

Office of TECHNOLOGY TRANSFER

BULLETIN

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National Institutes of Health

May 1992

NTIS Transition Underway

Developing and implementing mechanisms to improve the handling of licensing activities involving PHS inventions — particularly royalties — is underway as part of a transfer of these functions from the National Technical Information Service (NTIS) to NIH. *Dr. James O. Mason*, DHHS Assistant Secretary for Health, officially notified NTIS of the transition in a letter in late February.

As a follow-up, OTT has assisted in the preparation of a NIH workplan detailing tasks and a timetable for the transition, which will affect licensing and handling of royalties from inventions at NIH, ADAMHA, and other PHS agencies.

A key element of the NIH workplan focuses on OTT working closely with the NIH Division of Financial Management (DFM) to implement procedures necessary to facilitate and expedite tracking and disbursement of royalties to inventors and to Institutes/Centers/Divisions.

The workplan is the result of ongoing meetings and discussions involving *Ellen Wormser*, OASH; *Douglas Campion*, NTIS; *Penelope Strong*, DFM; *Sandy Shotwell*, Chief, OTT Licensing Branch; *Tom Wiseman*, Acting Chief, Patent Branch, and *Kim Hooven*, OTT Administrative Officer. *Mike Miller*, OTT Technology Management Branch, is acting as transition coordinator.

Other aspects of the workplan involve weekly meetings between NTIS and OTT licensing specialists to coordinate licensing activities during the transition period. Some activities of the Patent Branch involving foreign filings will also be affected by the transition. As a preliminary step, OTT has begun to handle all international phase PCT filings for new cases filed with the U.S. Patent and Trademark Office as of April 2, 1992.

OTT Licensing Activities Show Growth

Over the past two and one-half years, the number of license agreements negotiated by the OTT Licensing Branch has shown a steady increase. Staff size has increased dramatically this fiscal year, and we are able to pursue licensing agreements more effectively in addition to making licensing determinations behind the scenes. Beginning in FY 90, the branch began handling

some PHS license agreements using its own staff, rather than relying totally on NTIS licensing specialists.

Between October 1-April 30 of this fiscal year, OTT licensing specialists equaled the number of license agreements negotiated by OTT during all of FY 91, as shown in the following table:

FY	Exclusive	Non-exclusive	Totals
90	1	8	9
91	3	13	16
92	2	14	16

Note: Non-exclusive numbers include Biological Materials Licenses and Commercial Evaluation Licenses

Licensing Of Unpatented Materials

To encourage the wider commercialization and distribution of research materials developed by intramural scientists, last fiscal year the Technology Licensing Branch established a program for the licensing of unpatented biological materials. Biological materials — such as cell lines, antibodies or bacterial clones — are licensed to companies for commercial use or sale, as is the customary practice in academia.

Unpatented biological materials are ones for which patent protection is unavailable due to prior publication and distribution or for materials whose value cannot justify the expense of patent filing. Unlike therapeutics and diagnostic applications, patent protection of such materials for research reagent sales or company internal use is not always necessary.

To help insure the success of the Biological Materials Licensing (BML) Program, inventors are asked to refer all material transfer requests from companies for unpatented materials to their ICD Technology Development Coordinators, who will contact the OTT Technology Licensing Branch. Companies whose requests are clearly commercial in nature will be asked to sign licensing agreements for their use or sale of the NIH-developed materials.

The cost of obtaining such a license by the firm is modest, reflecting the non-exclusive nature of the agreement and the lack of patent expense associated with the materials. Royalties collected by the Technology Licensing Branch under these

See special insert for NIH/PMA Technology Transfer Conference registration form and agenda

agreements are shared with the inventors and ICDs by the same formula used for patent licensing.

An additional advantage to inventors in having their unpatented materials licensed is that some companies may want to license the material and sell it to the research market. This can relieve inventors of the burden of supplying a unique material to other interested investigators in their field.

Companies with which OTT has signed BMLs this fiscal year are: BioMakor, Boehringer Mannheim, Charles River Lab, Epicentre, Genentech, Greystone Therapeutics, Makor Chemicals, Mitsubishi Kasai, Nippon Gene Company, Pfizer, Inc., Southern Biotechnology, and Upstate Biotechnology.

New CRADA Studies Cataract Prevention

OTT assisted the National Eye Institute in the negotiation of a CRADA with Storz Pharmaceutical Company, a division of American Cyanamid Company. The CRADA represents a multicenter, randomized clinical trial that will be conducted to assess the effects of high dose vitamins C and E, and high dose zinc, on the development and progression of Age-Related Macular Degeneration (AMD) and cataract.

Eleven Clinical Centers, enrolling 4,600 eligible participants to be followed for at least seven years, will participate in the study. Information resulting from the study should provide important stepping stones toward preventing these disorders.

OTT staff, have you taken your vitamins today?

ddI Patents Recognized

Two NIH patents and their inventors were finalists in the "1992 Inventor Of The Year Award" sponsored by the Intellectual Property Owners, Inc. Nominated for their work on the AIDS drug ddI (U.S. Patent Numbers 4,861,759 and 5,026,687) were *Samuel Broder, M.D.*, *Hiroaki Mitsuya, M.D.*, and *Robert Yarchoan, M.D.*, all of the National Cancer Institute. ddI, licensed by NIH to the Bristol-Myers Squibb Company, received FDA approval in October, 1991.

The Intellectual Property Owners, Inc. is a nonprofit association representing patent, trademark and copyright owners.

OTT Highlighted In White House's National Technology Initiative Conferences

In recognition of the leadership role NIH has played in encouraging private sector commercialization of federal research, NIH and its Office of Technology Transfer have been chosen to participate in the President's National Technology Initiative Conferences.

Speaking at the first two of a series of regional conferences on the new National Technology Initiative were NIH Director *Dr. Bernadine Healy*, OTT Director *Reid Adler* (Boston, MA) and OTT Licensing Branch Chief *Dr. Sandra Shotwell* (Research Triangle Park, NC).

These conferences have been designed to spur U.S. economic competitiveness by promoting a better understanding of the opportunities for industry to commercialize new technology advances. The program highlights the federal government's

investment in advanced technologies, such as biotechnology, much of which has strong commercial potential.

Encouraging closer cooperation among U.S. companies and better links with PHS laboratories is a central element of the initiative. As a result of OTT's participation in this initiative program, additional CRADAs and license agreements are anticipated for PHS research. For some ICDs, payoffs look to be immediate. Upon hearing *Sandy Shotwell* discuss opportunities at the nearby National Institute of Environmental Health Sciences, one firm has already begun CRADA discussions with NIEHS TDC *Jerry Phelps*.

POTPOURRI

Softball Update

The mighty warriors of the softball diamond, the Tech Transfusions, are off to a slow start this season in the NIH co-ed softball league. After the first game was rained out, *Mark Hankins*, our illustrious coach, led the team to another undeserved defeat in the second game. The score was something in double digits to something in single digits (it was closer than the score indicates).

The joint OTT/Hematology team includes *Dawn Ayers*, *Angela Barnes*, *Dacia Clayton*, *Art Cohn*, *Kelly Cummings*, *John Fahner-Vihtelic*, *Todd Leonard*, *Steve Ferguson*, *Larry Hyman*, *Darnell Martin*, *Dan Pence*, and *Sandy Shotwell* of OTT, along with teammates from the Hematology Department of the Clinical Center on the NIH campus. A growing number of friends and family gather weekly after work to cheer on the team (maybe we need more cheerleaders and fan support). Come on out and join in the fun!!

The schedule for the rest of May is:

Thursday, May 7: Fleming Field

Wednesday, May 13: Rock Creek Park #2

Wednesday, May 20: Rock Creek Park #2

Thursday, May 28: Fleming Field

Pats On The Back

To *Marjorie Hunter*, Senior Licensing Specialist; and *David Sadowski*, Senior Patent Advisor; for their generosity in equipping the OTT workroom to facilitate storage and preparation of lunchtime goodies. Marjorie donated a fabulous microwave oven, and Dave donated (and transported) a terrific refrigerator. Thanks from all the brown-bag bunch!!

We want to thank *Steve Ferguson* and *Todd Leonard*, Technology Licensing Branch, for their many contributions to this issue.

The OTT Bulletin is the unofficial internal monthly bulletin for the staff of the Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892. Tel: 301-496-0750. Any part or all of the Bulletin may be copied. Please send ideas, suggestions and written contributions to Elaine Ray, Technology Management Branch. The deadline for the June issue is May 22.

OTT Profiles

Carolyn Craig, a Program Analyst in the Technology Management Branch (TMB), is an old timer in OTT. She is one of three (including Dr. Philip Chen and Kathy Conn) who established OTT. (By the way, OTT was previously called the Office of Invention Development - OID.)

Carolyn serves as Project Officer on the annual PHS Technology Transfer Forum and on the publication of the annual NIH/ADAMHA/CDC Technology Transfer Directory. She also assists with the coordination of the foreign filing of PHS inventions. In March 1991, Carolyn was awarded the PHS Employee of the Month award by Dr. Louis Sullivan, DHHS Secretary.

When Carolyn isn't working or attending evening academic courses, she enjoys horseback riding and swimming. Most of all, Carolyn and her husband enjoy babysitting their eleven week old grandson, Michael. And, yes, it is the grandparents' prerogative to spoil their grandchildren, admits Carolyn.

Kelly Anne Cummings, a Legal Technician in the Patent Branch, is a former law firm paralegal from Texas who studied and worked in Spain before coming to OTT in December of 1990.

She is an alumna of Southern Methodist University, Dallas, where she received her Bachelor of Arts in May 1989, with a double major in English/Ibero-American Studies and a minor in Spanish. At SMU, she participated in the SMU-In Spain Program in the Spring of 1988, living with a Spanish family while studying at the Center for International Studies. Between September 1989-June 1990, she taught various levels of English to students ranging in age from 10 to 40 years of age at Parainfo Academy in Madrid, Spain.

Born and raised in El Paso, Kelly likes to travel, ski, and read. Hablas Espanol, pardner?

Margaret Griffin-Young, a Legal Technician with the OTT Patent Branch (currently serving as Docketing Administrator), joined the Branch when it was fully staffed under the Office of General Counsel, Public Health Service, in October 1988.

A Washingtonian, Margaret has 25 years' Federal government service. Most of those years were with the U.S. Government Printing Office as a writer/editor advertising government publications for sale by the GPO.

She enjoys taking various courses, vacationing at Myrtle Beach and editing, which she frequently does while reading newspaper editorials, magazines, and books.

James C. Haight, a Senior Patent Attorney, joined the Office of Technology Transfer in July, 1991. He is a graduate of the University of Notre Dame, and attended Georgetown School of Medicine prior to changing fields and transferring to the University of Maryland School of Law. While attending evening law school, he worked in immunology and virology for Baltimore Biological Laboratories and Flow Laboratories, Inc.

He became a patent examiner with the U.S. Patent and Trademark Office for three years after graduating from law school and returned in 1989 as an Examiner-in-Chief on the Board of Patent Appeals and Interferences, which is the final agency level of review for rejected patent applications. In

between these periods, he was in private practice of patent, trademark and copyright law, both with his own firm and "Of Counsel" with other patent firms.

He is a registered patent attorney and admitted to practice in Maryland, Virginia, and the District of Columbia and to the U.S. District Courts of Maryland and the District of Columbia, the Court of Appeals for the Federal Circuit, and the Supreme Court of the United States. He holds an "av" rating from Martindale-Hubbell Legal Directory and is a biographee in Who's Who in American Law.

Jim lives with his daughter Emily, who attends Montgomery College. His hobbies and interests include flyfishing, skiing, tennis, bike riding, jazz, reading, and travel.

Linda Harris, Secretary to the Chief of the Licensing Branch, originally worked in the Patent Branch as the Secretary for a year before transferring to licensing a year and a half ago.

For six and a half years, Linda worked at the NFL Players Association in Washington, DC as Assistant to the Director of Licensing and Special Events. She then worked for a year at PETA (People for the Ethical Treatment of Animals), where she was Special Events Director. (This was before PETA staged protests at NIH).

A native of Maryland, Linda is a licensed hairdresser, with a manager's license. As a certified open-water diver, Linda's outside interests center around water sports, such as water skiing, SCUBA diving, and just lying around at the pool/beach; and trying to keep track of her 18-year-old-son.

Todd Leonard, a Senior Licensing Specialist in the Licensing Branch, joined OTT in March 1991. He is responsible for the licensing activities associated with the AIDS and Cardiovascular portfolios. Todd is also responsible for assisting in the review and negotiation of Cooperative Research and Development Agreements (CRADAs).

From December 1986 to January 1991, Todd was Vice President of Business Development and Co-Founder of Medimorphics, Inc., a Minnesota-based biopharmaceutical company specializing in the commercialization of therapeutics and a subunit vaccine for the treatment of Cytomegalovirus. Prior to founding Medimorphics, he was employed in sales and marketing for a division of American Home Products and as a basic research scientist.

Todd's wife, Beth, works for the GAO. They have 2 sons—Danny and Zach. Todd's hobbies and interests include skiing, biking, SCUBA, sailing, reading, and travel.

Patricia Winston, a Stay-In-School in the Technology Management Branch working with Carolyn Craig, has been with OTT for 2 1/2 years. Prior to working at OTT, she was office assistant to the Acting Dean of Faculty at Bowie State University.

Not only is Patricia's face familiar around the office, but also around the college campus. That's right! She attends Bowie as a senior, majoring in Banking and Finance. After obtaining her B.S. degree, Patricia plans to become a Certified Financial Planner.

OTT Calendar

OTT CALENDAR OF EVENTS¹ 1992

MAY

- 11 **Grand Rounds**, 1/Wilson Hall - 12:30. "How the National Technology Transfer Center Can Assist Inventors in Technology Transfer" — Joseph P. Allen, Director, Planning and Development, NTTCC, Wheeling, WV
- 11 **TDC Meeting**, 1/Wilson Hall - 1:30-3:30
- 19 **CRADA Subcommittee Meeting**, 1/151 - 1:00-3:00
- 26 **PPB Meeting**, 1/151 - 1:00-3:00

JUNE

- 3-4 **Joint NIH/PMA Technology Transfer Conference**, Sheraton Washington Hotel, Washington, D.C. **Contact:** Mike Miller, OTT, 496-0750.
- 8 **Grand Rounds**, 1/Wilson Hall - 12:30. "How Scientists Can Use The Maryland Incubator Program" — Mr. Richard B. Frank, Director, Technology Advancement Program, University of Maryland at College Park
- 8 **TDC Meeting**, 1/Wilson Hall - 1:30-3:30
- 16 **CRADA Subcommittee Meeting**, 1/151 - 1:00
- 22 **PPB Meeting**, 1/151 - 1:00-3:00

JULY

- 13 **Grand Rounds**, 1/Wilson Hall - 12:30 Speaker: Ms. Bobbie Brandon, Associate Director, American Type Culture Collection
- 13 **TDC Meeting**, 1/Wilson Hall - 1:30 - 3:30
- 21 **CRADA Subcommittee Meeting**, 1/151 - 1:00 - 3:00
- 27 **PPB Meeting**, 1/151 - 1:00 - 3:00

1992 TECHNOLOGY TRANSFER CONFERENCES AND COURSES

MAY

- 17-19 **Association of Biotechnology Companies Sixth International Biotechnology Conference**, San Diego, CA

18-20 **Entrepreneurial Technology Transfer**, San Francisco, CA. **Contact:** MIT Enterprise Forum, (617) 862-0397

21 **Maryland Biotechnology Network Monthly Breakfast**, Administration Building, Senior Lunch Room, NIST, Gaithersburg, MD. **Contact:** (301) 762-6325

27 **"From Lab Bench to Boardroom"**, Innovative Financial Strategies for Emerging High-Tech Companies, Suburban Maryland Technology Council, Bethesda, MD. (Dr. Bernadine Healy and Reid G. Adler are speakers.) **Contact:** Maura Connell, (202) 637-8662.

JUNE

- 18 **Maryland Biotechnology Network Monthly Breakfast**, NIST, Gaithersburg, MD. **Contact:** (301) 762-6325
- 24-26 **17th Annual Conference of the Technology Transfer Society**, Atlanta, GA. **Contact:** Dr. McGovern (404) 542-6283 or Maureen Swinney, Technology Transfer Society, (317) 262-5022

JULY

- 13-14 **Eastern Regional Meeting**, Association of University Technology Managers, Herndon, VA
- 15-16 **Inaugural Meeting**, Association of Government Technology Managers, Herndon, VA

SEPTEMBER

21-22 **NIH Research Festival**

OCTOBER

29-30 **Third Annual PHS Technology Transfer Forum**, Lister Hill Auditorium. **Contact:** Carolyn Craig, OTT, 496-0750.

NOVEMBER

2-5 **FLC Technology Transfer Meeting** - Scottsdale, AZ. Meeting information coming out September 1

DECEMBER

1-3 **Third Annual TECHNOLOGY 2002**, sponsored by NASA for federal labs, Baltimore, MD.

¹The OTT Calendar of Events is updated monthly. Call the OTT at 496-0750 to confirm dates or request updated calendars.