STANFORD UNIVERSITY OFFICE OF TECHNOLOGY LICENSING ANNUAL REPORT

2014/15

We delight in
the beauty of the
butterfly, but rarely
admit the changes it
has gone through to
achieve that beauty.

—MAYA ANGELOU

CHANGE

Trite but true: change is the only constant in the universe. And for most of us, the rate of change is faster than ever before. In our bubble of Stanford, we cannot avoid change — our President John Hennessy will step down next summer and new leadership will emerge. In the world of research, our relationship with the U.S. government, foundations and companies is changing as organizations cope with their own fluctuations and uncertain futures. The Office of Technology Licensing, too, is experiencing the changing landscape — new patent laws, royalties going down in the coming years, and new inventions that hold the potential for creating big changes in the world we live. It is not a boring time!

OTL celebrated our 45th anniversary this year. Much has changed in 45 years.

When OTL started in 1970, we did not have a Bayh-Dole law to give us guidance on licensing government-funded university inventions. In fact, there was no uniform patent policy among all the existing government agencies. Today, the U.S. Government wants effective and faster transfer of university technologies to companies, particularly to start-ups to foster the American entrepreneurial spirit. Companies are changing faster than ever, new business models are being invented, patent law is constantly being reinterpreted, and science is ever moving the boundary between what is known and what is not known.

Existing companies have been under increasing competitive pressure to innovate and be more profitable; they are often looking for easy-to-commercialize, relatively risk-free inventions. Unfortunately, university innovations are usually very early-stage and risky — years ahead of their time. In addition, existing companies hope that university research can shore up their own research capabilities and sometimes expect the university to be the proprietary research arm of the particular company, which we are not. Start-up companies have been touted as the answer to the translation of university research into products but start-ups struggle to find sufficient capital and management talent in order to have a chance to compete with the existing companies. It is not an easy time for companies.

At OTL, we know that our inventions have the potential for changing the world.

In 1970, The Fluorescence Activated Cell Sorter (FACS) was disclosed to our office. The cell sorting apparatus has been a game-changer in biological research ever since Becton Dickinson sold the first instrument. In 1971, FM Sound Synthesis was invented. This invention was the basis for Yamaha's electronic piano and ultimately the basis for many of the sound chips that are in our electronic devices. In 1973, we received a database invention which described the characteristics of prescription drugs and their interactions with other prescription drugs. This has helped change our lives with respect to knowing more about the medicines we take every day. And of course, Google changed our lives.

The inventions that we are seeing today could change the future.

What would the world be like if we eliminate Alzheimer's or dementia?
One of our 2015 inventions is entitled "Treating Age-Associated Impairments." The Stanford Wyss-Coray laboratory and UCSF 's Villeda laboratory collaborated to identify a first-in-class approach to treat aging-associated cognitive impairments by targeting a specific blood-borne protein that is involved in neurogenesis, learning and memory in mice. This technology can be used to treat the effects of cognitive diseases and aging on the central nervous system. Since there are currently no therapeutics that successfully treat the cognitive decline associated with aging, this could be a game-changer.

What if prosthetic limbs had a sense of touch?
Professor Zhenan Bao and her colleagues are developing flexible and highly sensitive pressure sensors. These sensors could be stitched together into an artificial skin to enable prosthetic limbs to distinguish the difference between a soft touch and a firm handshake.

What if we could really assess breast cancer risk, not just through genetics, but also analysis of our bodies?
Researchers in Dr. Daniel Rubin's lab have created an automated method to quantify breast density and predict the risk that a woman will develop breast cancer. This method may be used to stratify women according to breast cancer risk and enable tailored screening and personalized patient management.

What if we could truly rely on our GPS system?
With increasing use of drones, driverless cars and certainly airplanes, we are relying heavily on GPS systems. But GPS systems are currently vulnerable to jamming and interference. More reliance on GPS in commercial aviation for functions such as landing and takeoff could save millions of dollars each year, not to mention increased time efficiency. Prof. Per Enge and his colleagues have developed a backward compatible solution that provides the answer to both problems.

What if we could treat Down's syndrome?
Scientists in Dr. Michael Clarke's lab have discovered methods to treat diseases associated with Down's syndrome, a complex clinical syndrome associated with higher risk of multiple pathological conditions, including heart problems, intellectual disabilities, osteoporosis and diabetes. Recent findings from the Clarke lab identified cyclophilin D and USP16 as new therapeutic targets for treatment of several of the diseases associated with Down's syndrome.

What if we could compute really hard problems in minutes rather than years?
Prof. Robert Byer and Prof. Yoshihisa Yamamoto developed a new approach to computing with optics and it promises to solve hard problems with less energy than other quantum computing machines. This super-duper computer operates at room temperature and uses commercially available optical technologies.

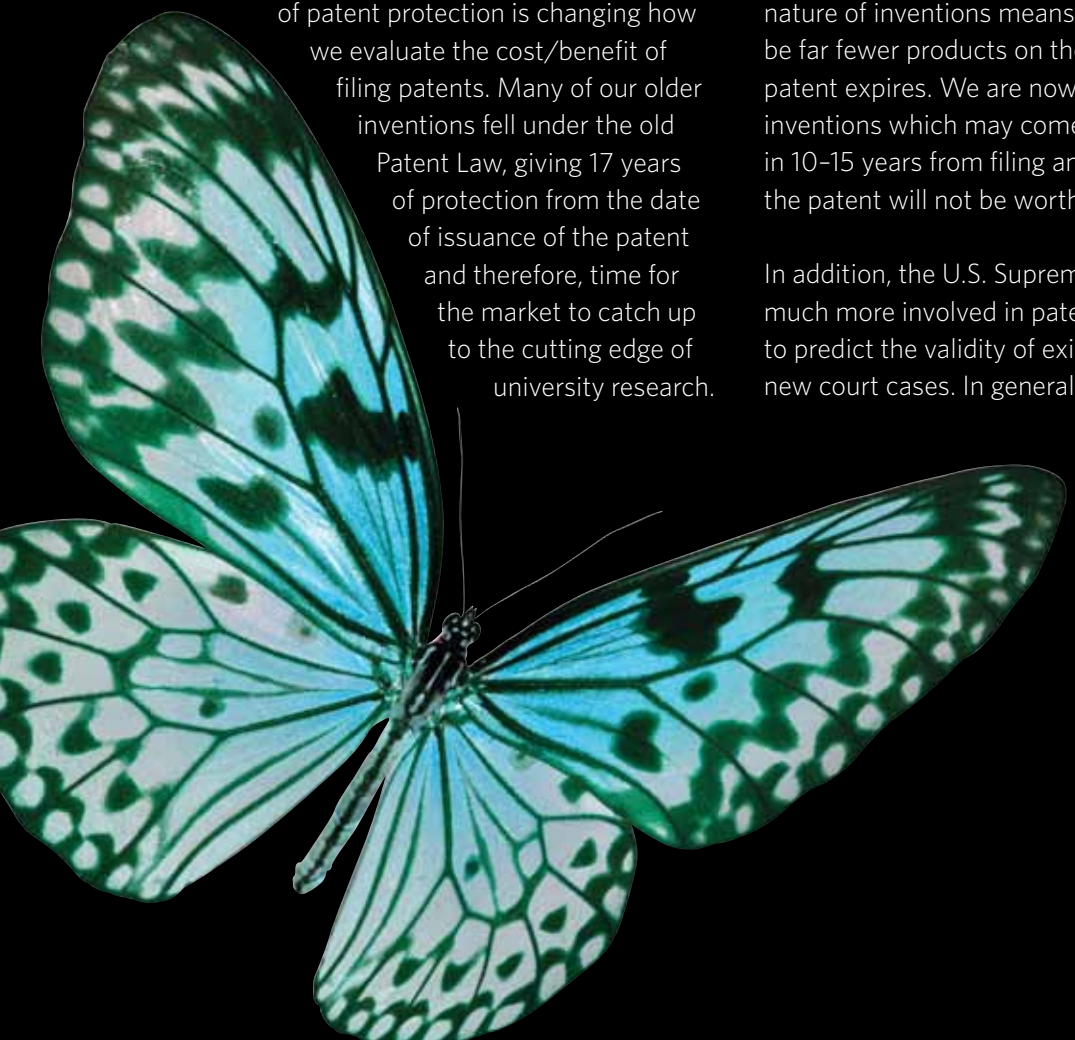
What if we could have an eye examination anywhere we wanted?
One of our 2015 inventions enables smartphones to capture images of the eye. These images can be transmitted to ophthalmologists who can then diagnose eye problems without an office visit.

What if we could reduce healthcare costs in both developing and developed countries?
Prof. Manu Prakash and his colleagues are inventing low-cost tools for use throughout the world. What would the world be like if we could look at organisms with a microscope that cost 50¢ to make or if we could process fluids with a centrifuge that costs less than $1? These tools can be used in remote areas with no external power source.

New challenges for technology transfer

Changes in the Patent Landscape

At OTL, we are feeling the full impact of the America Invents Act. The 20-year length of patent protection is changing how we evaluate the cost/benefit of filing patents. Many of our older inventions fell under the old Patent Law, giving 17 years of protection from the date of issuance of the patent and therefore, time for the market to catch up to the cutting edge of university research.



In contrast, the current patent law gives 20 years from the date of filing, regardless of when the patent issues. For most universities, the early stage nature of inventions means that there will likely be far fewer products on the marketplace before a patent expires. We are now protecting only those inventions which may come to commercial fruition in 10–15 years from filing an application; otherwise, the patent will not be worth the expense.

In addition, the U.S. Supreme Court has been much more involved in patents. It is now harder to predict the validity of existing patents in light of new court cases. In general, the pressure on the U.S. Patent Office to grant strong and valid patents makes it is harder to obtain meaningful and broad patent coverage on new inventions without extensive data and supporting information, which is not always available prior to publication of the research results in a scientific journal and at the time of filing a patent application. Patents are often narrower than in a previous time, and therefore companies can invent around them more easily.

Changes in the Funding Landscape

Many disease-focused foundations are also funding pre-clinical research and hope to both bring better medicines to their particular patient population and to have a return on their investment. We have seen many more foundations want a share of royalties if universities are able to license inventions that were funded in part by them.

Changes at OTL

In the 1970s and early 80s, we recorded our notes on pink sheets of paper so that we could separate office notes from other documents. Our typist typed out all correspondence as a draft, we reviewed it and made edits, and then she finalized the letter. We used onion skin to make carbon copies. We all pitched in to file our papers on Friday afternoons as we drank Henry Weinhard beer — thus we started OTL's "Henry's" tradition. We still do monthly Henry's but we don't have to file, thanks to our powerful IT system.

What hasn't changed is the basic philosophy of the office: to maintain good relationships with our inventors and licensees, the keys to our success; to plant as many seeds (licenses) as possible so that we can enable the transfer of research to companies; to be flexible, be reasonable and be business-like within a university environment.

We have grown significantly. In 1970, OTL was comprised of 2 people. Today we are 47 strong.

The Industrial Contracts Office (ICO) joined OTL in FY1997–98. Although focused primarily on industry sponsored research contracts, ICO has been essential for supporting any kind of sponsored research (e.g., foundations, industry-government consortia) whenever there are intellectual property negotiations. ICO also handles equipment loans from industry, Material Transfer Agreements, collaboration agreements, Affiliates program review, data use agreements and many other miscellaneous agreements.

In 1970, we received 18 invention disclosures. Today we process close to 500 inventions a year. Our Associates handle more than 300 inventions at any one time out of a total of 3500 active cases.

Our first license was for $5,000. To date, we have generated cumulatively $1.77B in gross royalty revenue. We have distributed $308M to Schools, $319M to Departments and $318M to Inventors. In addition, we have given:

$16.5M to the Provost's Office
$77M to the Dean of Research
$13M to the Vice Provost for Graduate Education

OTL has funded 74 Stanford Graduate Fellowships.

The biggest change in the coming years is the expiration of the last patent that covers our largest royalty-producing invention at Stanford. The loss of this income over the next few years impacts the financial operation of OTL. In FY17–18, we anticipate that for the first time in 32 years, the 15% administrative fee per Stanford's royalty sharing policy will not cover OTL's operating budget. The University, however, recognizes the contributions of OTL and the resources needed to effectively transfer Stanford technology to society and will continue to support OTL.

FY 2015 Year in Review

Stanford received $95.1M in gross royalty revenue from 695 technologies, with royalties ranging from $5.47 to $64.77M.

Thirty-nine of the 695 inventions generated $100,000 or more in royalties. Eight inventions received $1M or more. It is clear that we have a long tail of inventions that bring in less than $100,000 in royalties but this long tail is the steady royalty base for Stanford.

In 2015 we evaluated 483 new invention disclosures. Filing and maintaining patents is an expensive proposition and we spent $9.58M in legal expenses. Of the 112 new licenses we signed this year, 38 were nonexclusive, 43 were exclusive and 31 were option agreements.

Royalty Distribution

Stanford's royalty-sharing policy provides for the distribution of cash net royalties (gross royalties less 15% for OTL's administrative expenses, minus direct expenses) to inventors, their departments and their schools. Inventors received personal income of $24.5M, departments received $21.8M and schools received $20.7M. The University assessed an infrastructure charge on the department and school shares of royalty income.

We contributed $1M to the University General Fund and $1M to the OTL Research Incentive Fund, which is administered by the Dean of Research for the support of early-stage, innovative research ideas, novel interdisciplinary research, cost sharing of shared instrumentation and other research facilitation needs.

With respect to liquidated equity, we transferred $1.2M each to the Dean of Research for the OTL Research Fund and to the Vice Provost for Graduate Education for the VPGE/OTL Graduate Education Fund. Stanford also paid other organizations $730,000 for jointly-owned technologies for which Stanford has licensing responsibility.

Expenses

OTL spent $9.6M on patent and other legal expenses, of which $4.4M was reimbursed by licensees. We have an inventory of $20.6M, which represents patent expenses for unlicensed inventions. Our operating budget for the year (excluding patent expenses) was $7.9M.

We take a financial risk each time we decide whether or not to file for a patent. In this period of tremendous change in the intellectual property landscape as court cases determine new patent law, we must weigh the likelihood of licensing a technology versus the expense of patenting or litigation. In addition, because of the America Invents Act (AIA), we sometimes need to decide whether or not to file patent applications earlier than would be optimum. We are being more selective in our filings now than in the past because the U.S. Patent Office is requiring more data to support the invention and issuing fewer broad patents.

IN FY 2014-15, STANFORD RECEIVED

$95.1M

IN GROSS ROYALTY REVENUE FROM

695

TECHNOLOGIES.

483

NEW INVENTION DISCLOSURES WERE EVALUATED, AND

112

NEW LICENSES WERE SIGNED.

OTL SPENT

$9.6M

ON PATENT AND OTHER LEGAL EXPENSES, OF WHICH

$4.4M

WAS REIMBURSED BY LICENSEES.

Equity

As of August 31, 2015, Stanford held equity in 121 companies as a result of license agreements. For institutional conflict-of-interest reasons and insider trading concerns, the Stanford Management Company sells our public equities as soon as Stanford is allowed to liquidate rather than holding equity to maximize return. This year, we received equity from 28 companies. 27 of these were licensed to start-ups defined as a "start-up based primarily on Stanford technology." We also received $3.2M in liquidated equity from 11 other companies.

New Disclosures

In FY2015, we received 483 new technology disclosures. About 10% of the inventions were considered such an amalgam of both physical sciences and life sciences so as not to be able to categorize them in one group or the other, evidence of the results of interdisciplinary research. Approximately 47% of inventions were in the life sciences, 35% were in the physical sciences and 8% were considered medical devices.

Stanford Trademark Enforcement Fund and Patent Expenses

The Stanford Trademark Enforcement Fund (STEF) was established as a source of funding for extraordinary cases associated with the protection of the Stanford name and associated logos and trademarks. Funding for the STEF comes from 1% of the department and school shares of net revenue OTL receives. In addition, the President authorized OTL to set aside an additional 1% to provide a fund to offset expenses associated with the new America Invents Act Patent Law.

Happenings at OTL

We moved this year, as we often have in the past. We are now located in Palo Alto Square (3000 El Camino Real, Building 5, Suite 300, Palo Alto, CA 94306).

In May, 2015, we celebrated Stanford Inventors. Many inventors flew in from other parts of the country to celebrate with us. We inducted 6 new inventions into the Stanford Invention Hall of Fame:

Data Visualization (Robert Bosch, John Gerth, Mendel Rosenblum, Patrick Hanrahan, Christopher Stolte, Diane Tang)

Error Detection Software (Benjamn Chelf, Andy Chou, Dawson Engler, Seth Hallem)

Cy7 – Allophycocyanin Conjugates (Mario Roederer)

Ranking Nodes in Large Directed Graphs (Taher Haveliwala, Glen Jeh, Sepandar Kamvar, Gene Golub)

The Education Program for Gifted Youth (EPGY Team from Stanford Pre-Collegiate Studies)

Teacher Performance Assessment (Teacher Assessment Team from the School of Education)

In addition, we recognized 27 newly inducted inventors who have invented at least 7 technologies that, in aggregate have generated over $500,000:

Helen Blau
Patrick Brown
Michele Calos
John Cooke
Abbas El Gamal
A. Sanli Ergun
Kenneth Fesler
Steven Foung
Virginia Gonzalez
Leonore Herzenberg
Mark Kay
Chaitan Khosla
Byoung Yoon Kim
Daniel Kim
Brian Kobilka
Diana Laurent
Kate Lorig
Daria Mochly-Rosen
Daniel Palanker
Arogyaswami Paujlraj
F. Fabian Pease
Norbert Pelc
Stephen Quake
Julius Smith
James Swartz
Sebastian Thrun
Paul Wender

OTL has established a relationship with the Stanford Digital Repository (SDR) whereby we deposit licensed software into SDR so that Stanford and its licensees have an archived copy of the software OTL transfers to industry. This both ensures Stanford's access to software developed by Stanford researchers and memorializes the version of the original software transferred to the licensee.

OTL's database now connects directly with Stanford's Outside Professional Activities Certification System (OPACS), and OTL and faculty can submit conflict-of-interest reviews directly into the system for Deans' review.

THE OTL OPERATING BUDGET, EXCLUDING PATENT EXPENSES, WAS

$7.5M

STANFORD HELD EQUITY IN

121

COMPANIES AND RECEIVED

$3.2M

IN LIQUIDATED EQUITY FROM 11 COMPANIES.

OF THE NEW DISCLOSURES, ABOUT

47%

WERE IN LIFE SCIENCES,

35%

WERE IN PHYSICAL SCIENCES AND

10%

WERE IN BOTH LIFE AND PHYSICAL SCIENCES.

8%

WERE MEDICAL DEVICES.

IN FY 2014–15, ICO FINALIZED

157

NEW INDUSTRY SPONSORED RESEARCH AGREEMENTS .

APPROXIMATELY

460

MTAS WERE FOR INCOMING MATERIALS, AND

182

FOR OUTGOING MTAS.

ICO FACILITATED MORE THAN

169

AMENDMENTS TO EXISTING SPONSORED RESEARCH AGREEMENTS.

ICO

Part of OTL, the Industrial Contracts Office (ICO) specializes in research agreements with industry. In FY15, ICO finalized 157 new industry sponsored research agreements, where companies fund, and sometimes collaborate on, research projects in Stanford laboratories. The School of Medicine accounted for about 52% of the sponsored research agreements and the School of Engineering accounted for about 29% of these agreements. The School of Humanities and Sciences accounted for another 8% of the total. The rest of the agreements were for projects in the School of Earth, Energy and Environmental Sciences, the Graduate School of Education, the Graduate School of Business and the Independent Laboratories.

Among the other agreements that ICO finalized, Material Transfer Agreements (MTAs) continued to account for the largest number — with about 460 new MTAs for incoming materials and 182 outgoing MTAs. Another 58 agreements were for sending out human tissues for research purposes.

Other ICO agreements included more than 169 amendments to existing sponsored research agreements, plus new collaborations, data sharing, equipment loans, non-disclosure and other research-related agreements. ICO also handles agreements for Industrial Affiliates programs.

ICO negotiated several agreements with Ford Motor Co. for the School of Engineering. In addition to lending a car to Professor Chris Gerdes (in Mechanical Engineering) for automated vehicle research studies, Ford provided a total of $1.28M to Engineering faculty in support of four sponsored research projects. Ford also participates in the CARS and Computer Forum industrial affiliates programs. Ford funded the following projects:

Professor Gerdes to investigate incorporating expert path planning in automated driving; Professor Reinhold Dauskardt (in Materials Science & Engineering) for a two-year study of coating for polymeric glazing; Professor Larry Leifer (in Mechanical Engineering) for a two-year study on shared control in driver vehicles; and Professor Werner Ihme (in Mechanical Engineering) for a two-year study to conduct detailed modeling and investigate combustion issues relevant to spark ignition engines.

Professor Alison Okamura (in Mechanical Engineering and Computer Science) received funding from the virtual reality company Oculus VR LLC, a subsidiary of Facebook, to perform research related to skin stretch haptic feedback.

Professor Russ Altman (in Bioengineering) received funding from Pfizer Inc. to create analytic methods for understanding drug response at the molecular level and quantitatively through

analyzing retrospective and prospective data. The goal of the project is to harness data to better predict drug side effects, drug treatment efficacy and new uses for existing drugs.

Total E&P Recherche Developpment SAS of France is funding Professor Hamdi Tchelepi (in Energy Research Engineering) to investigate a physics-based, multi-scale framework for modeling fracturing and oil and gas production from source rock.

The Columbian petroleum company Ecopetrol is sponsoring the research of two faculty in Energy Resources Engineering: Professors Anthony Kovscek and Margo Gerritsen are investigating effective and predictive modeling of thermal enhanced recovery processes.

Takeda Pharmaceuticals, Inc. funded the research of Professor Daria Mochly-Rosen (in Chemical and Systems Biology) on Treatments for Neurodegenerative Diseases.

Takeda Pharmaceuticals, Inc. also funded Professor Hiro Nakauchi's research (in Genetics — Stem Cell) on Generation of Human Liver by Interspecific Conceptus Complementation of an Engineered Developmental Niche in Rats, with the goal of eventually creating human organs for transplantation purposes.

Fibrocell Science funded Professor Jean Tang's research (in Dermatology) on characteristics of patients with Recessive Dystrophic Epidermolysis Bullosa, an inherited disease affecting the skin and other organs.

Professor Jill Helms (in Plastic and Reconstructive Surgery) received funding from Ankasa Regenerative Therapeutics. With Ankasa's support, Prof. Helms' lab will perform research related to speeding bone regeneration in a variety of lead indications.

Professor Matthew Porteus (in Pediatrics — Stem Cell Transplantation) received funding from StemCells, Inc. to use genome editing technologies to create genetically modified human neural stem cells. The project's goal is to develop transplantable, gene-modified neural stem cells for the treatment of neurological diseases, disorders and injuries.

F. Hoffman-LaRoche Ltd. funded two projects in fiscal year 2015 under its Extending Innovation Network master agreement with Stanford: Professor Thomas Sudhof (in Molecular and Cellular Physiology) is researching Synaptic Basis of Stereotypic Behaviors, which looks at neural dysfunction that results in repetitive behaviors found in certain neurological conditions; and Professor Liqun Luo's project in Biology on Exploring Connectivity Defects in Mouse Models of Tuberous Sclerosis, which studies neural issues common in conditions such as autism.

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