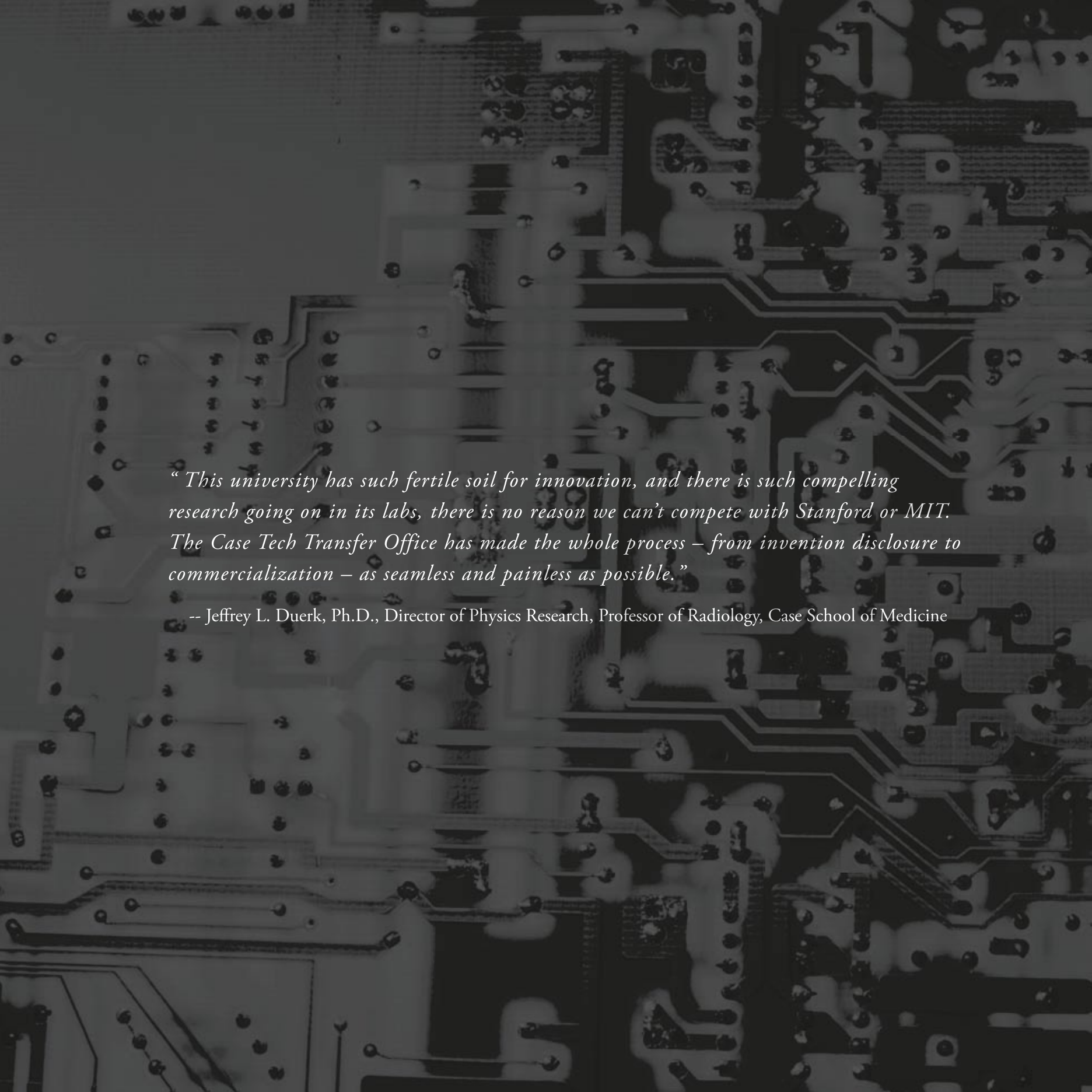


Technology Transfer Office :: 2005 Annual Report



CASE

CASE WESTERN RESERVE UNIVERSITY



*“This university has such fertile soil for innovation, and there is such compelling research going on in its labs, there is no reason we can’t compete with Stanford or MIT. The Case Tech Transfer Office has made the whole process – from invention disclosure to commercialization – as seamless and painless as possible.”*

-- Jeffrey L. Duerk, Ph.D., Director of Physics Research, Professor of Radiology, Case School of Medicine

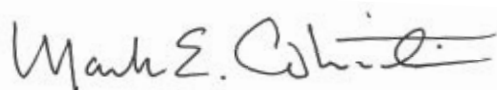
**:: WELCOME TO THE CASE WESTERN RESERVE UNIVERSITY TECHNOLOGY TRANSFER OFFICE'S 2005 ANNUAL REPORT**

Fiscal year 2005 continued to build upon the momentum that began in late fiscal year 2002 when the current Technology Transfer Office was established. Our commitment to the university and the community was to create and sustain a world-class technology transfer function to move innovations created by Case's world-class researchers into the marketplace. Over the past several years, with incredible support from faculty, administrators, and the leadership of the institution, we have done just that. Case is now recognized as a national leader in technology transfer and ranks among the best institutions in the country across a wide range of metrics.

Over the past year we have also greatly expanded our staff and implemented new internal procedures to improve operational efficiencies and deliver superior service to our researchers and faculty members. Case now has ten full-time licensing professionals dedicated to supporting the commercialization of innovations created within our schools and our affiliate institutions – the most in

the entire history of the university. Our expanded staff has allowed us to provide even greater levels of support to a number of important programs across the university, including providing assistance with new academic-industry consortia funded by the State of Ohio's Third Frontier and Biomedical Research Technology Transfer programs. We have also focused on expanding our educational and outreach programming to engage more of our researchers in the technology transfer process, conducting a record thirty-five events during the past year.

This report details some of the highlights of our operation and results for the past year. We are particularly proud of the increase in our deal flow, with twenty-six license and option transactions completed (a 44 percent increase over the prior year). While we could not include information on every success, we hope that the stories contained in this report provide some insight into our office's wide variety of activities and services.



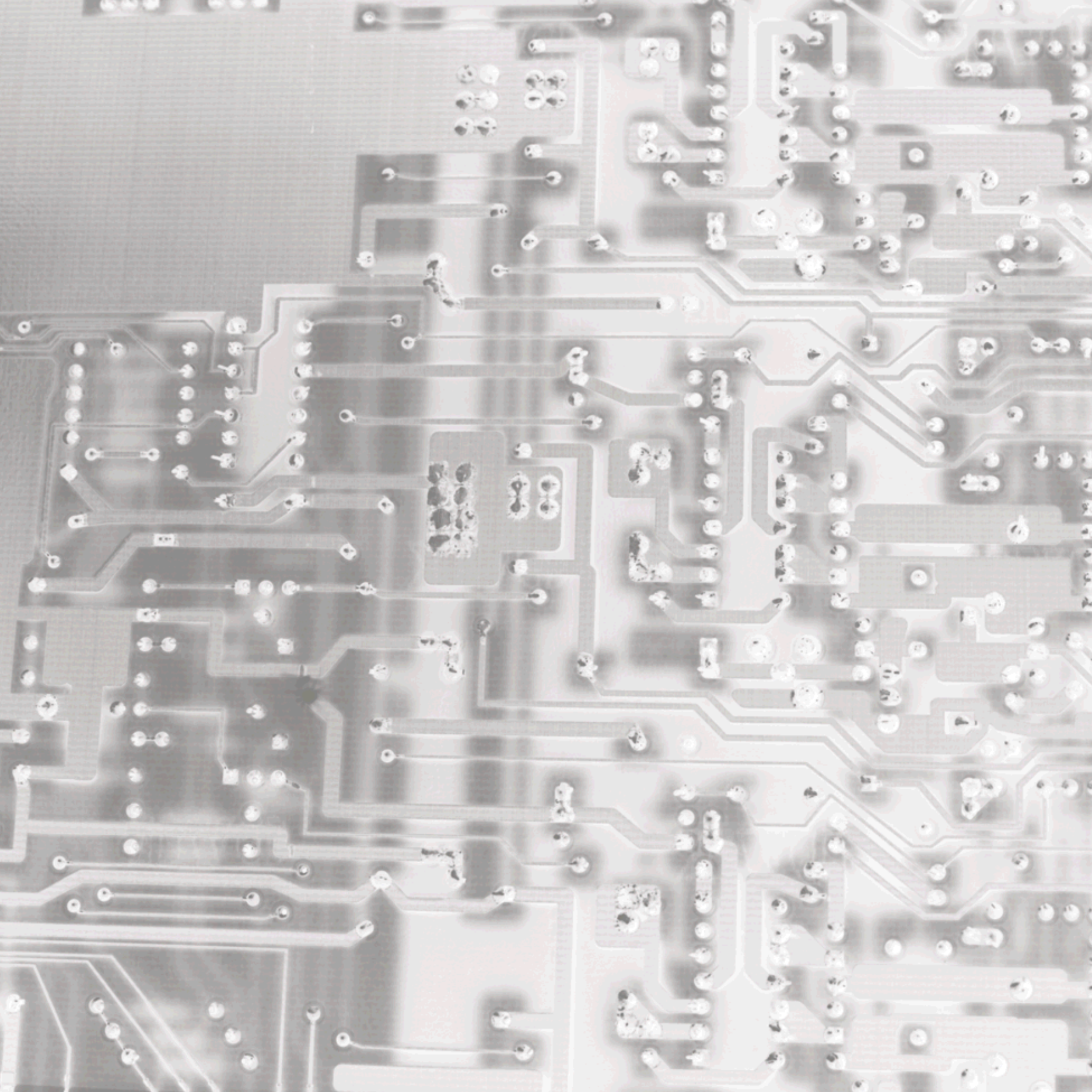
Mark Cotichia  
Vice President  
Research and Technology Management



Nick Frollini  
Assistant Vice President for Technology Transfer  
Engineering & Physical Sciences and Operations



Joseph Jankowski, Ph.D.  
Assistant Vice President for Technology Transfer  
Biomedical Sciences



## :: **PROTECTING DISCOVERIES, MARKETING INVENTIONS**

Case's Technology Transfer Office offers a wide variety of services to the Case community and the researchers, faculty members, and other inventors who help Case strive to be the most powerful learning environment in the world.

As steward of the university's intellectual property assets, the Technology Transfer Office (TTO) protects the discoveries of researchers and safeguards the interests of the university in intellectual property matters and in the commercialization of research conducted at Case.

### **Soliciting and Evaluating Ideas**

The TTO works to encourage university faculty members and researchers to submit **Invention Disclosures** to the office. The first step in the technology transfer process, the invention disclosure enables the TTO to evaluate the commercial merit of an innovation. Our licensing professionals act quickly on each disclosure, working closely

with the inventors to determine areas where the innovation might have commercial application, together challenging each other to think outside of the box. The key questions include, "Where can this technology be used today?" and, "Where might it be used tomorrow?" Each inventor is assigned a **Case Manager**, a member of our licensing team, who works with the inventor on all of his or her innovations.

### **Protecting Intellectual Property**

For those inventions that appear to address substantial commercial opportunities and have the potential to be patented, the TTO will work with patent counsel with significant and domain-appropriate expertise to craft a patent application.

Of course, patents represent only one type of intellectual property. Researchers at Case frequently collaborate with peers around the world. When researchers need to send materials such as cell lines, antibodies,

vectors, or database information to or obtain materials from another institution, the TTO negotiates a **Material Transfer Agreement (MTA)** on their behalf with the other party. These agreements protect the intellectual property rights of researchers at both organizations, define use and control of material, and cover ownership and liability issues. As is true at many institutions of our size, the Case TTO dedicates substantial resources to the MTA process.

### **Confidentiality Agreements**

In order to conduct discussions about new ideas and technologies without compromising intellectual property rights, TTO case managers make certain that a **Non-Disclosure Agreement (NDA)** is in place before any information is shared, both as part of our discussions with industry on licensing and to enable our researchers to speak openly during visits by external parties to campus.

**Hillel Chiel, Ph.D.**

Professor of Biology, Neurosciences, and Biomedical Engineering

**H**illel Chiel navigates the continuum between basic research and applied science with great agility. In July 2004, with the help of the TTO, he obtained a patent for a “Peristaltically Self-propelled Endoscopic Device,” a flexible device that pulls itself into the body, rather than having to be inserted. The TTO helped with all aspects of the patenting process, including researching the patentability of the device and identifying and working with patent counsel through the process with the U.S. Patent and Trademark Office, which can take several years. As part of its efforts to identify licensing partners, the TTO attracted the interest of a large endoscope manufacturer, which has since sponsored research in Chiel’s lab to develop the next generation of the device.

**:: A WIDE RANGE OF SERVICES**

**Connecting to Industry**

One of the TTO’s primary goals is to facilitate the introduction of technologies developed at Case to the marketplace so that these innovations can benefit the general public. We play the role of “matchmaker,” working to find the best and most appropriate home for each technology in our care. Our case managers work closely with inventors as we identify potential commercial opportunities and leading firms, and then market the inventions to companies in the best position to make

these innovations commercial realities. Once a strong candidate for licensing is identified, we help negotiate a license agreement that makes sense for both sides and enables the transfer of the technology.

**Government Compliance**

Government compliance is an important aspect of our day-to-day operations because Case, like most institutions, receives a substantial portion of its research funding from the federal government. Lapses in compliance could jeopardize our ownership of intellectual property developed with

government funding, or even hurt the institution’s ability to obtain government support for its research efforts. The TTO is required to track and report to the federal government all invention disclosures resulting from research funded by federal grants. In addition, the TTO must report all decisions to pursue patentability and commercialization resulting from such invention disclosures. This year, the TTO’s paralegal staff set up a new internal system that streamlines the compliance process and makes us a leader in this area.

**Jeffrey L. Duerk, Ph.D.**

Professor of Radiology, Biomedical Engineering, and Oncology  
Director, Case Center for Imaging Research  
Vice-Chair for Basic Science Research, Department of Radiology,  
University Hospitals of Cleveland

**J**effrey Duerk works with the TTO in a variety of ways. He is a faculty researcher, regularly making invention disclosures (about ten to fifteen a year) and working through the patent and licensing process with the TTO staff. He is also the co-founder of a spin-off company, Interventional Imaging, Inc. (also called I3 and pronounced “I cubed”).

Duerk and his colleagues in imaging research, veterans of the TTO process, conduct their own rigorous internal review of their work to determine if it is commercially viable prior to submitting a disclosure. “We take a hard look at whether elements of our work



Many biologists study organisms on the cell level – Chiel looks at whole systems. “How do the brain and the body work together to generate adaptive behavior?” is one question Chiel asks in his lab in the DeGrace biology building. He uses a variety of approaches – neurophysiology, modeling, and computer simulation – to come up with answers. Currently Chiel is studying the biomechanics and neural control of the marine mollusk *Aplysia californica*. He has recently developed a gripper device based on *Aplysia californica*’s feeding apparatus, which may have applications in medicine and plumbing. The TTO continues to support Chiel’s efforts and, working with him, filed a patent application on the gripper in June 2005, based on the substantial indications of commercial interest Case has seen in his device and on

its high potential to have a significant impact on the endoscopy market.

Chiel counts himself lucky to be working at a university with a strong engineering program where students with training in computer science and in mechanical, electrical, chemical, or biomedical engineering can help with research, build prototypes, and create simulations. He says, “Building models, which we need to understand our biological system, can lead to the creation of useful devices. A prototype helps funders and patent experts see that an idea could be commercially viable. But best of all, the process of building models leads to deep insights into biological systems.”

### Creating New Companies

Investment from **Case Technology Ventures (CTV)**, a \$5-million, pre-seed fund managed by the TTO, provides significant financial support to start-ups based on technology developed at Case and its affiliate institutions. CTV’s investments range from \$50,000 to \$250,000. Financial support for CTV comes from Case and from Ohio’s Third Frontier Project.

Beyond the value of the investment provided, support from CTV provides

the credibility many start-ups need to attract other investors and enables them to complete important validation tasks at an early stage of business development, maximizing the chances of long-term commercial success. In addition to providing venture capital for Case start-ups in all fields (life sciences, engineering, physical sciences, and information technology), CTV offers coaching, advising, networking assistance, and general support to its portfolio companies.

CTV’s investment process is based on a study of best practices in academe, venture capital firms, and the financial services industry. It’s designed to enable CTV to fund companies with the highest potential and to give them effective support as they grow and develop. With three portfolio companies, and more on the way, CTV’s economic impact is just beginning to be felt, but the fund has already received substantial recognition for its efforts and continues to work to create high potential ventures for the region.



are patentable, or whether we should protect it at the early stage to buy time to develop it further.”

I3 is poised to produce an interventional MR catheter and the necessary software tools that will enable physicians to obtain high-resolution images of blood vessel walls. The TTO has provided funds for I3 through Case Technology Ventures and put the company in contact with other venture capital firms as it has worked to raise additional outside capital.

Duerk encourages other faculty to engage with the TTO. He observes, “These activities are one of my normal responsibilities, like teaching and getting

manuscripts published.” In Duerk’s experience, the TTO prepares researchers fully for all phases of licensing negotiations and provides excellent guidance to researchers and faculty embarking on a startup – recruiting a CEO, getting accounting help, and finding legal representation. He points out that commercializing research can yield enormous payoffs. “One success in licensing could result in revenues of millions of dollars a year. That’s a source of revenue the university should be in a position to capture. It comes back to the school and to the labs and makes so many things possible.”

*“We have spent a significant amount of resources to engage the community. It is part of our mission to contribute to high-tech economic development in our region by getting our research results commercialized to benefit the public.”*

Mark Coticchia, Vice President for Research and Technology Management  
Case Western Reserve University

## :: REGIONAL IMPACT, NATIONAL REPUTATION: THE ECONOMIC BENEFITS OF TECHNOLOGY TRANSFER

Cleveland and Northeast Ohio fared well in the old economic order; the region boomed with its access to vast natural resources, a large labor force, and mass production. Economic development in the twenty-first century is driven by technological innovation, a highly skilled and educated work force, and the emergence of visionary new sources of capital. Technology transfer, strong research universities, and protection and commercialization of intellectual property are crucial in this new environment.

Cleveland is well positioned for the new economic boom, and Case has led the way by establishing the Innovation Network, an infrastructure for growth made up of organizations that promote investment and job creation. This network began with the founding of the current Technology Transfer Office in late fiscal year 2002 and now includes Case Technology Ventures, which funds businesses based on technologies generated at Case; JumpStart, an entrepreneurial advisor and investment organization that invested \$1.2 million

in five companies in 2004; the Cleveland Clinic Foundation's CCF Innovations office (a counterpart of the TTO); and BioEnterprise, which, since 2002, has helped build thirty-five bio-tech companies that have attracted \$140 million to the area. Thanks to the collaboration, cooperation, and partnering activities of the constituents of the Innovation Network, the region is now aligned for high-tech economic development. Just five years ago there was only a handful of technology transfer and commercialization professionals working in

the area – now there are sixty. The future truly looks bright.

The TTO also looks to license technologies locally first. While Case has an obligation to make sure all of its licensees are capable of bringing the technology in question to market, it looks first to Cleveland, the region, and the state of Ohio. More than 50 percent of the university's licenses over the past four years have gone to companies in Ohio, maximizing the local economic impact of technologies developed at Case.

### **IN FY 2005, THE TTO:**

- Received 128 invention disclosures;
- Handled 343 Material Transfer Agreements and Non-Disclosure Agreements;
- Completed 26 deals (licenses, options, and related transactions), a 44 percent increase over FY 2004; and
- Brought \$8.4 million in licensing revenue into the university.

## :: CASE RANKS IN TOP TEN FOR TECHNOLOGY TRANSFER SUCCESS

A survey conducted by the Association of University Technology Managers (AUTM) reveals that Case is a national leader for many key indicators among universities with \$250 million or less in research funding (its peer institutions at the time the data were collected). The survey covers July 1, 2002, to June 30, 2003, the latest period for which data are available. In the United States, Case ranks:

- Number 5 in university-based start-up companies;
- Number 6 in income generated by technologies developed at the university and licensed to outside companies;
- Number 7 in invention disclosures;
- Number 8 in licensing income as a percentage of research funding; and
- Number 10 in overall levels of research funding.

In just four years, the Case TTO has joined the ranks of the top technology transfer operations in the U.S., both in terms of quantitative results and in terms of adopting and developing best practices.

**:: A PORTFOLIO OF BUSINESS LAUNCHES – 2005 UPDATE**

Case's goal is to create three to four new companies each year. The TTO is meeting its goals and maintaining the momentum of 2004, with four start-ups in 2005. Updates from CTV's three portfolio companies show that they continue to move the technologies they have licensed from Case forward, and that all are making progress.

*“Nationally, universities generate one invention disclosure for each \$2.5 million in research funding they receive and one start-up company for every \$100 million in funding. With more than 125 invention disclosures and four start-ups in each of the past two years, Case meets or exceeds the national averages in almost all key metrics of innovation.”*

Nick Frollini  
Assistant Vice President for Technology Transfer  
Engineering & Physical Sciences and Operations

*“2005 was marked by the continued creation of start-ups at Case and the dramatic progress made by these organizations as they worked with the Innovation Network. The collaborating member organizations are far greater than the sum of their parts, and we expect the network to aid the continued growth of the biosciences in our region.”*

Joseph Jankowski, Ph.D.  
Assistant Vice President for Technology Transfer  
Biomedical Sciences

**Interventional Imaging, Inc. (I3)**

*“This year I3 has made significant progress toward its goal of becoming the leading provider of disposable interventional catheters used by cardiologists – progress in software deployment and in developing and manufacturing prototypes.”*

Vincent Kazmer, President and CEO

**Arteriocyte, Inc.**

*“Arteriocyte has made rapid progress this year – as the company has moved from a pre-clinical-stage company toward FDA review and agreement to enter its first clinical trial at University Hospitals.”*

Don Brown, Chief Executive Officer

**Cleveland NanoCrystals, Inc.**

*“Cleveland NanoCrystals has taken great strides over the past year toward refining its product strategy and initial testing of nanoparticles adapted for specific market applications.”*

Donna Richardson, President

An early-stage medical device company focused on detection and treatment of vulnerable plaque in the coronary arteries of the heart, I3 is based on technologies developed in the Department of Radiology at University Hospitals of Cleveland and the Case School of Medicine by Dr. Jonathan Lewin and Dr. Jeffrey Duerk.

As of January 2005, the company had raised more than \$1 million in outside capital. Prototypes of the interventional coil catheter device and related components are working and will be complete in the fourth quarter of 2005. The prototypes will be used for animal trials (likely to be conducted at University Hospitals) to confirm the efficacy of the device. Then additional animal trials and a limited

number of patient trials will be completed at several sites around the country. With several predicate devices on the market, I3 anticipates applying for FDA approval via a 510K filing once these trials are complete. Approval to market and sell the coil catheter will enable the company to penetrate not only the research market, but also the far larger commercial market.

A significant milestone for I3 in 2005 was hiring Ingmar Viohl, Ph.D., as Chief Technical Officer (CTO). Dr. Viohl has over twelve years of experience managing research and development organizations as well as expertise with intravascular MRI medical devices. Under his leadership, the company's product has evolved rapidly and moves ever closer to becoming a commercial reality.

Arteriocyte, Inc., is an early-stage, adult-stem-cell company developing treatments to grow new blood vessels in patients suffering ischemic disease. The company was founded in 2004 by Mary Laughlin, M.D., and Vincent Pompili, M.D. – faculty members from the Case School of Medicine and University Hospitals of Cleveland. Arteriocyte is based

on technologies developed by the founders and Stephen Haynesworth, Ph.D., associate dean of the College of Arts and Sciences at Case. The company is the first spin-off of the university's new Center for Stem Cell and Regenerative Medicine, which was established with the help of a \$19-million state grant in 2003.

This year, Arteriocyte received the first installment of its

combined Phase I/II "fast track" Small Business Technology Transfer Award grant from the National Heart, Lung, and Blood Institute (NHLBI), a component of the National Institutes of Health (NIH). The first installment of the NIH grant is for the initial phase of a ten-patient study to test the safety of using stem cells to repair ischemic heart tissue caused by an inadequate blood supply to the heart. The balance of

the funding from the NHLBI is expected to be awarded later in 2005, contingent on successful completion of the Phase I work. This important step in the commercialization of a cell therapy product could lead to innovations in additional diseases such as stroke prevention and new treatments for vascular disease associated with diabetes. It's a sign of great progress for this young company.

Nanotechnology has the potential to revolutionize many industries, including medicine, solar energy equipment, paint, coatings, and materials.

Cleveland NanoCrystals was founded by Dr. Clemens Burda, assistant professor of chemistry in Case's College of Arts and Sciences and director of the Center for Chemical Dynamics and Nanomaterials, and Ms. Donna Richardson, who met at Case's Research ShowCase in April 2004. With help from the TTO, they succeeded in launching the company just three months

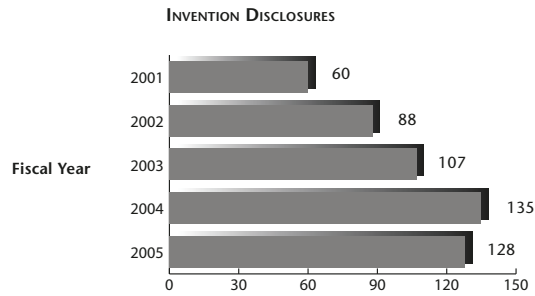
later. The TTO moved swiftly to protect the intellectual property, and took the lead in helping Richardson and Burda conduct a national search for a law firm specializing in nanotechnology patents.

Assistance with patenting and protecting intellectual property early in the start-up process is crucial to the success of many high-tech ventures, including Cleveland NanoCrystals. Donna Richardson observes, "Because of the support we received from the TTO, we were able to attract the interest of a high-profile patent firm. The TTO really threw its weight behind establishing

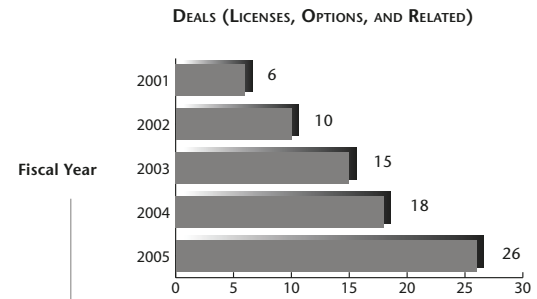
this relationship, and that was a tremendous help." Early this year, CTV completed a second round of investment in Cleveland NanoCrystals – this time for \$200,000 – bringing CTV's total investment in the company to \$250,000.

Cleveland NanoCrystals has begun feasibility testing of the nanocrystal technology and has identified a market opportunity. The technology will be used to "dope" or change the chemical composition of titanium dioxide, a material used widely in the paint and coatings industry. The company has completed a sponsored research agreement

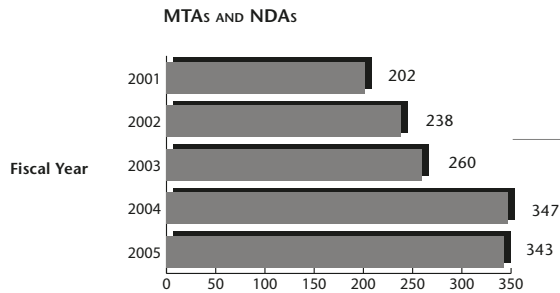
with Case and will be doing anti-microbial and anti-fungal testing at Case and elsewhere. Data from the feasibility testing will be used to raise funds for the next stage of business development. The paint and coatings industry has a strong presence in Cleveland, which is one reason Cleveland NanoCrystals chose to concentrate its efforts in this market. Says Richardson, "We wanted to focus regionally, allowing a technology developed here to benefit other firms that call Northeast Ohio home. This initial market opportunity is large enough for us to do just that."



*Invention Disclosures have reached a sustainable level of 120 to 140 per year.*

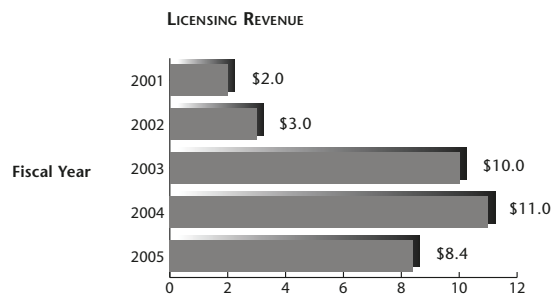


*Transaction volume continues to increase substantially year over year.*

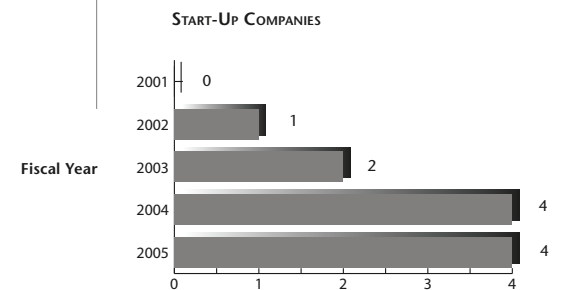


*The TTO continues to handle a substantial volume of NDAs and MTAs, which aids commercialization and enhances customer service.*

*Revenues show solid, sustainable growth.*



*Case's goal is to create 3 to 4 new companies each year.*



**:: TTO Staff** The TTO has a full staff of professionals with broad experience in both science and technology transfer management.



**Laura Adams**  
*Department Assistant*



**Rebecca Barker**  
*Executive Aid*



**Virginia Olszewski**  
*Senior Paralegal and Compliance Specialist*



**Steve Tan, M.D., Ph.D.**  
*Senior Licensing Manager, Life Sciences*



**Carrie Thomas**  
*Director, Finance and Administration*



**Mark Cotichia**  
*Vice President for Research and Technology Management*



**Michael Haag**  
*Senior Licensing Manager, Life Sciences*



**Jim Pae**  
*Senior Licensing Manager, Engineering  
& Physical Sciences*



**Daniel Pendergast**  
*Licensing Associate, Engineering & Physical Sciences*



**Nick Frollini**  
*Assistant Vice President for Technology Transfer,  
Engineering & Physical Sciences and Operations*



**Joseph Jankowski, Ph.D.**  
*Assistant Vice President for Technology Transfer, Biomedical Sciences*



**Arlicia Headd**  
*Paralegal*



**David Spencer**  
*Licensing Associate, Life Sciences*



**Neil Veloso**  
*Licensing Manager, Life Sciences*



**Patrick Klepcyk**  
*Licensing Associate, Life Sciences*



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