

The AUTM Briefing Book: 2015



Key issues in the technology transfer business.



Association of University Technology Managers®
Advancing Discoveries for a Better World®

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INTRODUCTION

Introduction to AUTM Advocacy

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AUTM implements a pragmatic advocacy program aimed at education, promotion, endorsement, advancement and protection of the technology transfer profession globally. With stakeholders and constituents, through government, media, university administrations and corporate leadership, AUTM tackles university R&D commercialization issues, as well as proposed policy solutions, to accelerate the path of research into the marketplace and the lives of citizens worldwide.

Formally and informally, AUTM communicates and partners with its global membership, with public officials, with business and industry and with tech transfer practitioners everywhere to advocate for technology commercialization and its stakeholders—from support of the pro-commercialization measures of The TRANSFER Act of 2013 to gene patenting/licensing practices.

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TECHNOLOGY

Technology Transfer Shapes Our World in Ways Large and Small

As vast as the world's need for fresh drinking water and as minuscule as a molecule that targets cancer, technology transfer activities conducted by universities and other nonprofit entities span the globe and yet facilitate work at the microscopic level to improve the human condition.

At the same time, university tech transfer powers the innovation economy, creating jobs, saving and enhancing lives, improving productivity and offering solutions to environmental challenges. By moving discoveries from basic research laboratories to commercial partners capable of transforming the inventions into beneficial products and services, tech transfer makes the world a better place in which to live.

The Association of University Technology Managers (AUTM) plays a key role in the process by highlighting the public value of tech transfer; promoting important intellectual property protections, including ongoing benefits of the Bayh-Dole Act and supporting its members through education, advocacy and industry engagement.

The results of this work can be seen all around us: in lifesaving therapies and cures, in productivity advances that connect the world more closely and in clean technologies that offer a brighter path for future generations.

AUTM's role in technology transfer

From its inception in the mid-1970s as the Society of University Patent Administrators, AUTM has developed best practices for university technology transfer offices and facilitated relations with industry to ensure that inventions with high commercial potential reach the marketplace for the benefit of people everywhere.

Along the way, AUTM's work on behalf of its members has contributed to improved intellectual property protection and the establishment of a profession dedicated to tech transfer.

Today, the results of AUTM's efforts can be seen in the millions of people who have been treated for conditions ranging from vitamin D deficiencies and epileptic seizures to cancer and HIV, thanks to the more than 153 drugs approved by the U.S. Food and Drug Administration that started in university laboratories.ⁱ From 1997 to 2007 alone, according to a recent study by the Biotechnology Industry Organization, university licensing had a \$187 billion impact on U.S. gross domestic product, added \$457 billion to the U.S. gross industrial output and led to the creation of 279,000 jobs.ⁱⁱ

AUTM's impact continues to grow. Yet much as it functions today, the

association's early direction was based on the needs of its members—practitioners at university patent and licensing organizations who sought to ensure ongoing funding for research that would benefit the general public.

Founding members of the organization set their sights on improving patent policies that hampered the broad dissemination of university technologies arising from federally funded research. Before 1980, most federal agencies mandated that inventions made with federal dollars be assigned to the government; however, the policies were inconsistent and many promising discoveries remained under government ownership and were not developed commercially.

AUTM founders also recognized the benefits of establishing a network of colleagues whose knowledge and experience could help others navigate the complexities of the emerging field. Their efforts could not have come at a better time: The U.S. was mired in a deep economic malaise and the federal government had succeeded in licensing just 5 percent of the 28,000 patents it had amassed.ⁱⁱⁱ

Recognizing the vast potential of the technologies sitting dormant on government shelves, early AUTM members embarked on a major outreach and coalition-building effort involving leading academic research institutions and key members of Congress. Their efforts paved the way for passage of the landmark Bayh-Dole Act in 1980.

Landmark law helped universities lead the way

The Bayh-Dole Act fundamentally changed the nation's system of tech transfer by enabling universities to retain title to inventions and take the lead in patenting and licensing groundbreaking discoveries.

The new system provided clear incentives for universities while creating new opportunities for faculty members to extend their contributions to society beyond publishing in peer-reviewed journals. Importantly, Bayh-Dole encouraged academic institutions to seek partnerships with industry to develop campus inventions into commercial products.

This new dynamic stimulated billions of dollars in private sector investment and helped leverage taxpayer-funded research to create millions of jobs, improve public health and promote a renaissance of American innovation. Between 1980 and 2002 alone, U.S. universities generated a tenfold increase in patents, launched more than 2,200 university spinoffs to further develop research arising from campus labs, created 260,000 jobs in the process and contributed \$40 billion annually to the U.S. economy.^{iv}

TECHNOLOGY

Technology Transfer Shapes Our World in Ways Large and Small

In addition to boosting the nation's economy, the early momentum created by Bayh-Dole fundamentally changed public perceptions about the importance of university tech transfer and its role in generating revenue to support the academic research enterprise. At the same time, these early successes raised public expectations for universities to extend their efforts beyond the traditional scope of education and research and become more deeply involved in stimulating economic development and entrepreneurial activity.

AUTM provides forum to showcase impact of tech transfer

These changing public expectations create new challenges for many AUTM members. For all but a few of the nation's elite research universities, consistently linking tech transfer activities with steady job creation and gains in business vitality is quite challenging.

Breakthrough discoveries are by their nature unpredictable, and tech transfer success occurs only when these discoveries are suited to appropriate intellectual property protection and align with industry needs and capital availability. Even then, commercial success is not guaranteed.

Blockbuster technologies remain rare, making it difficult for individual institutions to report steady progress in terms of job growth or spinoff success. While some practitioners argue that these expectations for economic impact extend beyond the core mission of tech transfer offices, long-term public support for federal research spending depends on the ability to quantify beneficial outcomes in terms of economic advancement as well as gains in human health and well-being.

AUTM addresses these challenges through its unique ability to collect, aggregate and analyze member data over time. While economic impact results may vary considerably among individual institutions, taken together, the performance of AUTM's members offers compelling testimony about the impact of tech transfer.

For example, institutions responding to the 2012 *AUTM U.S. Licensing Activity Survey* reported \$36.8 billion in net product sales from licensed technologies in fiscal year 2012 while the university tech transfer offices themselves received \$2.6 billion in total licensing income. In addition, startup companies formed by 70 key institutions employed 15,741 full-time employees.^v

Table I provides a closer look at the ongoing impact of university technology transfer.

Table I

Description	Number	% change from prior year
Total U.S. patent applications filed	22,150	+11.3%
New patent applications filed	14,224	+7.2%
U.S. patents issued	5,145	+9.5%
Licenses executed	5,130	+4.7%
Options executed	1,242	+7%
Executed licenses containing equity	483	+16.1%
Total license income	\$2.6 billion	+6.8%
Startup companies formed	705	+5.1%
Startups still operating as of the end of FY2012	4,002	+1.9%

Source: AUTM U.S. Licensing Activity Survey: FY2012

TECHNOLOGY

Technology Transfer Shapes Our World in Ways Large and Small

Changing intellectual property landscape brings AUTM's work into focus

The America Invents Act (AIA) dramatically altered the U.S. intellectual property landscape by conferring patent protection to the first inventor to file an application, rather than to the first inventor responsible for the discovery. The new “first-inventor-to-file” system took effect for applications filed on or after March 16, 2013.^{vi}

The law, combined with changing interpretations of what constitutes a patentable discovery, necessitates a number of changes for university tech transfer offices. Of particular concern is the Myriad Genetics case of 2013, in which the U.S. Supreme Court ruled that human genes may not be patented.^{vii}

Together, these developments force university tech transfer offices to direct increased resources to evaluating discoveries for patentability before undertaking the costly filing process. At the same time, patenting and licensing offices face increased pressure to complete applications as quickly as possible to avoid the prospect of losing intellectual property rights globally, thereby reducing the incentive for licensees to invest in developing an invention.

As part of its work to support and advance tech transfer, AUTM provides a number of resources to help members succeed amid the ongoing changes to U.S. patent law and policies of the U.S. Patent and Trademark Office. Through workshops, webinars, blogs, networking opportunities and its *Technology Transfer Practice Manual (TTP Manual)*, AUTM encourages its members to stay on top of the evolution and share ideas for addressing emerging challenges.

AUTM prepares members for the future through education, advocacy, industry relations

Beyond addressing the immediate needs of members in response to patent law and policy changes, AUTM works proactively to ensure member access to the education opportunities and resources they need to be more effective and successful in their careers. Through a variety of initiatives, AUTM also strives to support a favorable environment for tech transfer globally.

With 35 percent of its members hailing from the private sector, AUTM bridges the gap between industry and academia by fostering productive relationships and working collaboratively to develop

workable standards for performance in tech transfer agreements and relationships. Sample documents found on AUTM's website and frequent workshops at sites around the U.S. help corporate technology scouts and academic tech transfer practitioners develop shared expectations for how best to accomplish the movement of inventions from campus to company.

Meanwhile, AUTM's Better World Project raises the profile of groundbreaking university discoveries and technology commercialization efforts for all the world to see.

In the years ahead, AUTM anticipates additional advocacy efforts and a focus on training and targeted communications to help members take advantage of emerging trends, including intellectual property exchanges and valuation tools. As changes in U.S. patent law bring domestic intellectual property practices into alignment with the practices of key trading partners, AUTM's global leadership in the academic and nonprofit technology transfer profession will ensure its members continue to benefit humanity with lifesaving tools and groundbreaking technologies.

Footnotes:

- i. McDevitt V, Mendez-Hinds J, Winwood D, Nijhawan V, Sherer T, Ritter J, Sanberg P: More than money: the exponential impact of academic technology transfer, *Technology and Innovation* 16:75–84, 2014.
- ii. Pradhan AS: Defending the university tech transfer system, *Bloomberg Businessweek*, 2010.
- iii. Bremer H, Allen J, Latker N: The Bayh-Dole Act and revisionism redux, *Industry and Higher Education* 23(5):351–366, 2009.
- iv. Editorial: Innovation's golden goose, *The Economist Technology Quarterly* Q4, 2002.
- v. AUTM U.S. Licensing Activity Survey: FY2012.
- vi. Leahy-Smith America Invents Act, 125 Stat. 284, Public Law 112–29, Sept. 16, 2011.
- vii. Association for Molecular Pathology v. Myriad Genetics Inc., Supreme Court of the United States, Docket No. 12–398, June 13, 2013.

TECH TRANSFER

Benefits People, Society and the Economy

University Technology Transfer

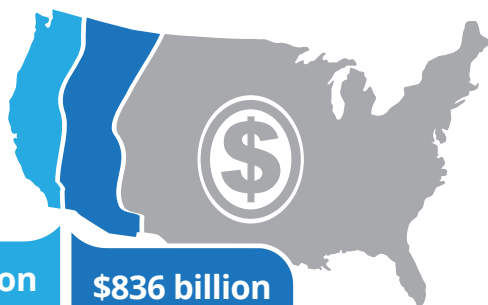
Benefits People, Society
and the Economy

Universities substantially contribute to the creation of new technologies, new companies, new industries ... and new jobs.

Highly specialized university employees known as **technology transfer professionals** manage the complex process of protecting discoveries and turning them into products and services. This is done by **securing patents**, so that a discovery can be licensed and further developed by an existing company or a startup to produce the new product.

University research sometimes yields a discovery that has commercial potential or the potential to improve—even change or save—lives.

From 1996 to 2010, the economic impact of university and nonprofit patent licensing was



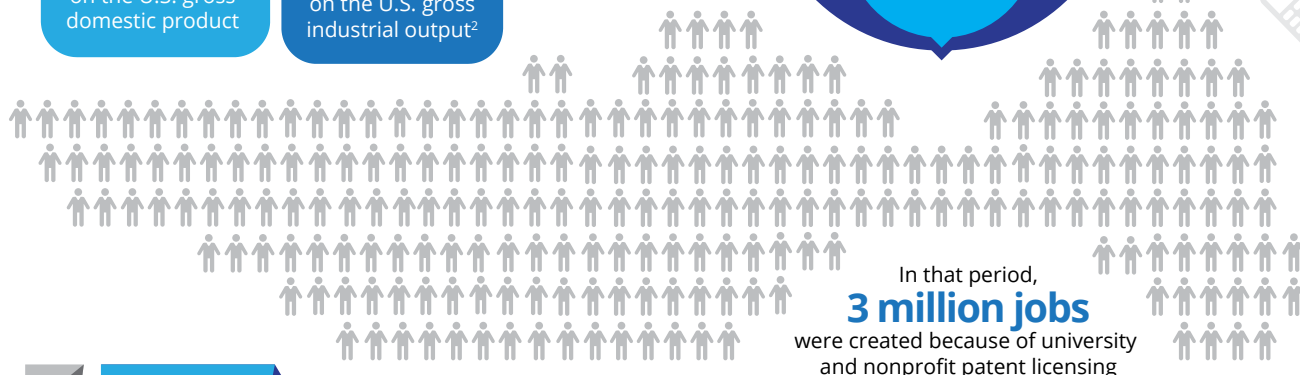
\$388 billion
on the U.S. gross domestic product

\$836 billion
on the U.S. gross industrial output²

Since 1980, universities in the U.S. have spun off

more than
4,000
startup companies

818
were launched
in FY2013



👤 = 10,000 jobs

719
new
products

were introduced to the marketplace, by universities, in 2013 alone

Over the past 30 years,

153 new FDA-approved drugs,

vaccines or new uses for existing drugs
were discovered through research carried out in public
sector research institutions³

¹ AUTM U.S. Licensing Activity Survey Highlights FY2013.

² Biotechnology Industry Organization: The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2010; June 20, 2012.

³ The Role of Public Sector Research in the Discovery of Drugs and Vaccines, *The New England Journal of Medicine*, February 10, 2011.

To learn more about technology transfer, visit the Association of University Technology Managers at www.AUTM.net

To read stories about innovations developed at universities, visit www.betterworldproject.net

BREAKTHROUGHS

Born of Necessity, Frustration and... Chance

Big Breakthroughs Born of Necessity, Frustration and ... Chance

Research often doesn't go in straight lines. Many times there are dead ends. On other occasions, almost by chance, scientists make breakthroughs that lead to new products, therapies or companies. Some of which are spectacularly successful and change lives for the better.

Take the case of two HIV-antiretroviral drugs that are now used by 95 percent of AIDS-infected patients in the United States. In the mid-1990s, Emory University researchers Raymond Schinazi, Dennis Liotta and Woo-Baeg Choi discovered the two drugs after giving up on conventional approaches to their pursuit of molecular synthesis.

Sold under brand names Emtriva (the Em stands for Emory and the tri for Triangle Pharmaceuticals, the company that originally developed the drug) and Efavir, both drugs are in the class known as *nucleoside reverse transcriptase inhibitors* (NRTIs), which work against the enzyme that copies HIV RNA into new viral DNA.

"When you do research, you try things that seem to make sense," says Liotta, a chemistry professor. "And then you do them and they don't work. But in this case, what we did worked beautifully and the rest is history."

Novel approach out of failure

Liotta says he and his colleagues hadn't been successful using conventional techniques to synthesize molecules. So they picked a highly unusual method that succeeded on the first try and was 300 times more selective than previous techniques they'd used.

"We never expected to be designing drugs," he says. "But because we had this great chemical synthesis methodology, we were able to run circles around our competition and find compounds like Emtriva that really worked like a charm."

Liotta says their breakthrough came from "serendipity with a little assist from necessity."

"We would never have tried something that novel if we wouldn't have had so much trouble with existing methods," he says.

At the University of Wisconsin-Madison, another chemist's work led to the creation of a highly effective rat poison and an anticoagulant widely used by heart patients. According to Kevin Walters, the Wisconsin Alumni Research Foundation (WARF) historian in residence, it all began

The patterns are simple, but followed together, they make for a whole that is wiser than the sum of its parts. Go for a walk; cultivate hunches; write everything down, but keep your folders messy; embrace serendipity; make generative mistakes; take on multiple hobbies; frequent coffeehouses and other liquid networks; follow the links; let others build on your ideas; borrow, recycle; reinvent. Build a tangled bank.'

in 1933 when an exasperated German farmer stormed into Karl Paul Link's lab.

Link, whom Walters describes as a "colorful fellow," said the farmer was carrying a bucket of cow's blood, shouting "*Mein Gott!* (My God!) My cows are bleeding to death."

When the farmer calmed down, he explained that after dehorning or castration, the animals' blood continued to flow until they died. It turned out the cows were eating sweet clover hay that had spoiled, producing a deadly anticoagulant.

It took six years of research, but in 1940, Link and his lab mates synthesized the hemorrhagic agent, which they later named dicoumarol. It was patented by the university in 1942. In 1948, it was first promoted as a rodenticide and the product was named warfarin, after the university tech transfer office that had funded the research for it.

"No one knew that from the study of spoiled hay, you'd get a drug to prevent blood clotting in humans and kill rats," Walters says. "That happened by chance."

BREAKTHROUGHS

Born of Necessity, Frustration and... Chance

It wasn't until 1954 that warfarin (under the brand name Coumadin) was approved for human use. The drug—and WARF—became famous in 1955, Walters says, after it was used to treat President Dwight Eisenhower, who had suffered a heart attack.

A saying at the time was “What’s good for a war hero and the president of the United States must be good for all, despite being a rat poison.”

Google, because the timing was bad

A third highly visible example of discovery by chance comes from Stanford University, where a pair of doctoral students—Larry Page and Sergey Brin—created the multi-billion-dollar search engine company known as Google. But that wasn't their initial plan, says Luis Mejia, associate director of Stanford's Office of Technology Licensing.

“The inventors did not want to do a startup company—they wanted to finish their Ph.D.s,” recalls Mejia, who worked with the pair in the mid-1990s. “They just wanted us to license the PageRank algorithm technology. So we spent half a year trying to market it and find licensees. But nobody really expressed much interest.”

Mejia says Page and Brin went to a few “road shows” with him and learned first-hand that no one understood what they were doing.

“So it was really out of frustration that they decided to start a company, because the timing for licensing a search engine wasn't good,” he says. “In that respect, it was chance.”

Mejia says the pair—who never finished their doctorates—did not have a business model when they licensed the technology.

‘The trick to having good ideas is not to sit around in glorious isolation and try to think big thoughts. The trick is to get more parts on the table.’

“But then a lot of things just sort of fell into place,” he says. “Maybe that’s where serendipity comes in. If we hadn't licensed it to them, there is a chance we could have licensed it to another company for a very nominal sum of money. But it isn't clear that they would have done anything with it. And there probably would be no Google today.”

‘Good ideas may not want to be free, but they do want to connect, fuse, recombine. They want to reinvent themselves by crossing conceptual borders. They want to complete each other as much as they want to compete.’



— Steven Johnson bestselling guru of breakthrough ideas, who is the keynote speaker at AUTM's 2015 Annual Meeting, held in New Orleans February 22-25. His book titled *Where Good Ideas Come From: The Natural History of Innovation* is an investigation of environments leading to breakthrough innovation in technology and science, as well as business and the arts. Johnson considers the volume to be “the closing book in a trilogy on innovative thinking,” coming after his earlier works — *The Invention of Air* and *The Ghost Map*.

ACADEMIA

Not-So-Strange Bedfellows in Effective Innovation

Industry and Academia: Not-So-Strange Bedfellows in Effective Innovation

With corporate R&D activities declining as costs rise, industry has turned a hungry eye to the university arena to help keep the innovation pipeline open and relevant. Academic institutions, long a productive fount of scientific research, are playing an increasingly important role in tech transfer. And the Association of University Technology Managers (AUTM) is key to that process, in the view of tech transfer leaders from both the business and academic worlds.

Chris Yochim, who recently retired from a 35-year career with global pharmaceutical company AstraZeneca—with two decades of it focused on technology transfer—says, “Right now, as a whole, industry is looking more toward academia as a source of innovative science to augment their own internal activities. It’s just how R&D has evolved.”

As companies have consolidated and reduced their research footprints, Yochim says, their appreciation for innovation at universities has increased.

“It’s not so much that companies have cut their research spending,” he stipulates. “Rather, they have shifted how they spend their money.

“Increasingly, that money is being spent on various kinds of significant strategic collaboration with academia. These tend to be large projects with multiple goals aimed at validating novel disease targets and translational science initiatives—as opposed to one research scientist and one industry scientist working together on a single effort.”

UVa driver of AstraZeneca cardiometabolic strategy

For example, Yochim relates, AstraZeneca formed an alliance with the University of Virginia in 2009 that was focused on the cardiovascular and metabolic disease areas. The partnership’s goal was to identify novel disease pathways and help validate knowledge about metabolic disorders. The relationship proved successful and was expanded and renewed.

“The results impacted our strategy in the disease area, as well as provided novel leads for innovative therapeutics,” Yochim says.

Concurrently, top universities are focusing on research and tech transfer as a key to economic development.

“Increasingly, universities are playing a role in spinouts and helping build companies that they hope will ultimately be profitable and

employ hundreds of people,” says Yochim. “That is becoming mission-critical for the top-tier institutions. They see that they do have a role in their state’s or region’s economic development.

“This is the life blood, the reason why the biopharmaceutical industry in this country is so strong,” he says. “It is the mandate of the Bayh-Dole Act that any institution receiving National Institutes of Health funding is supposed to make a good-faith effort to commercialize any intellectual property generated from that funding.”

Yochim says AUTM is successful at fostering academic/industry relationships because it is seen as “neutral turf” and a place to “come together to identify more productive ways of collaborating and sharing best practices so we don’t get bogged down with the miscellaneous details around contract negotiations and licensing agreements.”

Corporate piggybacking

Polly Murphy, currently in charge of business development and new product planning for Pfizer China, has also worked for the Salk Institute for Biological Studies and The Scripps Research Institute. In addition, she has been active on the AUTM board.

“It is undeniable that innovation starts in academia,” says Murphy. “Industry would not be what it is without academia,” she adds, lauding Bayh-Dole as “a ‘miraculous’ law and what has fueled the U.S. as a biotech hub.

“Tech transfer is how academic inventions make it out into the world. You can’t overestimate the role of certain discoveries and the technology and science that are happening in academia. It’s not that we aren’t doing innovation in industry as well. We certainly are. But we learn and piggyback on work that is being done in academia.”



ACADEMIA

Not-So-Strange Bedfellows in Effective Innovation

Murphy also has praise for AUTM and its work fostering technology transfer.

"If inventions don't have any way to get into the outside world, they won't fully blossom. That doesn't happen automatically. It takes professionals executing their timely and efficient transfer to industry.

"AUTM makes sure these pros are connected, well trained and rigorous as they possibly can be," she says. "Thirty-five years ago, it was all nascent. AUTM played a huge role in creating the industry and making sure it was an efficient and effective mechanism to transfer the technology."

'Industry needs disruptive technology'

Nila Bhakuni, who heads the tech transfer office at Rice University in Houston, says part of her graduate work in mechanical engineering was funded by Alcoa. She later worked at the company's R&D center while earning her MBA—which Alcoa also supported.

"I've benefited greatly from industry-university interaction," Bhakuni says. "At Alcoa, it was a lot like working at a university because we focused on publications and research. There were quite a lot of 'blue sky' projects."

The Alcoa R&D center still exists, but it has shrunk significantly. "When I was working at Alcoa in 1989, there were 1,500 people doing R&D. During my time there, it went down to 500. And the blue sky research, where you can really explore, really kind of went away. The research was directed more towards the business units, and you had to have a business unit sponsor, so the long-range research wasn't taking place."

That has made academic labs even more important, Bhakuni says. "Industry needs disruptive technology and really expert technical people, which can come from universities or other entities. There is also a great need for—look at Detroit—technically trained engineers. So there is a match in both those areas. It is up to us at universities to say that we are the place to get it. For example, researchers at Rice University have invented things like nanotubes and are making the world a better place."

Bhakuni says AUTM is key to her role at Rice. "You can become so entrenched in your university," she says. "It's important to be able to talk about issues and benchmark what others are doing and see how problems are solved. It's amazing how many solutions you can come up with when you work together."



CHALLENGES

Tech Transfer System Brings Innovation Success in Other Nations

Facing Challenges at Home, U.S. Tech Transfer System Brings Innovation Success in Other Nations

The U.S. system that provides intellectual property protection and supports technology transfer may not be perfect, but it remains a model for the rest of the world.

Michael Waring, executive director of Federal Relations for the University of Michigan, says the nation's patent and licensing system has served the country well for generations. And it will continue to do so ... although a vocal anti-patent faction is attempting to undermine important aspects of the system.

"Our founding fathers really got it right when they gave creative people the ability to control their inventions and the incentive to do so," says Waring, who also is assistant vice president for Advocacy with AUTM. "I find it amazing that people in the 1700s had the foresight to recognize the value of intellectual property, and it's the reason why we've remained on the cutting edge of innovation ever since. Even countries such as China, where the government has taken a more active role in the economy, have not achieved the same level of research productivity or success at moving discoveries from the lab to the marketplace."

The legal basis for the U.S. patent system stems from the Constitution, Article 1, Section 8, which defines the powers of Congress. It states that "Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."ⁱ

The Bayh-Dole Act of 1980 helped advance these basic principles by recognizing the critical role academic and other researchers play in transforming federal research dollars into breakthrough discoveries. The act allows universities to retain title to inventions arising from campus labs and develop licensing relationships with industry to move discoveries to the marketplace in the form of useful products and services.ⁱⁱ

The envy of the world

The results include lifesaving medicines, improved crops, productivity enhancements and clean technologies that lessen the environmental impact of human endeavors. The scope of these achievements remains the envy of the world, yet Waring says our system faces a number of threats.

The danger in domestic efforts to undermine the U.S. patent system and the Bayh-Dole Act can be seen in the world around us, Waring

says, as countries that have moved aggressively to adopt strong patent protections modeled after our own are now outperforming us on some measures.

South Korea represents a striking example. As the poorest country in East Asia in the 1960s with a per capita income less than half that of Ghana or Honduras,ⁱⁱⁱ Korea scored a No. 1 ranking in the 2014 Bloomberg Global Innovation Index.^{iv}

Thanks to its adoption of strong patent protections and recognition of the importance of intellectual property protections,^v the Bloomberg ranking scored Korea No. 2 in the world in terms of its patent activity and No. 3 in its research and development intensity.

By comparison, the Bloomberg 2014 ranking placed the U.S. in third place overall, following Sweden in second. The U.S. ranked fifth for patent activity and 10th for research and development intensity. The nation's concentration of researchers ranked 12th.

While these numbers represent a few of the dimensions captured by one ranking, the message remains clear, Waring says. The U.S. cannot afford to rest on its laurels or undermine the very system that has fueled innovation for decades.

"Policymakers need to continue to be reminded that a strong patent and licensing system is the foundation of our innovation economy," Waring says. "Technology transfer is what is going to create jobs for their children and grandchildren. Our challenge today is to look beyond the immediate interests of specific technology companies and continue to advance through the underlying protections that encourage individual creativity and research productivity."

Related article: Lions and Tigers and ... Trolls, Oh My!

Footnotes:

- i. The United States Constitution, The U.S. National Archives.
- ii. Bayh-Dole Act, Pub. L. No. 96-517 (Dec. 12, 1980), codified at 35 U.S.C. §§200-12.
- iii. Chang H-J: The East Asian Development Experience: The Miracle, the Crisis and the Future. Zed Books, 2006.
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- v. Erstling JA, Strom RE: Korea's patent policy and its impact on economic development: a model for emerging countries? San Diego International Law Journal 44:2010.

LIONS AND TIGERS AND...

Trolls, Oh My!

Lions and Tigers and...Trolls, Oh My!

Everyone knows that great things come out of universities. Aside from well educated graduates who will make up the future work force, there's the wealth of ideas and innovations that create economic prosperity and a higher quality of life. But, regrettably, there are always the few who have the potential to ruin it for the many. Such is the case with abusive patent litigation being practiced by patent-aggregators or, as they are less charitably called, "patent trolls." These sophisticated and aggressive firms are collecting patented research discoveries and holding them captive for use in litigation against companies that are actually using new technologies to produce products and services.

Although the word "trolling" is generally thought of as a way to fish by dragging a lure through the water (a practice actually ruled illegal in such popular fishing states as Wisconsin) the metaphor of "a troll lurking under the technology bridge" aptly describes a recent flare-up in the business of getting discoveries across that bridge into the marketplace.

Witness the latest brouhaha in the oftentimes obscure and unseen world of technology transfer.

A study by Robin Feldman of the University of California Hastings School of Law, and Nicholson Price of Harvard Law School created news recently because the authors conjecture that the biosciences industry is just as at risk from the practice of "patent-trolling" as other sectors of technology.

Setting the Record Straight

But people in the business of university technology transfer, and the leadership of their professional association known as the Association of University Technology Managers (AUTM) were not surprised by the Feldman study, although they are questioning the true extent of the problem in the biosciences. Technology management experts have known for a long time that there are trolls out there, practicing abusive litigation, crouched beneath the metaphorical bridge into the future.

Some media coverage of the Feldman study has suggested that AUTM was "reconsidering its policy" of not licensing university patents to companies that buy patents primarily to make money from litigation or even threatened litigation.

Jane Muir, who is the new president of AUTM and also the director of the Florida Innovation Hub at the University of Florida and associate director in the Office of Technology licensing at UF, says it is time to set the record straight.

"The fact is, AUTM does not have any such policy but is always looking to assist its members in licensing to industry partners," Muir said in a recent interview. "By suggesting that university tech-management offices are considering licensing to patent-aggregators because of pressure to increase licensing revenues is a gross over simplification. In fact, such an assertion is both unsupported by evidence and a misread of the dynamic technology-transfer playing field."

The so-called AUTM "policy" that such media reports refer to is in fact a 2007 document called "Nine Points to Consider in Licensing University Technology," that was authored by 12 leaders in academic technology transfer and posted on the AUTM web site for all to read and consider.

Muir was quick to point out, "AUTM as an association does not dictate policy. AUTM does not tell universities how to do business." Still, she notes, every university should consider all Nine Points when licensing a new technology, which Muir points out most universities already do.

The Complexities of Tech-Transfer

The Feldman study brings forward the observation that the practice of patent aggregating may be putting the biotech industry at greater risk than conventional wisdom has long held. The report also makes it clear to techtransfer practitioners like Muir that the authors don't fully grasp the many complexities inherent in the business of technology transfer. The fact of the matter is hi-tech companies such as those in the IT or electronics sectors procure patents at a rate ten times that of biotech companies. Therefore, the risk of being victimized by patent trolls is inherently smaller than for tech companies. The Feldman study made the point that the main pool of biotech patents are academic patents and academic institutions very rarely engage in patent litigation with the commercial sector on which they rely for further development of early stage ideas.

"Universities that license their patented research discoveries are doing so for the purpose of bringing to the market new cures for diseases and products that make the world a better place. They generally put milestones into their license agreements that require the company they're licensing to demonstrate progress in commercializing, rather than simply aggregating them for litigation against other companies.

"This issue is a lot more complicated than just saying, 'the sky is falling, and biotech, you're the next target for the patent trolls,'" Muir says.

The Huge Impact of Tech-Transfer

The Bayh-Dole Act, the 1980s legislation that is widely credited with creating the university technology transfer industry has proven to be incredibly beneficial to the U.S. economy. A 2012 study by the

LIONS AND TIGERS AND...

Trolls, Oh My!

Biotechnology Industry Organization (BIO) found that tech transfer from academia and other non-profit institutions added more than \$385 billion to the U.S.GDP, and created more than three-million jobs and 650 new companies between 1996 and 2010.

Muir points out that, “Universities -- depending on their size, research budget, and their licensing revenues -- have tech transfer offices with differing levels of capacity, differing expectations, and differing levels of resources available to them to respond to those expectations.”

The task of licensing a given technology is complex. Muir suggests that critics outside the profession of technology transfer often don't understand how it works, let alone what the whole process is producing for society and the economy. As she says, “Technology-management is not about licensing to the highest bidder, it's about finding commercial partners that have the ability to get the technologies to the market.

The Role Congress Can Play

In the opinion of AUTM leadership, the emphasis on Capitol Hill should be on stopping abuses of the U.S. Patent System, not on changing and certainly not dismantling the system itself.

According to David Winwood, vice president of advocacy for AUTM and chief executive of the University of Alabama Birmingham Research Foundation, there are at least nine patent reform bills now circulating on the Hill. While many bills are problematic and have unintended negative consequences, one bill currently before the Senate, the “Patent Transparency and Improvements Act,” (SB 1720) seeks to curb abusive litigation while preserving the right of patent holders to enforce, legitimately, their rights.

Proponents of the bill, including AUTM, point out that small businesses need a climate that supports innovation. Those small companies, especially start-ups, are extremely valuable engines of the economy. But provisions in a different anti-troll bill passed by the House late last year failed to strike the delicate balance between protection and enforcement.

“The bill as written states that anyone who has any liability or interest, such as the licensee, would be joined in the lawsuit, whether they wanted to or not,” Winwood says, noting that the burden would then fall squarely on the shoulders of inventors and universities.

The best way to prevent or discourage the so-called trolls from grabbing up patents for their own financial gain is to ensure quality patents, and the best way to do that, according to Muir and Winwood, is to assist over-burdened patent examiners in determining novelty,

non-obviousness and usefulness. To that end, AUTM has agreed to assist the U.S. Patent and Trademark Office in identifying subject matter experts who can help USPTO staff determine the quality of patents being approved.

“The idea is, if the patent examiners are trained to understand more completely what the invention is, they will be able to tell if someone has already made the discovery,” says Winwood. “So you won't clog the system with software patents that are of questionable quality, in terms of their patentability.”

The Real Challenge

There is no question that problems caused by patent aggregators need to be dealt with. But, as Muir says, the challenge facing the tech-transfer industry in the U.S. and abroad is much bigger than trolling. The challenge is to make sure people, especially those creating legislation and allocating resources, have a better understanding of how a well-managed tech-transfer process is not only helping create a healthier, safer world, it is also building a stronger, more diverse economy all over the world.

As for the trolls under the bridge, she says, “Even actions with the best intentions can have negative consequences, especially in such a complicated profession. And particularly so in one where people are being influenced by others who do understand the nuances and want to work them in their favor. That's our real challenge.”

By Jill Ladwig
Senior Writer
Blue Waters Group

The Blue Waters Group, Inc.

The Blue Waters Group, Inc. is a firm focused on explaining the societal benefits and economic impact of emerging research and new technologies in today's global knowledge economy. The firm served as an editorial resource for AUTM's Better World Reports in 2006, '07 and '08.

COALITION PATENT LETTER

April 2, 2014

The Honorable Patrick Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Chuck Grassley
Ranking Member
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Chairman Leahy and Ranking Member Grassley:

We the undersigned groups representing thousands of innovative companies, universities, and organizations and millions of workers in the United States write to express our serious concerns with the direction of patent legislation. It is our belief that the future of the U.S. economy and our ability to compete successfully in the global economy is dependent on Congress fostering a strong patent system that incentivizes innovators to invent.

We appreciate the hard work you and your staffs have undertaken to craft a bill to target abusive practices in patent litigation. All of the undersigned groups have worked constructively for months with your offices as well as with the other members of the Judiciary Committee to craft a responsible bill to address abusive practices. We are doing so in good faith, always with an eye toward helping those targeted by frivolous patent litigation, and even though the measures under consideration would add significant cost and burden to the enforcement of our own patents.

We are concerned that some of the measures under consideration go far beyond what is necessary or desirable to combat abusive patent litigation, and, in fact, would do serious damage to the patent system. As it stands, many of the provisions assume that every patent holder is a patent troll. Drafting legislation in this way seriously weakens the ability of every patent holder to enforce a patent. This approach clearly favors a business model that does not rely on patents and tilts the balance in favor of patent infringers, thereby discouraging investment in innovation.

The patent system is the bedrock of the U.S. economy. It should not be changed in this manner over the vigorous objection of some of America's most innovative industries. To do so would shortchange the future of our economy for a premature, unbalanced policy. The stakes are far too high not to get the balance right.

We remain willing to work toward that balance. We believe that an effective bill acceptable to patent holders is within reach. However, we cannot support changes to the patent system that substantially weaken all patents. If the provisions on discovery, customer stay, fee shifting and any associated measures, pleadings, and enforcement by the Federal Trade Commission do not achieve the appropriate balance, we will oppose the legislation.

We support efforts that target specific abusive behavior, and we look forward to continuing to work with you toward that end.

Sincerely,

3M
American Council on Education
American Intellectual Property Law
Association (AIPLA)
American Seed Trade Association (ASTA)
Amgen
Association of American Medical Colleges
Association of American Universities
Association of Public and Land-grant
Universities
Association of University Technology
Managers

AstraZeneca
BayBio
Biocom
Biotechnology Industry Organization (BIO)
California Healthcare Institute (CHI)
Caterpillar Inc.
CONNECT
Council on Governmental Relations
Eli Lilly and Company
GSK
HealthCare Institute of New Jersey (HINJ)
Illinois Tool Works Inc.

Innovation Alliance (IA)
Johnson & Johnson
Kentucky Life Sciences Association
Medical Device Manufacturers Association
(MDMA)
Monsanto
Pharmaceutical Research and Manufacturers
of America (PhRMA)
The Procter & Gamble Company
Technology Council
Washington Biotechnology & Biomedical
Association (WBBA)

Tech transfer industry shows gains

in patents filed and granted,
university-created startups,
commercial products
—but slippage in federal research funding cited



Highlights of AUTM's U.S. Licensing Activity Survey
FY2013



Association of University Technology Managers®
Advancing Discoveries for a Better World®

INTRODUCTION

The human context of technology transfer

Things weren't looking good for Valerie Esposito ...

... Long Island resident, government clerical worker and single mother of three who, at age 41, had been struggling with metastatic melanoma for four years and now had tumors throughout her body, including a large one on her lung and others pressing excruciatingly on her spine and spleen. Her condition, which had begun with a mole discovered during pregnancy, was now, in the early spring of 2011, considered end-stage.

But a new protocol combining recently approved immunotherapy drug Yervoy with radiation not only halted the metastases—it dramatically shrank her existing tumors in a matter of a few weeks.

Valerie Esposito today is healthy and enjoying her first grandchild. Her life was saved and prolonged by the practice of technology transfer, through which discoveries move from university and other research laboratories to commercial partners capable of transforming the inventions into beneficial products and services. The results of tech transfer can be seen all around us: in dramatic therapies and cures, in productivity advances that connect the world more closely and in clean technologies that offer a brighter path forward for future generations.



The story of Valerie Esposito is just one example of how technology transfer practices conducted by universities and other nonprofit entities span the globe and yet facilitate work at the microscopic level to improve the human condition. At the same time, academic tech transfer powers the innovation economy, creating jobs, improving productivity and offering solutions to environmental challenges.

And although tech transfer is a complex and time-intensive process, its ultimate value is simply that it makes the world a better place.



BACKGROUND

The challenge of quantifying tech transfer

The Association of University Technology Managers (AUTM) plays a key role in the process by highlighting the public value of tech transfer; promoting important intellectual property protections, including ongoing benefits of the pivotal Bayh-Dole Act; and supporting its members and other technology transfer professionals through education, advocacy and industry engagement.

Each year, AUTM conducts its *Licensing Activity Survey* to quantify tech transfer.

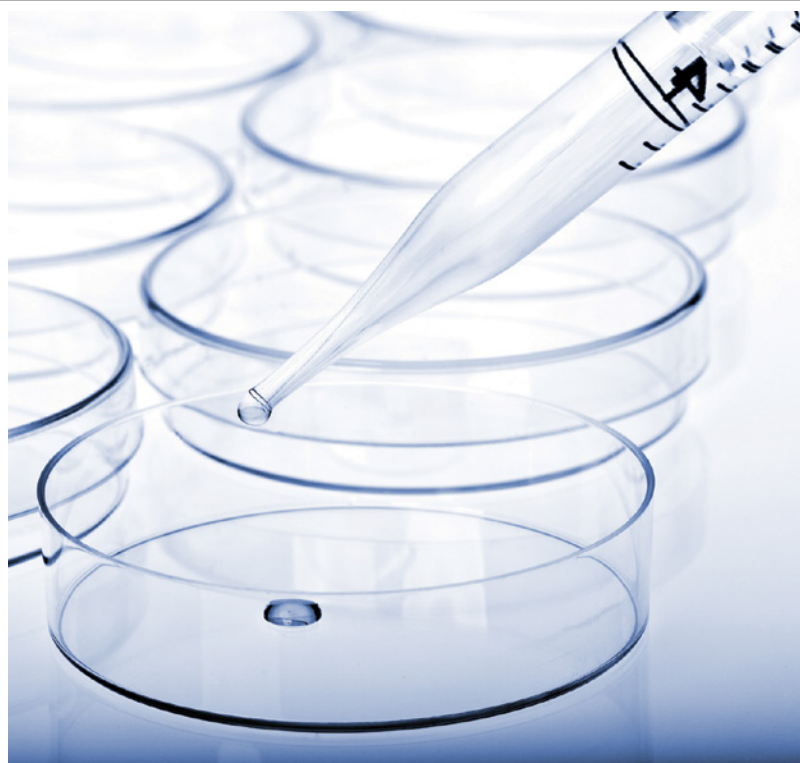
For more than two decades, AUTM has been the leader in collecting, synthesizing and disseminating academic technology transfer data as a valued resource for all aspects of the industry. In recent years, AUTM's survey data have continued to show impressive gains in several categories, including the number of university technology startups launched and employment at those fledgling companies.

The numbers reported in these *Highlights* of the survey are drawn from FY2013 as a measure of those U.S. institutions reporting (approximately 200 of a 300 total population) and therefore do not represent the composite activities comprising tech transfer. They do, however, reflect the major role tech transfer plays in transforming our society and our economy.

And yet, in attempting to assess the impact of tech transfer and determine future investment in its practice, can we really put a number on the benefits to society? By demonstrating significant growth over time, through metrics ranging from licensing income to new products, can statistical results quantify actual improvements in the human condition? Can numbers reflect the creative research achievements of individual institutions, while highlighting the need for continued support of intellectual protections and efforts to advance tech transfer globally?

"While we are a numbers-driven society," says Jane Muir, president of AUTM and director of the Florida Innovation Hub at the University of Florida, "it is important to note that some of the most important numbers are not actually captured in this survey. It is difficult to quantify the impact of the many people whose cancer is in complete remission as a result of immunotherapy research started in a university lab."

But when coupled with the compelling human stories behind them, metrics can indeed start to sum up the human impact of technology transfer.



When coupled with the compelling human stories behind them, metrics start to sum up the human impact of technology transfer.

This AUTM *U.S. Licensing Activity Survey* FY2013 *Highlights* provides a preview of the data found in the fiscal year 2013 report and offers a glimpse into the current state of the tech transfer field. The comprehensive AUTM *Licensing Activity Survey* FY2013 will be published later this year. That data will be supplemented with additional stories about the true impact of technology transfer and its substantial social impact as measured by products that transform lives—like Valerie Esposito's—improve its quality and increase the competitiveness and productivity of our global society.

And this edition of the *Highlights* shows that, despite reductions in federal research funding, academic and research institution licensing and startup activity are very strong and continue to play an important role in the economy. But that strength won't be sustained without ongoing investment into research by government.

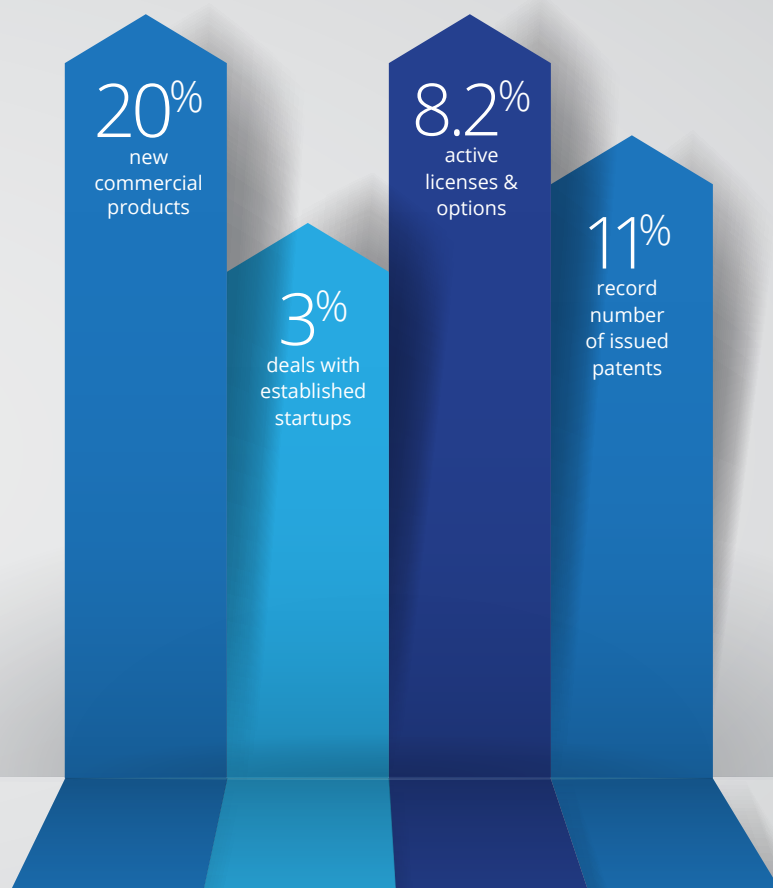
FINDINGS

Progress and issues in tech transfer

Healthy increases

The survey reveals that the combined number of executed licenses and options by the reporting institutions showed healthy increases over FY2012, as did the number of startups formed and those that were active at the end of the fiscal year. FY2013 saw a modest gain in total research expenditures, due in large part to a stronger contribution from industry. The number of issued patents topped last year's record numbers. Patent and legal expenditures increased, while legal reimbursements were essentially flat. Deals with established startup companies rose 3%. The total number of active licenses and options through the close of 2013 also increased. The number of new commercial products that were created grew more than 20%.

University-based research generates a significant return on investment for national and global economies. In addition to jobs created by startup companies, product sales for companies and new industries, research creates jobs directly through the hiring of principal investigators, research teams, lab technicians and others who help support the work. Indirectly, research creates jobs through innovations leading to new technologies, new companies and new industries.



After a period of steady growth in federal research funding driven by stimulus money, federal research dollars remained relatively flat (-0.7%) last year, and there are signs that additional headwinds can be expected. A study by the American Association for the Advancement of Science found that overall federal research and development funding could be reduced by \$57.5 billion or 8.4% if federal sequestration remains in place through 2017. Research grants funded by the National Institutes of Health (NIH) have declined every year since 2004.

This level of disinvestment occurs at the risk of diminishing the various benefits of technology transfer that AUTM and the industry overall have worked to achieve. As a result, universities have explored expanding their relationships with industry collaborators. This trend is reflected in a significant increase in industry-sponsored research expenditures, as follows:

\$65.1 billion

total research
expenditures ▲2.3%

\$39.9 billion

federally funded research
expenditures ▼-0.7%

\$4.58 billion

industry-sponsored
research expenditures ▲11%

NUANCES

Finding new ways to assess the benefits of tech transfer



John Ritter, vice president of Metrics and Surveys for AUTM and director of the Office of Technology Licensing at Princeton University, says the association is working hard to introduce new measures of societal impact through the data it collects.

“We’re finding better ways of asking questions and capturing answers that provide a more nuanced understanding of how technology transfer benefits society,” Ritter says. “We hope that our surveys help communicate the benefits of our work to university leaders, policymakers, scholars, alumni, industry and the general public.”

One facet of the effort includes working more closely with AUTM members, who are on the front lines, to learn of successful products arising from campus labs and progressing into the marketplace. Survey data show there are close to 10,000 patented products currently being sold that originated in academic research laboratories.



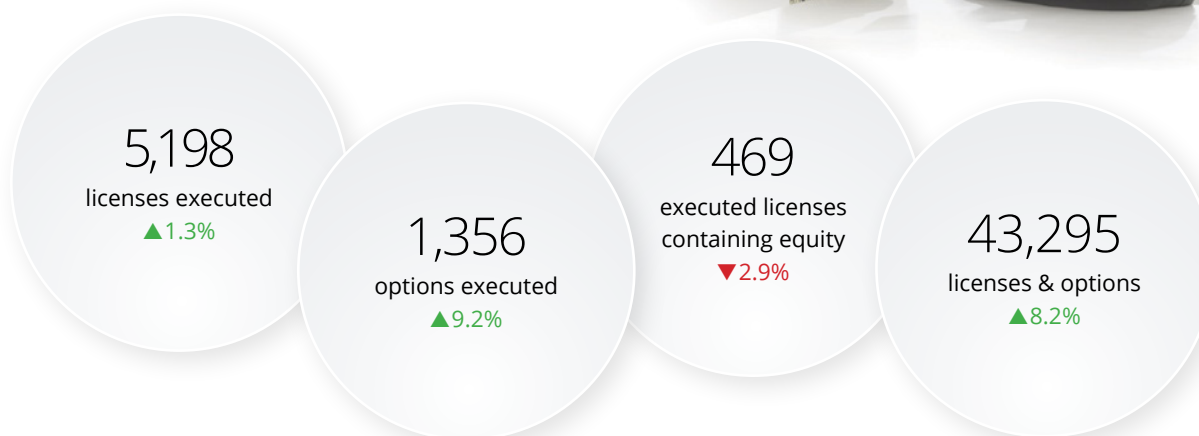
These products include blockbusters such as Allegra, which resulted from the efforts of a Georgetown University researcher to understand the role of fexofenadine in reducing symptoms of seasonal allergies. One out of 5 in the U.S.—a total of 60 million people—suffers from asthma and allergies. The Georgetown discovery was commercialized by Sanofi-Aventis and has helped allergy sufferers everywhere breathe more easily while avoiding the risks associated with earlier allergy medications.

COLLABORATIONS

Creating the innovation ecosystem

Boost in critical partnerships

Collaboration between academia and industry has increasingly become a critical component of an efficient national innovation ecosystem. The signing of a license agreement begins a long-term relationship between the university and its industry collaborator. Data pertaining to licensing activity in FY2013 shows an increase in partnerships established between academia and industry. Overall, the data revealed:

Case study: **Procysbi**

The drug Procysbi (a delayed-release prolonged-acting form of a generic drug: cysteamine bitartrate) was recently approved for treatment of a rare childhood kidney disease—nephropathic cystinosis. Although the utility for the treatment of cystinosis was discovered in the 1970s by researchers at the University of California, San Diego, the development of Procysbi is an example of the long-term diligence and collaborations often required to bring life-saving products to market.

The earliest trials of the drug eventually led to additional studies to improve its efficacy. The University of California filed patents in 2006, and clinical work, supported by the Cystinosis Research Foundation, commenced on a new drug formulation. Clinical validation helped elicit the interest of a corporate partner, Raptor Pharmaceuticals, which licensed the technology in 2007. By working closely with the inventors, Raptor was able to move Procysbi quickly into clinical trials, while continuing to fund research that may expand the indications for which this drug may be used. Although many drugs take more than a decade to get onto the market, Procysbi reached the market in 2013.

Case study: **SiNode**

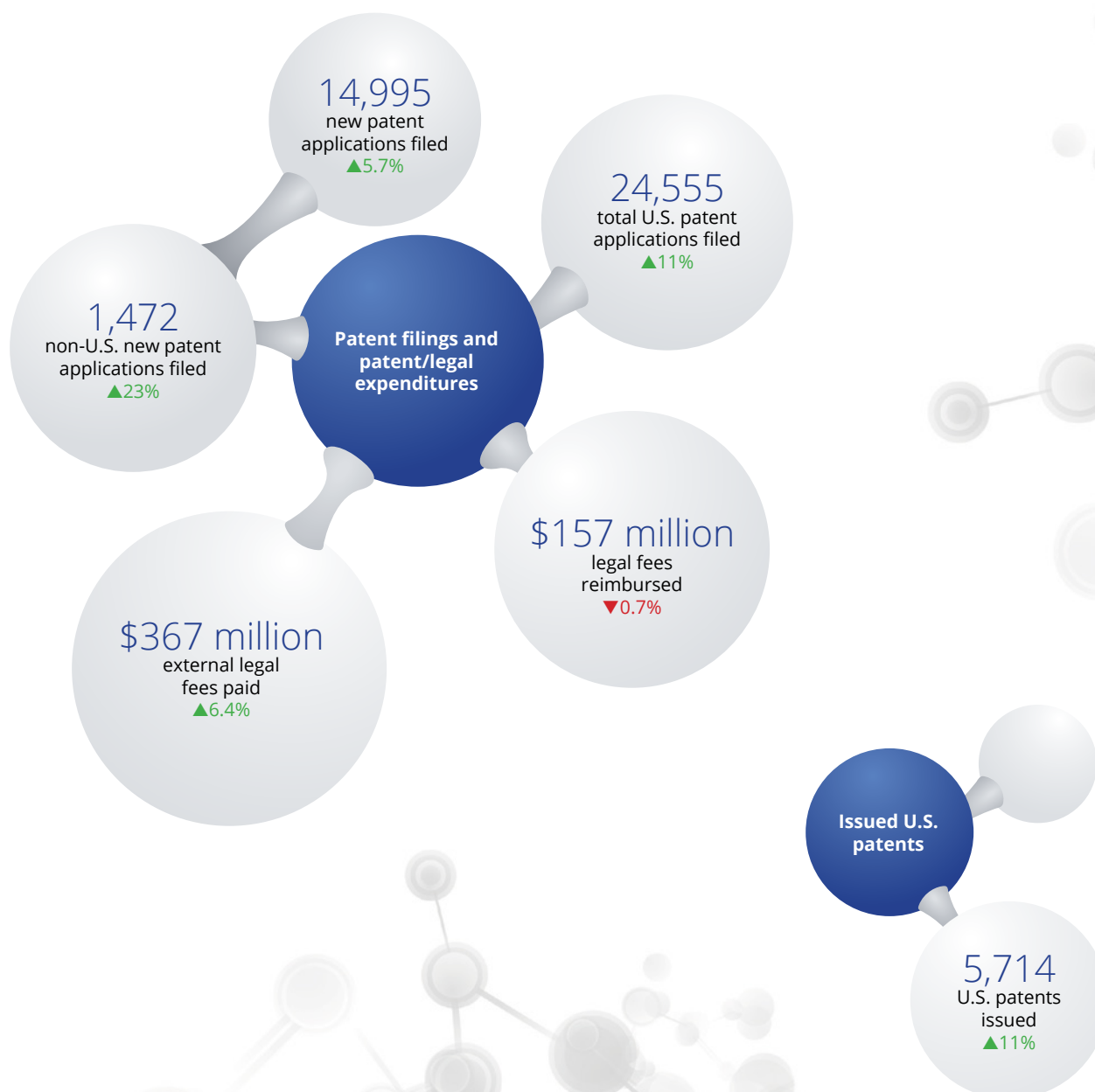
Another example of town-and-gown collaboration is SiNode Systems, a minority-owned clean-tech startup developing innovative lithium-ion battery anodes that significantly boost charging speed and increase energy capacity to 10 times longer than existing anode technology, responding to an increasingly basic need of modern life. The anode could greatly enhance battery life for hybrid and electric vehicles and smartphones.

Developed, optimized and patented in collaboration with researchers at Northwestern University and Argonne National Laboratory, SiNode technology uses a composite of silicon and graphene in a layered structure. SiNode Systems recently was awarded a \$1 million Phase II SBIR grant from the U.S. Office of Energy Efficiency and Renewable Energy (EERE).

A KEY ISSUE**The rise in intellectual property protection**

Academic research remains primarily focused on the education of the next generation of research scientists and engineers and the timely dissemination of research findings in peer-reviewed scientific journals. A portion of academic research findings may result in technologies that show commercial promise. After all, a significant portion of the U.S. economy is driven by industries that are extremely dependent on intellectual property. To encourage investment in technology that might otherwise lay dormant, research institutions file patents on these disclosures. Patents are essential to universities' role in encouraging uptake in the marketplace. Universities pursue patents so that entrepreneurs will invest and build businesses. Patents provide the basis for a company to invest substantial resources and time—five to 10 years or more—to develop the technology into commercially viable products.

Activities related to academic intellectual property management increased in FY2013, with data showing a rise in the initial expenses to academia for intellectual property protection:



CONNECTIONS

Health, security and economic payoffs

A study by the Biotechnology Industry Organization estimated the economic impact of university and nonprofit patent licensing from 1996 to 2010 was as much as \$388 billion on the U.S. gross domestic product and \$836 billion on the U.S. gross industrial output, while creating as many as 3 million jobs.

**Case study: Lyrica**

Lyrica, the work of a Northwestern University chemistry professor, represents another commercial success story through its unique ability to reduce epileptic seizures and provide relief to patients suffering from chronic pain associated with fibromyalgia. Licensed by Pfizer, Lyrica has helped millions of people and exemplifies the positive human health impact of a single blockbuster invention. Many university inventions captured in the AUTM survey may never be blockbusters like Lyrica, yet they still hold promise to improve people's lives in ways both subtle and important.

Case study: Self-de-icing pavement

Consider the carbon fiber strips developed at the University of Alaska Anchorage. When embedded in sidewalks and paired with a low-voltage current, this invention provides a cost-effective way to avoid shoveling all winter. An additional outcome from such a product is a reduction in the number of ice-related injuries.

**Case study: Vapor Wake canines**

Another example of a real-world benefit can be found in the Vapor Wake canines being bred and trained by scientists at Auburn University. The university's technology, now under license to a startup, results in dogs with an exceptional sense of smell and the unique ability to detect and track mobile explosives, such as bombs being carried through airports or crowded urban settings.

A NEW METRIC

Measuring the productivity of startups

In recognition of the potential impact of companies launched with university technology, AUTM has introduced new measures to help quantify the scope of startup activity.

So far, detailed data have been collected on close to a third of the 8,500 startups that have been reported through the AUTM survey over the years.

This year's survey revealed the following startup and product data:

818

startup companies
formed
▲16%▲

611

of them had their primary
place of business in the licensing
institution's home state
▲10.3%

4,206

startups in operation as
of the end of FY2013
▲5.1%

\$22.8 billion

of net product sales
were generated last year
▼38%

719

new commercial products
created by companies licensing
university technology
▲22%

Startup companies can be an effective mechanism for transferring nascent technology from the university research environment to the marketplace. In FY2013, the 818 new companies created as a result of technology transfer activities represent an increase of 16% over the prior year and an average of 2.25 new companies per day. Almost 75% of these companies remain local, stimulating economies and creating thousands of new jobs along the way. Small companies such as these are the American job creators, generating the majority of new jobs in the U.S., according to the U.S. Department of Labor's Bureau of Labor Statistics.

Another positive indicator is the total number of startups in operation as of the end of FY2013: 4,206, which is an increase of 5.1% over the prior year. According to the Science Coalition, "Companies spun out of research universities have a far greater success rate than other companies, creating good jobs and spurring economic activity."

Jane Muir emphasizes the inherent limitations of the numbers: "It is important to note here that only 70 institutions reported this startup company data, against a total population of approximately 300 institutions. Most tech transfer offices do not have the resources to track this data, so these numbers are grossly under-representative of the true impact of technology transfer on job creation."

AUTM reported more than \$22 billion in sales of products created and based on academic research. In FY2013, nearly 14 new commercial products were created each week—products based on university discoveries for which patents were typically filed five to 12 years prior. The goal of university technology transfer activities—to advance research discoveries from academia to the marketplace for society's benefit—is achieved when these new products reach the marketplace after years of development by industry collaborators.

Despite a 38% drop in net product sales, which could be largely attributable to agreements—and presumably patents—expiring and the products not being counted in the survey data, these products are still benefitting society. At Emory University, discovery of HIV antiretroviral drugs has led to significant patent agreements. More than 80% of people infected by HIV take at least one of the drugs invented by Emory professors. Some of the agreements recently expired, significantly reducing net product sales, but these life-saving drugs are still being prescribed in much of the developing world. Merck & Co. handles marketing and distribution of the first once-a-day, single-tablet regimen for adults with HIV. Merck announced it will lower the drug's cost in countries with high HIV prevalence using a sliding scale based on each country's wealth. The drug will be registered in 45 countries in the Middle East and Africa and in nine countries in Latin America, the Caribbean and Asia.

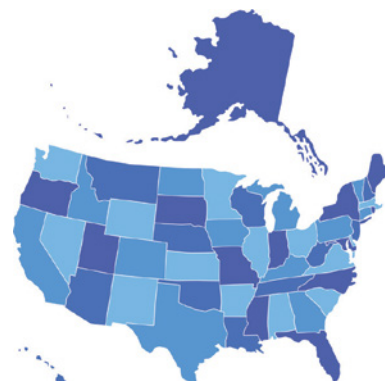
Taken as a whole, the FY2013 survey numbers, "paint a truly impressive picture of the breadth and depth of technology transfer and its economic impact," says AUTM's John Ritter. "Yet underlying all of these statistics are human examples of lives saved and lives better lived, thanks to discoveries that have arisen from basic research and reached people everywhere in the form of useful products and services."

ABOUT

The backstory

About the U.S. survey

The 2013 U.S. survey was distributed to 299 U.S. institutions (232 universities and colleges, 61 hospitals and research institutions, three national laboratories and three third-party technology investment firms). Of the 299 U.S. institutions contacted, 202 responded, for a response rate of 68%, a slight improvement over the 2012 survey, which generated a response rate of 65%. Respondents for 2012 included 170 universities, 30 hospitals and research institutions, one national laboratory and one third-party technology investment firm.



About technology transfer

Technology transfer moves ideas from research institutions to the marketplace to improve the quality of life and benefit society. Technology transfer offices assist the efforts of researchers to identify commercially viable technologies and obtain patents or other legal protection for the intellectual property. Technology transfer offices also help promote these technologies to potential licensees, negotiate licensing agreements and manage their respective institution's portfolio of licenses and patents. Licensees—from startups to large companies—are typically responsible for commercializing the licensed technologies by integrating the technologies into products and overseeing the development, manufacture and marketing of those products.

The patenting of discoveries is fundamental to attracting companies, entrepreneurs and investors into allocating the necessary resources to ensure that these discoveries have the opportunity to reach the stream of commerce. The returns on this investment are the products that benefit the public, drive economic growth and employment, and generate state and federal tax revenues. These technology transfer efforts are pursued in concert with the research institutions' core values of sharing research results, materials and know-how for the betterment of the community and society.

About AUTM

The Association of University Technology Managers (AUTM) is a nonprofit organization with an international membership of more than 3,200 technology managers and business executives. AUTM members—the majority of whom are managers of intellectual property, with IP being one of the most active growth sectors of the global economy—work at universities, research institutions and teaching hospitals, as well as numerous businesses and government organizations.

For more information regarding the FY2013 survey—including sponsorship opportunities and past surveys—please visit the AUTM website (www.autm.net).



A TECH TRANSFER VIGNETTE

How Yervoy came to be ... and helped Valerie Esposito

Immunotherapy

Among the tech transfer industry's significant latter-day focuses, immunotherapy harnesses the body's own immune system to fight tumors. Melanoma, the most dangerous form of skin cancer and that which threatened Valerie Esposito's life, is caused by uncontrolled growth in pigment-producing skin cells. Highly curable in its early stages, melanoma can often be surgically removed. But it is more likely than other skin cancers to metastasize, making treatment far more difficult. In the late stages of metastatic melanoma, the average survival rate is six months.

The American Cancer Society (ACS) reports that melanoma accounts for less than 5% of all skin cancer cases ... but it is responsible for the vast majority of skin cancer deaths. The ACS estimates that in 2014, 76,100 in the United States will be diagnosed with melanoma, and 9,710 will die from the disease.

James Allison, a professor in the Division of Immunology and director of the Cancer Research Laboratory at the University of California, Berkeley (UCB), studied immune responses to cancer, and how the disease proliferates by selectively suppressing T-cell activation.

In 1995, he showed that a checkpoint molecule called cytotoxic T lymphocyte antigen-4 (CTLA-4) puts the brakes on T-cell responses. Block CTLA-4 and the immune system could be activated, according to Allison's theory, unleashing a robust antitumor response. In preclinical experiments, he demonstrated that he could bind a special type of protein called a monoclonal antibody to CTLA-4, preventing it from interfering with T-cell activation.

Melanoma is responsible for the vast majority of skin cancer deaths.

For help in the patenting process and finding a commercial partner, Allison turned to UCB's Office of Intellectual Property and Industry Research Alliances. The road to commercialization generally is long and challenging, and Allison's immunotherapy study was no exception. His technology originally was licensed to NeXstar Pharmaceuticals, which merged with the biopharmaceutical company, Gilead Sciences Inc., which sublicensed the rights to Medarex, which developed a human monoclonal antibody and began testing in partnership with Bristol-Myers Squibb. Bristol-Myers Squibb acquired Medarex in 2009.

In clinical trials, the antibody—generically named ipilimumab—added months to the survival rates of patients with advanced melanoma, something no other drug had been able to achieve. Based on the results of a randomized, double-blind Phase III study, the drug was fast-tracked and approved as brand-name Yervoy by the U.S. Food and Drug Administration in March of 2011.

To date, well over 10,000 cancer patients—Valerie Esposito among them—have received Yervoy in clinical trials to treat advanced melanoma and other types of cancer, either alone or in combination with other drugs, with a survival rate of 17% to 22%. Bristol-Myers Squibb is testing Yervoy to treat specific prostate cancers, as well as small-cell and non-small-cell lung cancer.

Both federal dollars—through the National Institutes of Health—and, later, private funding supported Yervoy's path from the lab to the clinic.





Advancing Discoveries for a Better World®

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