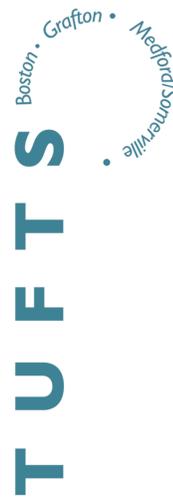




**ANNUAL
REPORT**

Fiscal Year

2000



TUFTS UNIVERSITY

Office for Technology and Industry Collaboration

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Message from the Director

The Office for Technology and Industry Collaboration (OTIC) officially opened its doors in fiscal year 2000 (ended June 30) and through the year attained its current staffing level of five full-time professionals. In addition to myself, OTIC personnel include Ojas Mehta, senior licensing manager, responsible for the School of Medicine and the School of Dental Medicine; Martin Son, licensing manager, responsible for the College of Engineering; Justyna Lipinska, licensing associate, responsible for the School of Veterinary Medicine; and Thomas McVarish, assistant director of operations.

In December of 1999 OTIC moved into new offices at 75 Kneeland Street on the Boston campus, where it shares a suite with the Office of the Associate Provost for Research, Grants and Contracts Administration and personnel from Corporate and Foundation Relations. The move brings together functions that affect interactions with industry, consistent with the University's goal of providing better service both to the faculty and to external collaborators.

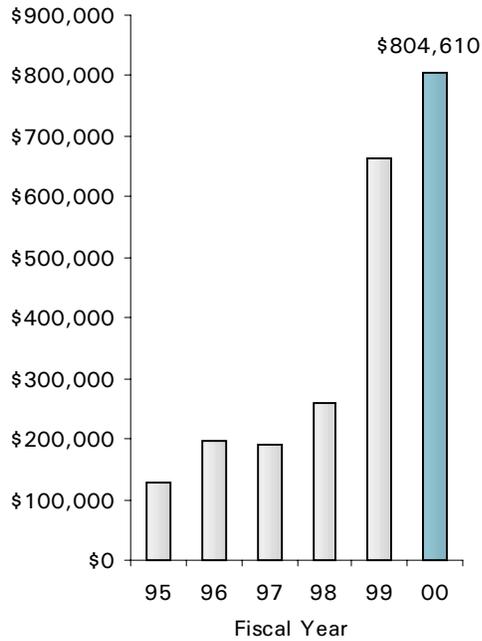
A key development for OTIC was the design and implementation of a new database (in Microsoft Access) for tracking invention disclosures, patent applications and agreements with industry. Developed under the supervision of Thomas McVarish, the OTIC database also tracks expenses and income by case and provides for better control of legal and other costs.

The organization of case files and data entry were major efforts during FY00, as was the work directed toward bringing technology transfer activities at Tufts into compliance with federal reporting procedures. These data organization efforts have resulted in the recovery of \$530,538 in legal expenses paid by the University. With the appropriate administrative infrastructure solidly in place, OTIC is now well positioned to handle Tufts University's intellectual property matters.

FRANCES TONEGUZZO

Fiscal Year 2000 (Ended June 30) at a Glance

License Income History



Income Summary

| | |
|------------------------------|--------------------|
| License Income | \$804,610 |
| Legal Expense Reimbursements | \$530,538 |
| Total Income | \$1,335,148 |

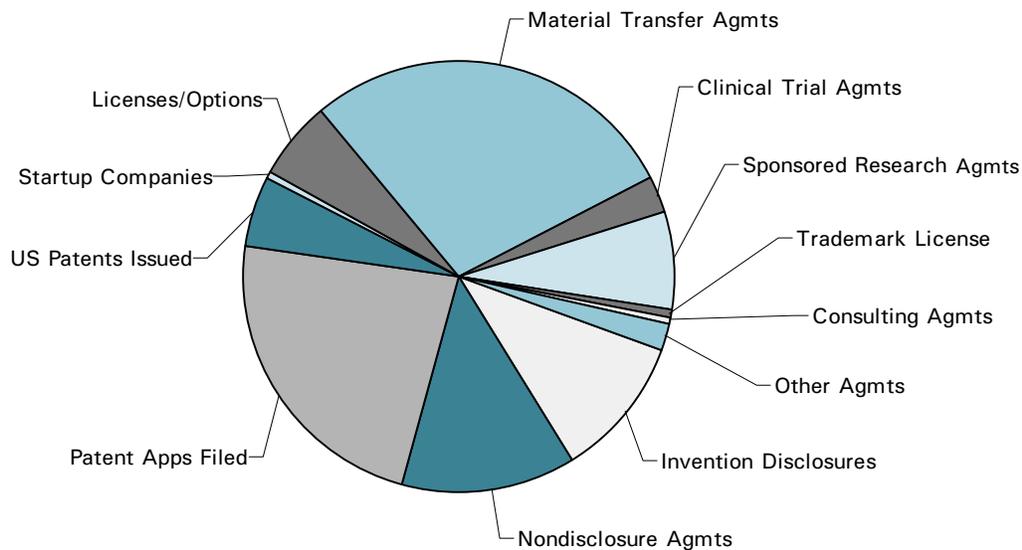
Technology Transfer Activities

| | |
|----------------------------|----|
| New Invention Disclosures | 28 |
| New US Patent Apps Filed | 20 |
| Total US Patent Apps Filed | 42 |
| Foreign Patent Apps Filed | 19 |
| US Patents Issued | 14 |
| Nondisclosure Agreements | 35 |
| Licenses/Options Concluded | 15 |
| Startup Companies Formed | 2 |

Research Support Activities

| | |
|-------------------------------|----|
| Materials Transfer Agreements | 76 |
| Sponsored Research Agreements | 19 |
| Clinical Trials Agreements | 8 |

OTIC Transactions



Technology Transfer Overview

OTIC Staff

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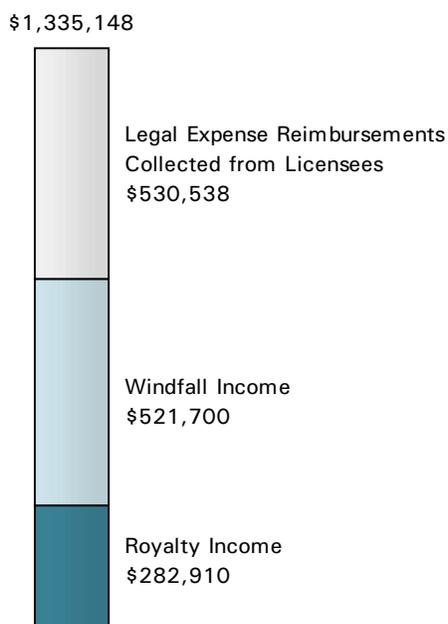
Through technology transfer, discoveries made during the course of research or other programs at the University are licensed to industry for commercialization. A key step in the transfer of technology is the protection of potentially useful ideas as intellectual property. Protection of intellectual property, because it offers a period of time in which others can be excluded from practicing an invention, is generally required if a company is to have an incentive to develop an invention into a product (or series of products). This is especially important for inventions that require the commitment of significant resources before a product can be marketed and sold, such as a medical product.

Tufts University fosters the process of technology transfer by supporting the Office for Technology and Industry Collaboration (OTIC), which is a resource for all Tufts personnel. The University pays out-of-pocket costs associated with the protection of intellectual property, and it provides financial incentives for Tufts personnel to participate in the technology transfer process. These include a share of licensing fees and royalty payments that result from the sale of products or the use of processes derived from an invention.

The mission of OTIC is to facilitate research at Tufts University by promoting appropriate interactions with industry. While our focus is on the protection and commercialization of intellectual property of all types (i.e. technology transfer), OTIC is ready to provide service and advice about relationships with industry regardless of whether they involve intellectual property. Consistent with this mission, OTIC shares space and interacts closely with the offices for grants and contracts administration and corporate and foundation relations.

Technology Transfer Activities, Fiscal Year 2000

FY2000 Income

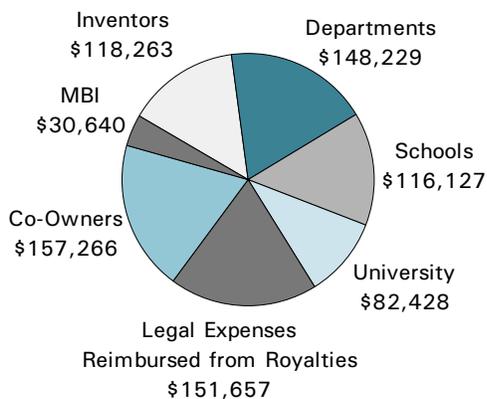


Income

Technology transfer income exceeded one million dollars for the first time in Tufts' history. While exciting, this figure is also somewhat misleading because it includes \$530,538 collected from licensees for legal expenses paid by Tufts before and during the current fiscal year. The total license income for FY00 was \$804,610, a 21% increase over income received in FY99. It is instructive to note that more than half of this amount derived from a milestone payment from one licensee.

License income (windfall and royalty) was distributed to Tufts inventors, departments, schools, and the University. In aggregate, the inventors' personal share amounted to \$118,263, the departmental share to \$148,229, and the schools' share to \$116,127. Tufts paid a total of \$187,906 to outside entities, of which \$157,266 went to co-owners of patents and \$30,640 went to Massachusetts Biomedical Initiatives (for deals negotiated prior to the expiration of an agreement between MBI and Tufts).

Distribution of License Income



From license income, \$151,657 was deducted to reimburse Tufts for legal expenses that had not been reimbursed by licensees. When combined with the \$530,538 collected from licensees and the \$82,428 distributed to the University as its share of license income, the University received \$764,623. After deduction of all legal fees paid by OTIC, a positive balance of \$34,802 remained at the FY00 close, representing income received over and above out-of-pocket expenditures. Combining this figure with the amounts distributed to the departments and the schools, Tufts retained a total of \$299,158 from the year's technology transfer activities.

The total of \$264,356 which was distributed to the various schools and departments represents an important source of discretionary income that can be used to fund innovative research projects (to bring them to a point

Academic investigators are often frustrated by the scarcity of unrestricted funds for research, so the departmental share of technology transfer income is an important source of support. With funds available for expenditure when needed, departments have a means of bridging interruptions in project-based sponsorship and of financing strategic purchases. Investigators can access these funds to test an idea quickly or pursue a promising but unorthodox line of research. This flexibility is critical to the research enterprise at Tufts and has a positive and lasting effect on the morale of the faculty and the overall health of the University.

B. DAVID STOLLAR
Chair, Biochemistry Department
School of Medicine

where additional support through federal or other sources becomes feasible) or to provide bridge funding to investigators. Technology transfer provides one of the few avenues through which this type of discretionary support is generated.

Patents and Legal Expenses

Twenty US applications were filed in FY00 that represented patent filings on new cases. With the addition of patent applications that represented new filings on existing cases, the total for US patent applications filed in FY00 reached 42. Fourteen US patents were awarded in FY00 (see table).

Expenses for patent filings and continued prosecution of existing patent applications totaled \$1,165,038 in FY00. Of this amount, \$675,234 was recovered by deducting from royalty income and invoicing licensees (\$240,017) and by having licensees pay expenses directly (\$435,217). This represents a yearly reimbursement rate of 58%, a respectable rate in the industry. (According to the FY98 Association of University Technology Managers survey, the reimbursement rate for US universities averaged 41%).

US Patents Issued in FY00, by School

| | | |
|--------------------|-----------|---|
| A&S | 6,023,540 | Fiber Optic Sensor with Encoded Microspheres |
| | 5,970,804 | Methods and Apparatus for Analysis of Complex Mixtures |
| Engineering | 6,049,574 | Blind Adaptive Equalization Using Cost Function That Measures Dissimilarity Between the Probability Distributions of Source and Equalized Signals |
| | 5,966,966 | Process and System for Freeze Concentration Using Ultrasonic Nucleation Useful in Effluent Processing |
| Medical | 6,066,723 | Nucleic Acid Encoding Vertebrate cdc37 |
| | 6,037,333 | Microbe-Inhibiting Compositions |
| | 6,068,972 | Methods and Compositions for Reducing Bacterial Tolerance to Antibacterials, Disinfectants and Organic Solvents |
| | 5,985,657 | Recombinant DNA Which Codes for Interleukin-1 |
| | 5,998,578 | Biologically Active Fragments of IL-1 Beta |
| | 6,040,145 | Potentialiation of the Immune Response |
| | 5,965,532 | Multivalent Compounds for Crosslinking Receptors and Uses Thereof |
| Nutrition | 6,030,778 | Diagnostic Assays and Kits for Body Mass Disorders Associated with a Polymorphism in an Intron Sequence of the SR-BI Gene |
| | 6,075,058 | Compositions for Increased Bioavailability of Carotenoids |
| Veterinary | 5,976,133 | External Fixator Clamp and System |

Regulators of Cell Architecture

Tufts Invention T001066

Ira Herman and his colleagues in the Department of Physiology at the School of Medicine have identified novel genes that regulate cell architecture by regulating key cytoskeletal components. These molecules may act as diagnostic targets or therapeutic agents for wound healing, or for repairing arterial wall damage resulting from balloon angioplasty. They may also be useful for inhibiting blood vessel growth (and thus have application in cancer treatment).

Disclosures by School

| | |
|-------------|----|
| A&S | 6 |
| Engineering | 5 |
| Dental | 0 |
| Medical | 12 |
| Nutrition | 3 |
| Veterinary | 2 |

Licenses/Options by School

| | |
|-------------|----|
| A&S | 0 |
| Engineering | 2 |
| Dental | 0 |
| Medical | 10 |
| Nutrition | 2 |
| Veterinary | 1 |

New Invention Disclosures

Twenty-eight new reports of invention were received in FY00. This number of new disclosures is on the low side for a school with a research base the size of Tufts'. The fact that OTIC was recently established in FY00 and that many among the faculty were not aware of its existence may have contributed to the low invention disclosure rate. The FY00 disclosure rate underscores the need for extensive faculty outreach during FY01 and beyond.

Nondisclosure Agreements

Nondisclosure agreements are an important component of the technology transfer process because they allow for an exchange of information without compromising the rights of the owner. Patent law requires that an invention be novel in order to be patentable. Public disclosure of a concept (and that can mean disclosure to one person who is not restricted in his or her use of the information and is therefore free to disclose to the larger public) destroys novelty and can present a bar to patenting. Nondisclosure agreements, by restricting the recipient's use of the information, are essential to protecting the patentability of an invention and to controlling proprietary information. OTIC has developed simple formats for the exchange of confidential information (mutual and one-way). In FY00, we negotiated 35 nondisclosure agreements.

License Agreements

Fifteen new license/option agreements were concluded in FY00, including four exclusive licenses, nine nonexclusive licenses and two options/letters of intent. Two of the exclusive licenses were contracts with startup companies founded on Tufts technology.

A significant proportion (67%) of the license/option agreements represent arrangements covering new biological materials developed in Tufts research labs. In general, these materials are commercialized for sale to the research community. Because the markets are limited, many of these biological materials are not patented—the costs of pursuing a patent application would exceed the returns

obtainable from licensing. Nevertheless, the licensing of such materials as tangible research property can and does generate income that can be used to support research at Tufts.

■ Of the 15 license/option agreements concluded in FY00, 10 covered the transfer of biological materials.

Research Support Activities, Fiscal Year 2000

Technology transfer is not the sole focus of the Office for Technology and Industry Collaboration: OTIC has the broader mission of protecting the University’s intellectual property in any relationship with industry while at the same time helping to formulate creative relationships that contribute to the research enterprise. OTIC tracks all agreements with industry to present the most accurate picture of our activity. During FY00, our office negotiated a total of 163 agreements.

Sponsored Research by School

| | |
|-------------|---|
| A&S | 0 |
| Engineering | 2 |
| Dental | 2 |
| Medical | 9 |
| Nutrition | 5 |
| Veterinary | 1 |

Sponsored Research and Clinical Trial Agreements

OTIC negotiated 19 sponsored research agreements and 8 clinical trial agreements during FY00. Collectively this activity generated approximately \$3,300,000 in sponsored research support across all campuses for this and future fiscal years. In a few cases, the sponsored research agreements flowed from licensing agreements; for the most part, however, these arrangements were stand-alone agreements with an industrial partner.

Clinical Trials by School

| | |
|-------------|---|
| A&S | 0 |
| Engineering | 0 |
| Dental | 6 |
| Medical | 0 |
| Nutrition | 2 |
| Veterinary | 0 |

During FY00, OTIC began exploring novel arrangements with industry to leverage expertise at Tufts. This approach was pioneered with the School of Nutrition Science and Policy, for which a format termed the “intellectual access agreement” was developed. In return for the payment of fees, companies gain access to faculty members’ time for advice on specific topics. The intellectual access agreement, in essence, formalizes interactions between faculty members and industrial counterparts. To date two such arrangements have been concluded.

■ In December 1999, the National Institutes of Health issued a final rule on its principles and guidelines for disseminating and acquiring research resources developed with federal funds. The one-page material transfer agreement developed by OTIC (and available electronically from OTIC) is consistent with the NIH guidelines. For a copy of the NIH guidelines, please contact OTIC.

Genetic Test for Coronary Heart Disease

[Tufts Invention T001097](#)

Jose Ordovas of the Human Nutrition Research Center on Aging at the School of Nutrition Science and Policy has discovered a correlation between genetic variations in a specific gene and the frequency of coronary heart disease. His studies demonstrate that analysis of variations in the gene encoding a protein that facilitates the exchange of cholesterol between different cholesterol carrying particles can be used to assess the risk of developing coronary heart disease.

Clinical trial/product testing arrangements form a significant proportion of the industrial agreements for the School of Dental Medicine. To remain competitive, it is essential for the School of Dental Medicine and OTIC to work together to expedite contract negotiation. A streamlined, two-page template was specifically developed for this type of arrangement in FY00.

Material Transfer Agreements

The transfer of materials is an important component of today's research in the biological sciences. To make this process more efficient, OTIC developed a one-page academic-to-academic agreement to cover transfer of materials between academic labs. Investigators should use this agreement whenever they send materials to colleagues in other academic institutions, and they need not involve OTIC in this type of transfer.

When investigators receive materials from outside entities or when they send materials to outside entities that are not academic institutions, OTIC must be involved. Many of these transfers are covered by legal instruments that contain intellectual property provisions that are onerous to the recipient or are inconsistent with the University's policy on publication. During FY00, OTIC negotiated 76 material transfer agreements.

New Venture Formation, Fiscal Year 2000

FY00 saw the formation of two new companies based on Tufts technology. As part of the consideration for the license agreements, Tufts obtained stock in both. Tufts now holds equity in a total of six startups founded on Tufts technology (see table on page 12).

Triad Pharmaceuticals, launched in September 1999, was founded on proprietary technology that was developed in the Biochemistry Department at the School of Medicine.

The technology is used to identify specific inhibitors of cysteine and serine proteases, a group of enzymes that are critical to many metabolic processes. A number of cysteine and serine proteases have already been identified as valid targets for drug intervention, and Triad is working on compounds for specific disease indications. The arrangement with the startup includes a sponsored research agreement under which Triad funds additional research at the School of Medicine.

Tissue Regeneration, Inc was launched in June of 2000 to develop methods for culturing tissues for transplantation. The company licensed technology and a patent application that was developed in the Department of Chemical Engineering's Bioengineering Center. The license covers novel methods and devices for growing specific tissues. Tissue Regeneration, Inc is currently funding specific research projects at the Bioengineering Center.

FY00 also saw the growth of an enthusiastic interest in entrepreneurial activities at Tufts. The College of Engineering, through the dean's office, spearheaded an effort to evaluate the possibility of creating an incubator that would foster startup company formation at Tufts. With the help of a consultant, OTIC evaluated various incubator models (both local and national). While highlighting the resource- and labor-intensive challenges of establishing a physical plant, the report prepared by OTIC emphasized the need to support new venture formation on an institutional level. The report also identified approaches for providing this support in ways that do not involve a physical plant. The growing gap between high-risk academic technologies and the willingness of established companies to take on risk emphasizes the importance of establishing proof of principle for technologies developed at Tufts. Establishing proof of principle should not only add value to Tufts technologies, it should also make them more licensable. OTIC will continue to evaluate approaches to new venture creation and technology development at Tufts in FY01.



In a way, the creation of Tissue Regeneration, Inc (TRI) can be attributed to a football injury. While playing for the Jumbos as an undergraduate, Greg Altman, team captain and TRI founder, had the misfortune of tearing the anterior cruciate ligament (ACL) in his knee. The experience motivated him to investigate the feasibility of creating an artificial ACL. As a subsequent Tufts bioengineering PhD candidate, Altman developed a bioreactor capable of simulating the physiological conditions that a growing ACL would be subjected to in the knee. His efforts have led to promising intellectual property for which OTIC is currently seeking patent protection. Given Altman's integral role in the continuing development of this technology, TRI was an obvious license partner for Tufts. In fact, TRI is now a sponsor of additional research at Tufts. Alumni giving can come in many forms indeed.

Tufts University Startup Companies

| Company | Founder/Inventor | Market Focus | Equity Held by Tufts |
|---|-------------------------------------|---|----------------------|
| Ion Signature Technology Licensed 4/96 | A. Robbat A&S | Software for signal analysis | Yes |
| Paratek Pharmaceuticals Licensed 2/97 | S. Levy Medical | Antibiotic therapy | Yes |
| Point Therapeutics Licensed 5/97 | W. Bachovchin Medical | Compounds for increasing blood cell production, treatment of cancer | Yes |
| Securos Licensed 7/97 | K. Kraus Veterinary | Devices for bone fixation | No |
| Illumina Licensed 5/98 | D. Walt A&S | Fiber optic sensor technol- ogy; application to genomics and proteomics | Yes |
| Triad Pharmaceuticals Licensed 9/99 | W. Bachovchin Medical | Platform technology for identification of therapeutic compounds | Yes |
| Tissue Regeneration Licensed 6/00 | G. Altman, D. Kaplan Engineering | Methods and devices for generating tissues | Yes |

Trademark Licensing, Fiscal Year 2000



Tufts paperweight image
Eglomisé Designs, Inc

Beginning in FY00, OTIC became responsible for managing the protection of Tufts University trademarks, logos and insignias and for licensing the commercial use of these marks. One trademark license was concluded in FY00.

It is anticipated that over the coming year OTIC will work closely with the Office of the Provost, the Office of the General Counsel and the Office of the Executive Vice President to finalize and implement policy regarding the appropriate use of the University's name and insignias and to develop a licensing strategy consistent with these policies.

Licensing Activities at Tufts: Historical Perspective

Cumulative Activity

| | |
|-------------------------------------|-----|
| Active Cases | 229 |
| Inactive Cases | 142 |
| Total Cases | 371 |
| Cases Licensed | 63 |
| Active Licenses | 57 |
| Licenses Yielding Income in FY00 | 31 |
| Startup Companies | 7 |
| Issued US Patents (Active) | 84 |

Background

Technology transfer activities began at Tufts in the mid 80s with the filing of patent applications from the School of Arts and Sciences (Chemistry Department) and the College of Engineering. From then to the early 90s, this activity was managed internally through an effort led initially by James Lyddy and then by Robert Garrison.

In 1992, Tufts began negotiations with the Massachusetts Biotechnology Research Institute, which received subsidies to promote economic development in Massachusetts. This organization subsequently became known as Massachusetts Biomedical Initiatives (MBI). In addition to offering incubator space for startup ventures, MBI proposed to manage technology transfer for institutions not prepared to set up an internal office. The agreement with Tufts, concluded in 1993, specified that MBI would provide technology transfer services to Tufts and its faculty in return for an annual fee and ten percent of net income derived from licenses negotiated by MBI. Tufts' relationship with MBI concluded in 1998. At that point, Tufts recognized that its activity in the intellectual property arena had reached a level of importance that would preclude management by an external organization.

Tufts made the commitment to establish a fully staffed technology transfer office in the summer of 1998. Peggy Newell, then newly appointed as associate provost for research, spearheaded this effort. She hired Frances Toneguzzo as director of technology transfer in the early spring of 1999. Frances has both an industrial and an academic background. Following graduate studies and postdoctoral training in biochemistry, she held a number of positions in biotech and pharmaceutical companies. Most recently, she was associate director of technology transfer at Harvard University's Office for Technology and Trademark Licensing.

Active Cases by School

| | |
|-------------|-----|
| A&S | 31 |
| Engineering | 59 |
| Dental | 0 |
| Medical | 104 |
| Nutrition | 13 |
| Veterinary | 21 |
| Other | 1 |

Active Licenses by School

| | |
|-------------|----|
| A&S | 7 |
| Engineering | 5 |
| Dental | 0 |
| Medical | 39 |
| Nutrition | 4 |
| Veterinary | 2 |

Confocal Photonic Force Microscope

Tufts Invention T001095

Mark Cronin-Golomb and his colleagues at the College of Engineering have devised a method and instrument to determine real-time local viscoelasticity in a fluid or gel at high resolution. The device, which combines a scanning optical microscope with a photonic force manipulating element (e.g., laser trap or optical tweezers), will prove particularly useful in the fields of microbiology and medicine, enabling the direct visualization of fluid parameters in cellular systems such as cultures. Possible applications include real-time cell screening and cell sorting, as well as the creation of intracellular spatial maps.

Staffing of the Tufts technology transfer office began in earnest in the late spring of 1999 with the hiring of Thomas McVarish as assistant director of operations. Tom brings a background in research and intellectual property management gained through positions at Bristol-Myers Squibb and Harvard University, as well as a knowledge of financial management. He currently oversees the legal expense budget, the collection and distribution of income from licenses, management of the OTIC database, and government compliance. In the summer of 1999, Ojas Mehta joined OTIC as senior licensing manager in charge of the School of Medicine and the School of Dental Medicine. Ojas, who holds a JD and an MBA degree, has industrial experience in the biotechnology industry as well as a background in academic technology transfer, having held various positions in the licensing office at the University of Rochester. Justyna Lipinska officially joined OTIC in the fall of 1999 after having worked to bridge the gap between the termination of the MBI contract and the hiring of Frances Toneguzzo. During that time, Justyna single-handedly kept technology transfer activities at Tufts afloat. Justyna, who has a JD degree, currently holds the position of technology transfer associate with responsibility for the School of Veterinary Medicine. Staffing of OTIC was completed in the winter of 2000 with the hiring of Martin Son as licensing manager. Martin, who came to OTIC from the technology licensing office at Harvard University, holds a degree in physics and is responsible for the College of Engineering.

Consistent with its mission to “facilitate research at Tufts University by promoting appropriate interactions with industry,” OTIC provides service and advice to staff about relationships with industry whether or not intellectual property is involved. In FY01, OTIC will continue to play a role in formulating intellectual property policy at Tufts.

Trend Analysis

Over the six-year period between FY95 and FY00, the number of licenses granted, patent applications filed, and patents issued has been increasing. One notable exception to this trend is in the number of invention disclosures, which dipped to 28 in FY00 from a high of 63 in FY99. (For the six-year trend data, see table on page 19.)

During the organization of files that occurred in FY00, we noticed that a number of invention files lacked such critical information as the invention disclosure date. In many cases, the filing date of the patent application had been used as the invention disclosure date. This may have caused the incorrect assignment of inventions to certain years and may in part explain the high numbers of disclosures for FY98 and FY99. Even assuming that the FY98 and FY99 numbers are artificially high, however, the numbers for FY00 still show a downward trend. A rule of thumb in technology transfer is that an invention occurs for every \$2 million in funding. Using this as a guideline, Tufts should have an annual invention disclosure rate in the range of 35–45. The fact that the FY00 total (28 disclosures) was below this range may indicate that (i) many of the faculty were unaware of the existence of OTIC, (ii) some faculty may have been frustrated by the previous level of service in this area and (iii) many members of the Tufts community may lack experience with intellectual property, especially in deciding when to disclose a discovery. All of this underscores the need for a technology transfer outreach program in FY01 (see Future Directions on page 17).

Lyme Disease Vaccine

Tufts Invention T001075

Lyme Disease still poses a significant concern in the Northeast. While a vaccine is available, the current version elicits arthritis in certain patient populations. Brigitte Huber and her colleagues in the Department of Pathology at the School of Medicine have developed improved versions of the Lyme Disease vaccine that may reduce or eliminate the incidence of arthritis.

License income has also been increasing, with significant jumps beginning in FY98 and continuing through FY00. Upon closer inspection, however, it is clear that much of the increase is due to the receipt of large, one-time fees or milestones (windfall payments). The FY98 income reflects a windfall payment of \$142,000 in settlement of an infringement suit, leaving a balance of \$118,629 in royalty income. Similarly, the FY99 income includes two windfall payments—an advance on royalties of \$250,000 and a sublicense fee of \$200,000—leaving a balance of \$214,060 in royalty income. For FY00, a total of \$282,910 is attributable to royalty income (\$412,500 is from a single milestone payment and \$109,200 is from a settlement payment).

Royalty income is composed of income derived from the sale of products (a royalty is usually defined as a percentage of the net selling price of a product) and fees realized from the granting of new licenses. Although windfall payments can contribute significantly to the income achieved by a technology transfer office, it is difficult to predict when

such payments will occur. This makes the royalty portion of license income especially important, since it provides a sustainable and predictable income stream. Between FY99 and FY00, for example, a significant portion of the increase in royalty income was attributable to a single product that came to market in late FY99, an isoflavone-based dietary supplement for treating menopausal symptoms. The product, based on technology developed at the School of Medicine and marketed by McNeil-PPC under the name Healthy Woman™ Soy Menopause Supplement, has generated about \$440,000 in royalty income to date. Unfortunately, future benefits from this license are uncertain because of pending intellectual property issues and stiff competition from other companies. These risks point to the need for a strong effort to market new technologies and conclude new licenses. Both activities will increase the probability of new product development, which in turn will contribute to Tufts' royalty base.

Over the FY95–FY00 period, seven new companies based on Tufts technology were formed, and Tufts has an equity position in six of them. As might be expected, new company formation occurs somewhat sporadically and depends on both the financial climate (which governs the ability to raise funds for new ventures) and the availability of technology that is both groundbreaking and “platform” (i.e., capable of generating a number of products and/or services).

Animal-Free Toxicology Testing Tufts Invention T001069

Pressure in the pharmaceutical industry to develop new drugs has led to the development of high-throughput technologies for chemical synthesis and initial screening of compounds. However, because toxicology testing requires the use of animals and is not easily adapted to high-throughput screens, this portion of the drug development process remains a bottleneck. June Aprile, in the Department of Biology at the School of Arts & Sciences, has developed an assay that can be used to screen potential drug candidates for toxicological effects without recourse to the use of animals.

Looking Ahead

Tufts Pipeline

In the next 12–18 months, we expect products for analyzing gene expression to hit the market. These products, which are based on sensor technology originating from the Department of Chemistry at the School of Arts and Sciences, are being developed at a startup company called Illumina (Nasdaq:ILMN). Illumina has companion products in development for the analysis of proteins.

There are a number of leads in the human therapeutic area, also in development. Because of the extensive testing required to obtain approval by the US Food and Drug Administration, however, these compounds are still some years away from becoming products. Included in this category are

- Monoclonal antibodies developed at the School of Veterinary Medicine for the treatment of hemolytic uremic syndrome, a potentially fatal disorder caused by *E. coli* poisoning. The technology is currently under option to Life Sciences Research, Inc, and compounds will soon be entering phase I clinical trials. Because there is no treatment for this potentially fatal syndrome, and because its victims are usually children, the FDA may consider an expedited review, provided the compounds show no adverse effects.
- Novel compounds for restoring blood cell count in cancer patients. This technology, developed at the School of Medicine and licensed to a Tufts startup, Point Therapeutics, has undergone phase I testing in normal volunteers and has proved safe at all dosages. Plans are underway for the initiation of a phase I/II efficacy trial in cancer patients.
- Novel antibiotics for the treatment of infections that are resistant to known antibiotics. This technology, developed at the School of Medicine and licensed to a Tufts startup, Paratek Pharmaceuticals, is based on new chemistries for derivatizing known antibiotics. Although these compounds have not yet undergone testing in humans, their potential for untoward side effects is lower because they are based on known antibiotics. These compounds are in the preclinical phase of testing.

Methods for Efficient Cloning

Tufts Invention T001035

It is now possible to precisely modify or duplicate the genome of an animal through cloning technologies. As such, it is anticipated that cloning will enable a wider use of animal genetic resources in the production of biopharmaceuticals and animal-based food and fiber products. The efficiency of current cloning methods (i.e., number of viable offspring produced) is very low. Eric Overström at the School of Veterinary Medicine has developed improved procedures that promise to bring the efficiency rates up to a level where commercial implementation is feasible.

Future Directions

Although significant income has been realized from milestone payments and can be realized from the sale of equity in startup companies, such payments are often unpredictable. When realized, they constitute windfalls. To sustain a consistent income from technology licensing, it is

critical to establish a base of royalties from the sale of products. Because technologies arising from academic research are typically early-stage, often with little or no established proof of principle, it is extremely difficult to pick the winners. And a significant proportion of academic technologies fail. Thus, for success in technology transfer, it is important to place as many technologies as possible in the hands of industrial partners who can establish proof of principle and begin product development. In other words, success in university technology transfer requires the conclusion of many license agreements. This in turn dictates that one of the main areas of focus in the coming years must be the marketing of Tufts technologies.

Coming Soon . . .

<http://techtransfer.tufts.edu>

Marketing of technologies is a labor-intensive process through which potential licensees are identified and made aware of Tufts discoveries. The Internet is a useful tool for identifying potential partners, and it can be used to advertise Tufts technologies. Accordingly, during FY01 OTIC will post a web site that hosts a directory of Tufts technologies. The web site will also provide general information, including agreement formats for potential industrial partners. The OTIC web site will house various forms, including invention disclosure forms, nondisclosure agreements and academic material transfer agreements, as well as general information for Tufts personnel about intellectual property protection.

The low number of inventions reported in FY00 suggests that a second important direction for the future is outreach to faculty. It is critical that faculty, staff and students be made aware of the existence of OTIC and their obligation to report new discoveries to this office. In addition to posting information on the OTIC web site, the office plans to conduct seminars on intellectual property, entrepreneurship and startup company formation. Also important are one-on-one meetings with individual faculty members and presentations to individual labs. The faculty outreach effort, which was started in FY00, will continue through FY01.

Because technology transfer is an evolving process, policies must be reviewed periodically to ensure that the interests

of the University and its faculty, staff and students are being served. The Tufts University Intellectual Property Policy was reviewed in FY00, and revisions to clarify particular points have been suggested. In addition, a Policy on the Use of the Tufts Name was drafted. The purpose of the latter is to establish consistent use of the name across the University. We anticipate that the two policies will be finalized and implemented during FY01. ■

Annual Data, FY95 to FY00

| | FY95 | FY96 | FY97 | FY98 | FY99 | FY00 |
|-----------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Invention Disclosures | 36 | 31 | 24 | 51 | 63 | 28 |
| New US Patent Apps Filed | 11 | 9 | 12 | 26 | 29 | 20 |
| Total US Patent Apps Filed | 22 | 12 | 21 | 37 | 50 | 42 |
| Foreign Patent Apps Filed | 4 | 6 | 11 | 13 | 21 | 19 |
| Total Patent Apps Filed | 26 | 18 | 32 | 50 | 71 | 61 |
| US Patents Issued | 4 | 6 | 7 | 9 | 11 | 14 |
| Licenses Granted | 6 | 3 | 5 | 13 | 14 | 15 |
| Startup Companies | 0 | 1 | 2 | 2 | 0 | 2 |
| Royalty Income | \$128,547 | \$196,227 | \$190,164 | \$118,629 | \$214,060 | \$282,910 |
| Windfall Income | | | | \$142,000 | \$450,000 | \$521,700 |
| Total License Income | \$128,547 | \$196,227 | \$190,164 | \$260,629 | \$664,060 | \$804,610 |

Printed November 2000.

This report is available electronically in .pdf format. For a copy contact Martin Son at 617.636.3605 or martin.son@tufts.edu.