more dynamic, agile and flexible organization to keep up with the changing needs of our science programs.

Sincerely,

Richard M. Rodriguez, M.B.A.
Acting Director, OTT

Mark L. Rohrbaugh, Ph.D., J.D.
former Director, OTT



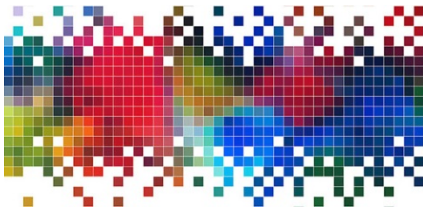
Mission Statement

The mission of the Office of Technology Transfer (OTT) is to improve public health and safety through the management of National Institutes of Health (NIH), Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) inventions and in doing so serve a leading role in public sector biomedical technology transfer policy and practice.

NIH, FDA, and CDC are agencies of the Department of Health and Human Services (HHS).

PURPOSE

OTT serves as a bridge that connects the inventive discoveries made by scientists in the NIH, FDA, and CDC 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. OTT also serves as the lead technology transfer office for HHS. In carrying out its mission and purpose, OTT applies its policies and practices to the management of HHS'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 in the development of the technology to ensure commercialization milestones are reached, products are brought to the market, and royalty fees are paid. In addition, OTT makes agency determinations for requests from both intramural scientists and extramural institutions to assign invention rights to inventors or to third parties, and requests for waivers of US manufacturing requirement for products sold in the US under licenses of NIH funded inventions.

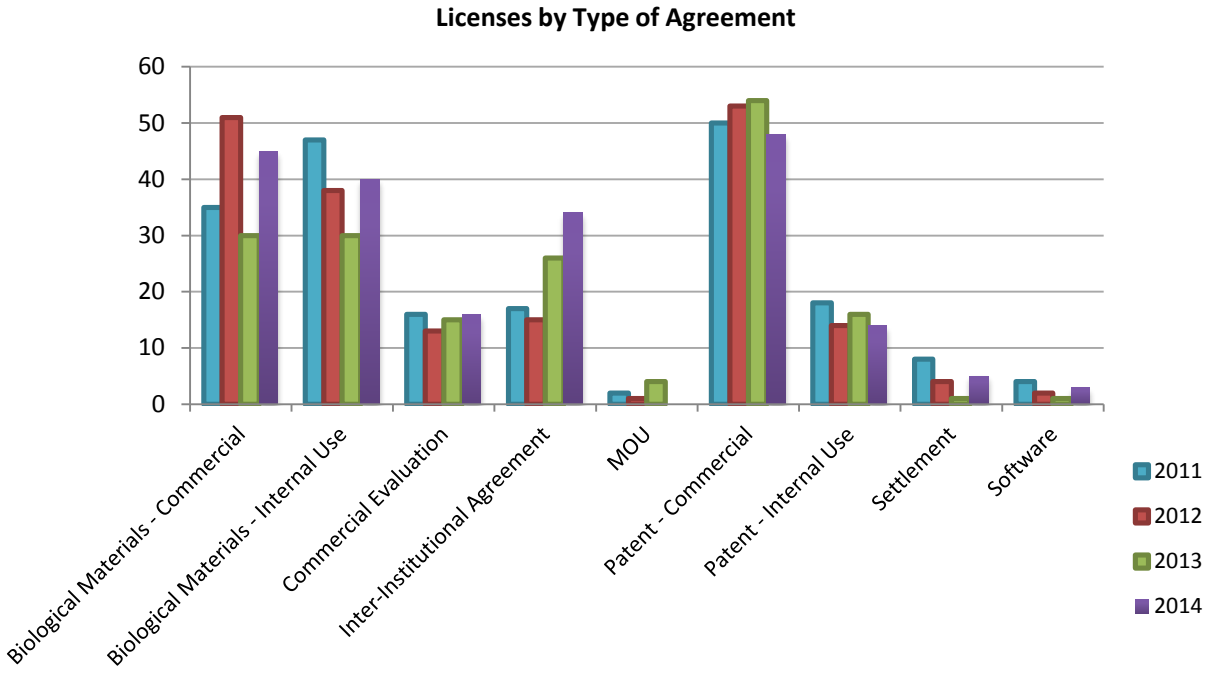


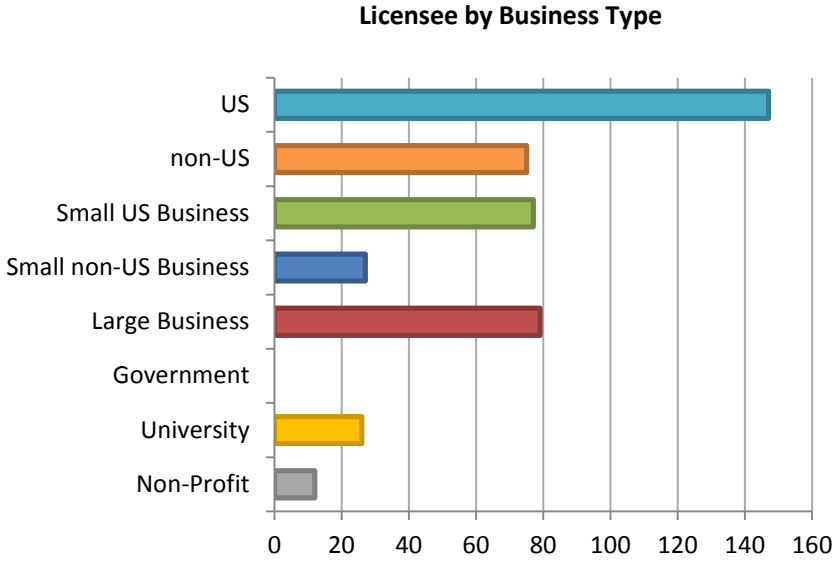
Licensing and Patenting

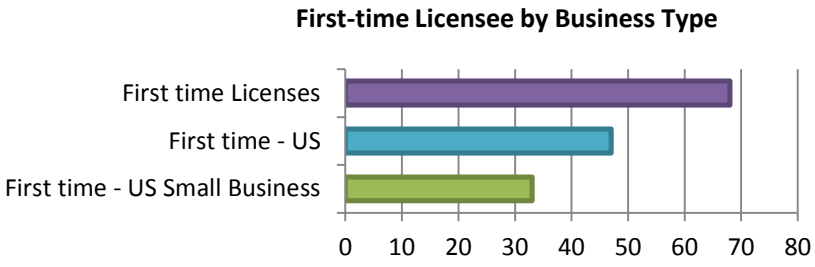
The ultimate goal of any technology transfer office is effective and responsible licensing to facilitate the development of early stage technologies. Inventions made by scientists in the NIH Institutes and Centers (ICs), the FDA, and the CDC are reported to the NIH OTT through their respective Technology Development Coordinators (TDCs) who provide important input to OTT for its assessment of patenting and licensing decisions. OTT has continued its efforts to work ever more cooperatively with IC technology transfer staff and companies to facilitate the licensing of inventions, which at times is enhanced by collaborations with scientists in the ICs to support commercial development of the technologies. The goal for all involved is to enhance the likelihood that these efforts will lead to products to improve public health. In addition, these licensing activities help stimulate the economy when the Government's high-growth technologies are developed into products by small entrepreneurial companies as well as by large biotechnology and pharmaceutical companies. Charts of our metrics involving NIH and FDA inventions can be found at http://www.ott.nih.gov/tt-metrics-intro. The metrics include CDC activities except where noted.

In Fiscal Year 2014 (FY14), OTT received 370 invention disclosures from HHS intramural scientists, and in sharing power of attorney with our contract law firms filed 153 new US patent applications, filed a total of 358 US patents, and had 197 US patents issue. Outside the US, 77 new patent applications were filed and 102 patents issued.

In FY14, OTT executed 222 license agreements, more than each of the previous three years. Of these, 66% were with US companies (35 more than last year), half of which were small businesses—9% more than last year. The number of licenses to non-US companies rose by seven. There were 68 first-time licensees—47 were US based and of these 33 were small businesses. The Start-Up license remains attractive to start-up companies with 37 new agreements (for more information see www.ott.nih.gov/nih-start-exclusive-license-agreements). The number of patent commercial licenses dropped by six, while the number of biological materials commercial licenses increased by 15.

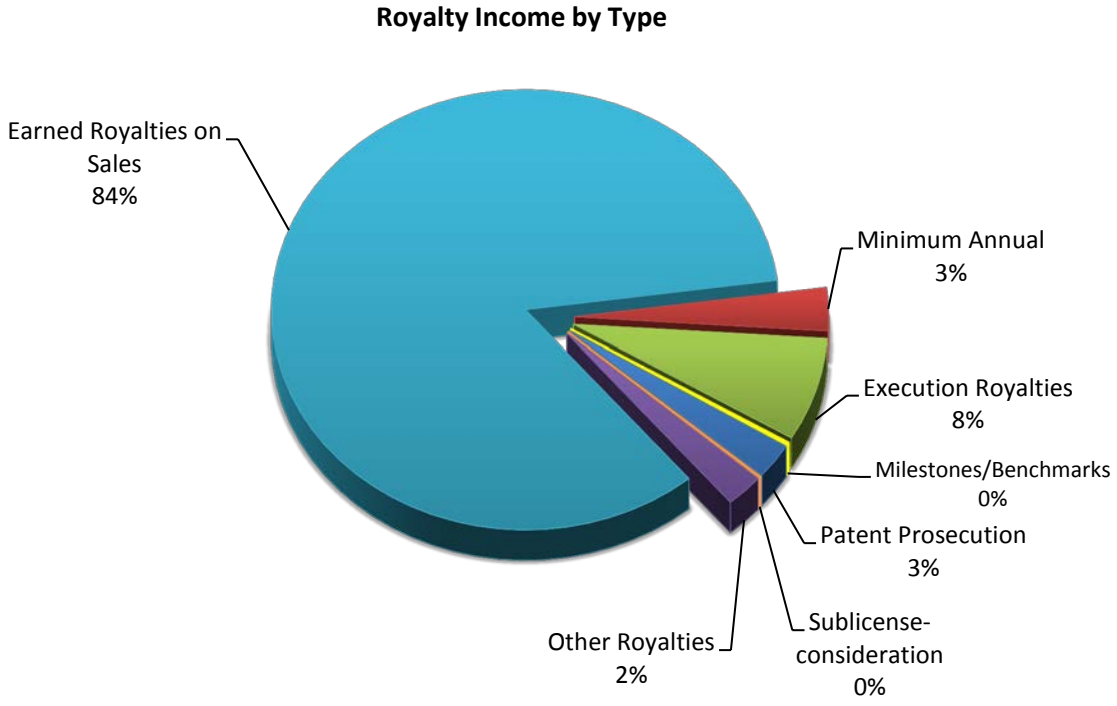

Licenses by Type of Agreement
60
50
40
30
20
10
0
Biological Materials - Commercial
Biological Materials - Internal Use
Commercial Evaluation
Inter-Institutional Agreement
MOU
Patent - Commercial
Patent - Internal Use
Settlement
Software
2011
2012
2013
2014


Licensee by Business Type
US
non-US
Small US Business
Small non-US Business
Large Business
Government
University
Non-Profit
0
20
40
60
80
100
120
140
160



Sales of products built around licensed inventions remain strong with 367 licensees reporting a total of $7.6B in sales of these products. While the total product sales by licensees increased by $0.6M (8.6%) over FY13, the actual number of licensees reporting sales increased by only 9 (2.5%). This is in line with the increasing royalties from the top products. It is anticipated that royalties will begin to decline after FY17 when patents expire on these higher income products.

Royalties collected on product sales, primarily drugs and biologics, account for 84% of the $138M in royalties collected in FY14 (see the chart below), five percentage points higher than last year. The top 20 products generating royalty income account for nearly 84% of the total royalty income. Thus, sales of a limited number of products generate the vast majority of the royalty income.



The FY14 technology transfer outcomes follow a long trend of successful licensing of biomedical inventions made by NIH and FDA scientists and reflect HHS's dedication to technology transfer — the broader economic impact of which becomes especially important during difficult economic times. While most of the royalty income collected by OTT is based on sales of pharmaceutical and biotechnological products and services, most of the actual products and services 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.

As was the case last year, the three best-selling products utilizing technology licensed from NIH are Prezista™, a novel protease inhibitor for the treatment of HIV-1 in patients who are non-responsive to existing antiretroviral therapies, Gardasil®, a vaccine to protect against cervical cancer, and Synagis®, a monoclonal antibody for the treatment of Respiratory Syncytial Virus (RSV) in infants.

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

The National Cancer Institute (NCI) working with the OTT and in partnership with the nonprofit Center for Advancing Innovation (CAI) and the Avon Foundation for Women,

launched The Breast Cancer Startup Challenge, a first-of-a-kind, international, university-based competition. Through the creation of startup companies, it represents a new model to accelerate the transfer of federally funded inventions to the marketplace, specifically focused on increasing the volume of developing emerging breast cancer technologies. In 2013, NCI entered into a Partnership Intermediary Agreement (PIA) with CAI to evaluate and offer recommendations to market the NCI patent portfolio. An outcome of that effort was the idea to create a business startup challenge to move certain technologies forward. Breast cancer was selected as the challenge focus, and a three-way collaboration agreement was developed to implement the challenge by NCI, CAI, and the Avon Foundation. Nine patented NCI intramural research technologies that show great promise to advance the treatment, diagnosis, and prevention of breast cancer were simultaneously transferred to launch ten new Start-up companies in 2014 under the Challenge. The NIH/NCI's patented inventions include therapeutics, diagnostics, prognostics, and one device, vaccine, delivery system and health IT invention.

A second Challenge, The Neuro Startup Challenge, modeled after the previous one launched in September 2014 and is based on 16 neurologic-related inventions across multiple NIH institutes.

The NIH National Institute of Allergy and Infectious Diseases (NIAID) developed a new SBIR-TT pilot program under which small businesses will compete for SBIR funding to advance the development and commercialization of diagnostic inventions selected from a group of 18 from the NIAID intramural program. OTT will work with the NIAID Technology Transfer and Intellectual Property Office to license the technologies to the recipients of these grant awards.

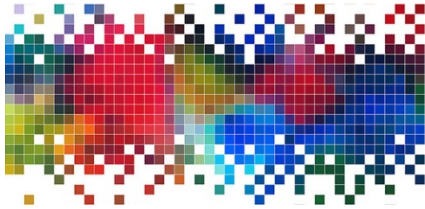
A tissue microarray (TMA) is an important technique used by pathologists to accurately analyze tissue samples. It is a means of aggregating tissue samples in an organized grid fashion for high throughput analysis. Automated TMAs are commercially available, but they are expensive ($16,000-$230,000) and require specialized training and experience to apply the technology. This technology from the NIH/NCI addresses the high instrumentation cost and specialized training barriers of existing commercial tissue microarrays, and offers a simplified, manual, low-cost tissue alternative for use in clinical and research settings to validate the immunohistochemical (IHC) assays for cancer diagnosis. The NCI team was led by Dr. Stephen Hewitt, a research pathologist who first conceived this invention in response to his observation that the community needed a simpler and more affordable instrument for the discovery and validation of biomarkers to ultimately improve cancer research and diagnosis. Once patented, the

NCI Technology Transfer Center identified that the advancement of the technology could be well-served by the Small Business Innovation Research Technology Transfer (SBIR-TT) program, and subsequently recommended it as one of the first NCI technologies for the program. The technology was released as a contract topic for the SBIR-TT and was awarded to a small company, Micatu, Inc., which secured a patent license from OTT. Micatu completed Phase I of the award, and was later awarded Phase II grant funding in June 2014. The transfer of this NCI technology highlights the use of the SBIR-TT mechanism to transform a patented NCI invention into a commercialized product. The commercialization of this instrument provides researchers and pathology laboratories with access to a technology that was not previously accessible because of technical complexity and significant cost. From Dr. Hewitt's original 2003 drawing, a high-quality, precision instrument with functional and speed capabilities rivaling automated instruments that cost from 8 to 30 times as much is being realized. The "Microarray," likened to a "histology lab in a box," operates without power, making it accessible in the field. Through the vision of Dr. Hewitt and the engineering know-how of Micatu, the result of this technology transfer is an affordable, turnkey instrument that gives investigators the ability to construct their own TMAs rather than having to go to a core service laboratory.

In April 2013, President Obama unveiled the "BRAIN" initiative, which called on the scientific community to better understand the human brain in an effort to treat, prevent, and cure neurological diseases. For example, anxiety, depression, substance abuse, and post-traumatic stress are a few pervasive neuropsychiatric diseases that afflict more than 150 million people in developed countries, and approximately 15 million of those are in the U.S. A joint effort from the NIH National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Drug Abuse (NIDA) developed a unique H-coil configuration for a deep therapeutic transcranial stimulation (dTMS) system. This dTMS system is capable of delivering magnetic fields to the deep brain, where it stimulates the limbic system, an important area of the brain modulated by dopamine and implicated in multiple neurological and neuropsychiatric disorders. Dr. Abraham Zanger, who originally developed the technology at NIDA, left NIH and cofounded the company Brainsway, to which OTT exclusively licensed patents covering the H-coil design and its implementation in therapeutically stimulating the deep brain. The company later engaged the NINDS Technology Transfer Office to put in place a clinical collaboration to study the uses of its dTMS system for treating Parkinson's disease. In this technology transfer transaction, the inventor was able to license from the federal government the technology in which he had played a crucial development role; find market-experienced people with whom to start a company; find

multiple national research organizations for collaborations, including re-engaging with his original collaborators at NIH to initiate a clinical research protocol; and, ultimately market a device that received clearance from the Food and Drug Administration (FDA) under a 510K application. In July 2011, FDA approval was awarded for the treatment of specific depression disorders, and approval is pending for a variety of other neuropsychiatric disorders. The dTMS system has also been approved in Europe (under the CE mark) for use in treating all forms of clinical depression, bipolar disorder, post-traumatic stress disorder (PTSD), schizophrenia, smoking cessation, Parkinson's disease, neuropathic pain, Alzheimer's disease, and autism. Ongoing studies include the use of dTMS in a variety of substance addictions, Tourette's syndrome, obesity, anorexia nervosa, ADD/DHD, and stroke rehabilitation. Currently, the system is in use at more than 15 hospitals and care facilities throughout the U.S.

Members of the CDC Office of Technology and Innovation and the NIH Office of Technology Transfer were selected as 1 of 13 teams (out of 72 submitted proposals) to join the Winter 2015 Class of The HHS Ignite Accelerator. The HHS Ignite Accelerator program provides funding for and teaches teams lean start-up methodologies to rapidly assess problems and create and iterate solutions across HHS. Over three months of intensive training starting at the boot camp in January 2015, the CDC/NIH team will have completed dozens of customer interviews (to assess the main tech transfer problems customers/inventors experience), developed and piloted an interactive web-based Technology Transfer Invention Disclosure Portal (to enhance internal collaboration, provide invention tracking information to CDC inventors, and simplify and streamline technology transfer processes, such as invention disclosures) and created two dynamic Educational Cartoons (that generate technology transfer awareness and teach the basic concepts of the process). The team's ultimate goal is to help accelerate the transition of innovations from public research into private development, thereby stimulating economic growth.



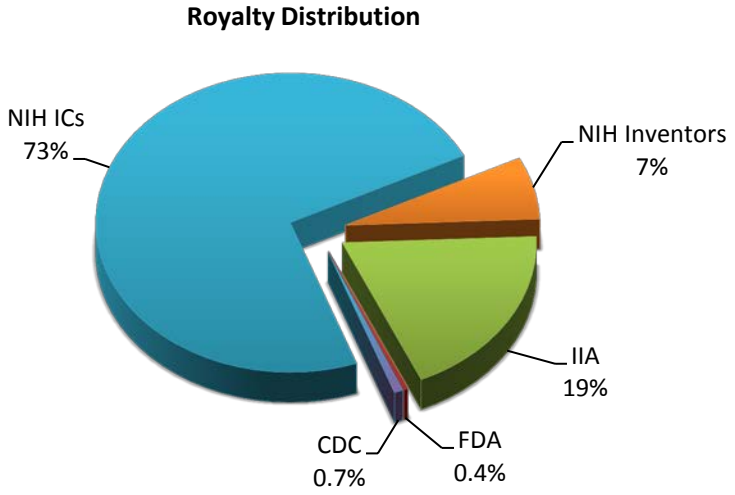
Royalty Administration

While the essential purpose of the technology transfer process is to improve public health and safety, the collection of royalties is an important by-product. Royalties collected from licensees of intramural research program inventions are distributed to the inventors, the Institutes and Centers (ICs) that developed the inventions, and, when relevant, extramural institutional co-owners of the inventions. There are various payments collected as royalties under licenses, including upfront license payments, patent reimbursement costs, annual minimum payments to maintain a license, payments associated with the achievement of commercial development milestones, and "running royalties" as a percentage of the sales of products or services. By far, the largest amount of royalty funds is received on sales of products. Royalty collections fluctuate from year to year as a result of factors such as sales volume, FDA approvals (when needed), competitive market forces, changes in standard of patient care, license termination when patents expire, etc. The intramural laboratories use the income to pay technology transfer expenses (such as patent expenses and technology transfer administrative costs) and to support research and training programs, including the purchase of expensive laboratory instrumentation or pharmaceuticals for clinical trials. Royalty funds thus support biomedical research and development activities that might otherwise remain unfunded.

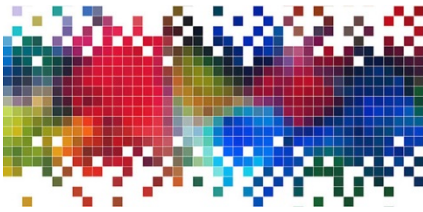
OTT administered $138M in royalties in FY14 with 73% of the total going to the NIH ICs and about 1% going to the FDA and CDC. Inventors from the three agencies received 6.7% of total royalties. NIH distributed 19% of the royalties under Inter-Institutional Agreements (IIAs) to our extramural partners that co-owner some of the licensed inventions.

This royalty income was received under 844 license agreements with 415 reporting sales. Royalty levels continued an upward trend with a 19% increase over FY13, setting a record high. Although royalties on some products decreased in FY14, others have been steadily increasing over the last few years with about three-quarters of all royalty income coming from product sales of five technologies. This also means that future royalty income will be highly sensitive to changes in sales of these products and expiration of patent licenses until major new products in the pipeline reach the market. In particular, patents and licenses on several of the top income producing products will expire after FY17.

In accordance with statutory requirements and NIH policy, inventors under a given license receive annually the first $2,000 in royalties; 15% of royalties above $2,000 and up to $50,000; and 25% of royalties in excess of the first $50,000 up to a cap of $150,000 per year per inventor. Inventors who have assigned their inventions to the US Government receive royalty payments even when they retire or move to other institutions. In FY14, 1,281 HHS inventors received royalty payments amounting to $9.3M. Of these, 258 were first-time recipients, and 30 reached the statutory cap.



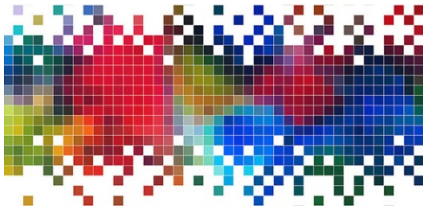
During this fiscal year, OTT obtained reimbursement of patent prosecution costs amounting to $3.5M.



Monitoring and Enforcement

To ensure compliance with license obligations and development of licensed technologies, OTT maintains a monitoring and enforcement program for its portfolio of 1,301 active license agreements. During FY14, 86 licenses expired, an increase of 17), and 34 licenses were terminated, four of which were "for cause" and the remainder at the request of the licensees. OTT identified and investigated nine cases of alleged infringement of HHS patents. One of these cases was settled with the party taking a license, four were closed for non-infringement, and four were closed for other reasons, such as the company merged with another company with an active license or the alleged infringing company no longer produced the product. At no time, however, did NIH ask for a product to be withdrawn or seek an injunction. OTT conducted internal audits of all licenses for administration and royalty compliance.

Additionally, OTT contracted with a firm to conduct an external audit of a licensee with significant licensed product sales to verify proper payment under the terms of the license. Overall, OTT's enforcement activities ensured proper payments by licensees and resulted in the collection of over $5.4 million in overdue royalties.



Policy Activities

The scope of OTT's policy activities is broad, including biomedical technology transfer and intellectual property matters and support of legislative affairs. Leveraging the experience of NIH and US universities in technology transfer, OTT drafts and communicates policies and procedures to enhance the translation of early-stage technologies into practical application for the benefit of public health. OTT, working through the NIH Office of Legislative Policy and Analysis, serves as a resource for NIH review of a variety of legislative initiatives directed to technology transfer, intellectual property policy, and associated operational issues. Additionally, OTT provided support for training activities and expert advice to programs within HHS as well as across the Federal Government.

Among its administrative duties, OTT provides the agency determination for requests by the extramural and intramural communities for waivers of rights in inventions. In FY14, OTT reviewed 60 extramural waiver requests, comprising 40 requests to waive title to inventors, 11 requests to assign title to a third party, and nine requests to waive the US manufacturing requirement. OTT also reviewed one request to waive title to an intramural inventor.

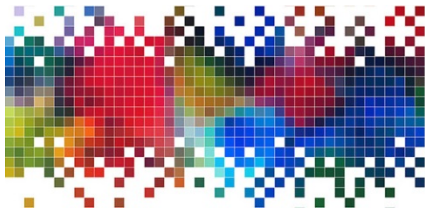
OTT has led a variety of initiatives directed to NIH-wide technology transfer policies and procedures. OTT representatives serve as Vice-Chair and Executive Secretary of the Public Health Service (PHS) Technology Transfer Policy Board (TTPB). The TTPB serves as the principal advisory board to NIH, the CDC, and the FDA in establishing and modifying, as appropriate, PHS technology transfer policies. In that capacity, OTT led work groups, which included representatives from the PHS technology transfer community, to complete the comprehensive review of policies and procedures related to patenting, licensing, Cooperative Research and Development Agreements, material transfer agreements, royalty disbursement, and extramural activities.

Members of OTT actively participate in a wide array of NIH and US Government projects that address programmatic components of technology transfer. Within the NIH, OTT staff serves on the Trans-NIH Task Force on Nanotechnology, the Data/Resources Sharing Interest Groups, the NIH Biomarkers Consortium, and the Cancer Human Biobank. Members of OTT represent HHS and NIH in interagency and intergovernmental fora, such as the Inter-Agency Working Group on Technology Transfer, Global Issues in Nanotechnology Working Group within the U.S. Government's

National Nanotechnology Initiative, and the Interagency Working Group for the Working Party on Biotechnology in the Organization for Economic Cooperation and Development. OTT is actively involved with the HHS Innovation Council and other intra-governmental efforts to apply innovative tools to enhance technology development and transfer.

OTT staff served as advisors to NIH and HHS on many *ad hoc* issues related to technology transfer and intellectual property, including gene diagnostic technologies, stem cells, biotechnology patenting, patent reform, mouse model access, and NIH's drug rescue and repurposing program.

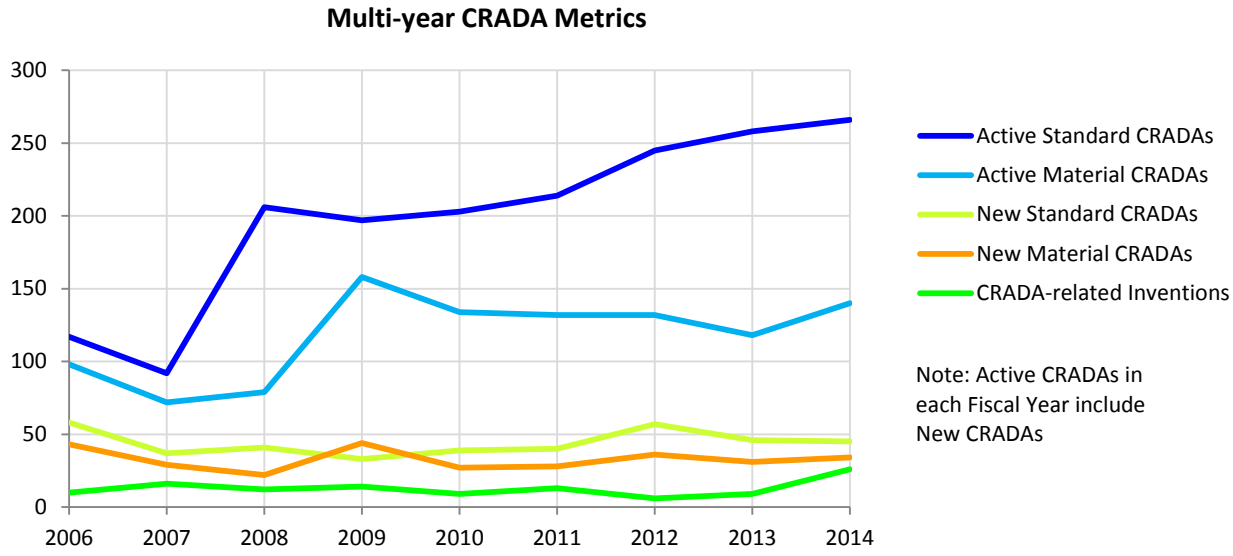
In support of negotiations of inter-institutional agreements between NIH and university collaborators, OTT staff spearheaded efforts to encourage and enhance dialogue between NIH and university technology transfer offices. OTT advanced discussions among representatives from NIH's extramural grantees, the Council on Governmental Relations, AUTM, and NIH IC technology transfer offices. These discussions facilitated efforts to update the various material transfer agreement models and draft new models. Through these activities, OTT policy staff supported the transfer of materials among researchers and non-profit entities in a direct and expeditious manner.



NIH 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 pursuit of common goals. CRADAs are negotiated by technology transfer staff in the ICs. OTT collates and administers CRADA data and serves as a member of the NIH CRADA Subcommittee, which reviews all NIH CRADAs. While there are various mechanisms that support collaboration between companies and NIH scientists, the CRADA is the only mechanism that permits the NIH to offer an exclusive option to license inventions that could be made within the scope of the collaboration agreement and, to the extent contemplated, allows laboratories to receive funds from the company collaborator. NIH is not legally permitted to transfer funds to the collaborator under a CRADA but can collaborate with companies receiving funds under separate awards, such as SBIR or STTR.

During FY14, there were 406 active NIH CRADAs, an increase of 8% over last year and the highest in the past ten years. Of these, 266 were standard CRADAs and 140 were Materials-CRADAs (a way to transfer a company's proprietary materials to the NIH for research purposes). During the year, NIH executed 79 new CRADAs; 45 of which were standard and 34 were Material-CRADAs. Eighty four percent of these were with US companies, of which 53% of these were small businesses. The number of new CRADAs executed in FY14 decreased by two compared to FY13, and the percentage of new CRADAs with small US companies was 14 percentage points higher. From the active CRADAs, 26 new inventions were reported by researchers at five different Institutes.

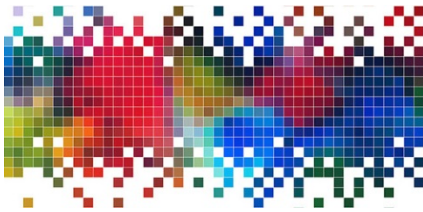


CRADAs are complex documents, due in large part to the wide variety of statutory and policy requirements involved. CRADAs negotiations can thus be a time-consuming activity, delaying promising science until the terms of the agreement can be agreed upon. This year the technology transfer offices in the NIH ICs and the OTT finished a comprehensive review of CRADAs with the intent of moving the document away from a "model" approach to a "term sheet" approach. As part of this process, NIH is designing an online system, named CRADA Builder, which would allow NIH, CDC, and the FDA to generate agreements using a series of guided questions to tailor the terms to the specific needs of the collaboration. The new system is expected to be available by the spring of 2015.

The Breast Cancer Startup Challenge (BSSC) is a partnership between the National Cancer Institute, the OTT, the Center for Advancing Innovation (CAI) and the Avon Foundation for Women. The primary goals of the BCSC are to accelerate the process of bringing emerging breast cancer technologies to market and to stimulate the creation of start-up businesses around the inventions. The BCSC was comprised of nine patented technologies from the NCI intramural program and one from an Avon-funded research facility judged appropriate for startups and showing great promise to advance breast cancer research. Teams of business, legal, medical/scientific, engineering, computer science students, seasoned entrepreneurs as well as others from industry competed by creating business plans, performing live pitches and developing elevator speeches focused on developing and commercializing the inventions. In March 2014, the challenge winners and finalists launched their startups, began to raise funding and negotiate a license for the invention. As a result of the BCSC, more than 270 challenge

competitors received startup and entrepreneurship training, 10 breast cancer-related inventions are being advanced, and 11 startups that can help create new jobs were launched. In recognition of this innovative program, NCI and OTT staff received a group award from the National Cancer Institute and an HHSinnovates Secretary's Pick Award.

Based on the successful BSSC model, the Neuro Startup Challenge (NSC) was launched in September 2014, centered around 16 unlicensed brain-related inventions from multiple NIH institutes. In this challenge, 61 teams comprised of graduate-level medical and business students and postdocs, as well as seasoned entrepreneurs, were accepted into the competition to create strategic business plans and launch startups to develop and commercialize the selected inventions. The CAI is continuing its partnership role with NIH Technology Transfer in this new challenge, and Heritage Provider Network is engaged as the philanthropic partner.



Other Initiatives

ENTREPRENEURSHIP AND ECONOMIC DEVELOPMENT

In FY14, OTT continued its active participation in entrepreneurship and economic development activities that support the development of new innovative biomedical products.

Highlights of the year included ongoing activities between OTT and BioHealth Innovation (BHI) under a Partnership Intermediary Agreement (PIA). BHI is a regional private-public partnership in Maryland focusing on commercializing market-relevant health innovations and small company access to early-stage funding. An OTT Entrepreneur in Residence (EIR) is an industry expert with scientific, entrepreneurial/managerial, and financial experience who works with NIH to identify, evaluate, and support the development of new start-up companies based upon technology license agreements from OTT. EIRs do not have access to proprietary information OTT receives from companies seeking or obtaining licenses. During the past year NIH benefited from BHI's assistance in evaluating the commercial potential of technologies via BHI's mentoring of the NIH Entrepreneur and Commercialization Club, which invites scientists from the post-doctoral community to explore the commercialization potential of intramural technologies as an educational exercise.

A second major effort for the year again was the expanded project with the Carey Business School at Johns Hopkins University in Baltimore, which conducts graduate level business educational programs with a specific focus on healthcare and health technology development. Operating under a Memorandum of Understanding Agreement, OTT staff worked with MBA students and faculty in their "Discovery 2 Market" classes for feasibility analysis and recommendations regarding technologies from the portfolio of NIH and FDA intramural inventions. In FY14, this program was expanded to include MBA students in classes at both the Baltimore, MD, and Washington, DC, campuses of the university. By providing actual current healthcare-related inventions for student analysis, OTT licensing and patenting managers receive additional feedback and insight into the market dynamics and commercial potential associated with inventions in their portfolios. As a result, NIH technology managers received several promising leads for both licensing and research collaborations with industry. OTT efforts with this program in FY14 were recognized by a Federal Laboratory Consortium (FLC) Mid-Atlantic Regional Award and as a Semi-Finalist in the "HHS Innovates" award program.

EDUCATIONAL AND TRAINING PROGRAMS FOR SCIENTISTS

FY14 continued as a very busy year in terms of educational and training activities conducted by OTT staff in the areas of technology transfer and entrepreneurship.

One of the most popular programs was the open enrollment courses organized or delivered by OTT staff members for the "Advanced Studies in Technology Transfer" certificate program hosted by the Foundation for Advanced Education in the Sciences (FAES) Graduate School at NIH. Interest in technology transfer training remained strong with this non-degree program still receiving the largest enrollment of any at the FAES Graduate School at NIH. Class offerings continued at a level of more than 20 different courses, ranging from "Introduction to Technology Transfer" to "Translational Medical Product Development".

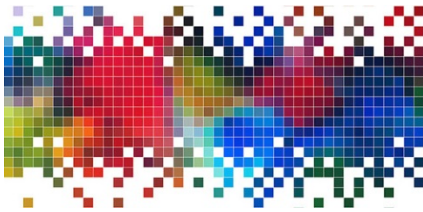
OTT staff members were again co-organizers and speakers for several programs with the National Council for Entrepreneurial Tech Transfer (NCET2). These included the "Research Commercialization Webinar Course," an introductory course given via the web during the spring and fall semesters, as well as the "University Start-Ups Conference" annual meeting and workshop at the Washington Convention Center.

Staff members also organized and participated in the "International Mentoring Program in Technology Transfer" whereby technology transfer officers and health officials from other countries come to NIH for a multi-week study and education program based at OTT. Preference is given for applications from developing countries – there is no fee charged but attendees must cover their travel and housing expenses. During FY14 OTT with the assistance of the NIH institute tech transfer offices hosted visitors from: Turin Polytechnic (Italy); University of Calabria (Italy); St. Anne's University Hospital Brno (Czech Republic); Bordeaux University Medical Center (France); Wellcome Trust (United Kingdom); Leloir Institute (Argentina); and the National Scientific and CONICET Technical Research Council (Argentina).

OTT also partnered with the NIH Clinical Center to offer an elective in "Technology Transfer" for visiting internal clinicians participating in their International Clinical Fellowship Program.

For the NIH Research Festival this year, OTT again organized and moderated a symposium entitled "Commercial Development of My Own Research Discoveries: Personal Stories of Former NIH Scientists" and presented two posters – one on "Careers

in Technology Transfer & Business Development for Scientists" and another on "NIH and the Federal Laboratory Consortium (FLC)".



Other Accomplishments

NATIONAL & REGIONAL AWARDS

Members of the Office were recognized with regional and NIH awards for their significant contributions to technology transfer as well as the overall mission of NIH. These included one group NIH Director's Award and two group Office of the Director Honor Awards, Four FLC Mid-Atlantic Region Awards, a FLC Mid-Atlantic Regional Partnership Award, the "Deal of Distinction Award" from the Licensing Executives Society, a group award from the National Cancer Institute, and an HHSinnovates Secretary's Pick Award.

PUBLICATIONS

"Leveraging Public Private Partnerships to Innovate Under Challenging Budget Times," Portilla, L.M. and Rohrbaugh, M.L. *Current Topics in Medicinal Chemistry*, Vol. 14, pp. 326-329 (2014).

"NIH Inventions Translate into Drugs and Biologics with High Public Health Impact," Chatterjee, S.K. and Rohrbaugh, M.L., *Nature Biotechnology*, Vol. 32, pp. 52-58 (2014).

"Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs" Steven M. Ferguson and Uma S. Kaundinya
In: Craig Shimasaki, ed. Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies, pp. 185-206, Elsevier Inc. (2014).