

OFFICE OF TECHNOLOGY LICENSING

INTELLECTUAL PROPERTY NEWSLETTER

2015 Issue

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A CHIMERIC ANTIGEN RECEPTOR DEVELOPED AT ST. JUDE SHOWS PROMISE IN IMMUNOTHERAPY

The use of cell therapy and immunomodulation has become a hot area of study and development which has resulted in the translation of academic research into successful clinical therapies for B-cell malignancies.

In 2003, Dario Campana, MD, PhD, and Chihaya Imai, MD, PhD, developed a chimeric antigen receptor (CAR) to be expressed in an immune cell to recognize the CD19 antigen, which is prevalent on the B cells that cause ALL, B-cell CLL and B-cell NHL. The CAR made at St. Jude is composed of an anti-CD19 single chain variable fragment extracellular domain, a CD8 alpha transmembrane domain, and a cytoplasmic domain containing 4-1BB and CD3zeta signaling domains. Anti-CD19 CAR immunotherapy works by genetically modifying a patient's immune cells to express the CAR protein, which in turn stimulates these cells to attack and kill CD19 antigen expressing cancer cells.

The Office of Technology Licensing (OTL) at St. Jude Children's Research Hospital filed a patent application based on Campana and Imai's CAR in 2003, claiming compositions for genetically modifying human immune cells to target and destroy cancer cells. Campana publicly shared his findings at a conference later in 2003.

This led to further research and collaboration and eventually to the testing of CAR modified T-cells in clinical trials that were so successful they garnered international attention.

Today, multiple therapies that utilize Campana and Imai's patented CAR are showing promising clinical results in trials at numerous institutions in the U. S. and abroad – many with commercial sponsors. Results associated with these trials have shown such promise that Science labeled cancer immunotherapy as the breakthrough of the year in its December 20, 2013 issue, and both progress and commercial funding have accelerated. Startups like Juno Therapeutics and Kite Therapeutics, as well as larger organizations like Novartis, aim to have an approved CAR T-cell treatment on the market soon, some as early as 2016. Other companies active in the immunotherapy field include Cellectis, Bellicum, Bluebird Bio and Celgene.

B-cell Lymphomas are “blood cancers” in the lymph nodes that develop more frequently in older adults and immunocompromised individuals, but are often very aggressive in children. More than 70,000 people in the U. S. suffer annually from a diverse collection of B-cell related diseases, including most non-Hodgkin's lymphomas (NHL), leukemias and myelomas.

St. Jude's patent claiming Campana and Imai's CAR issued in March of 2013. Later that same year St. Jude exclusively licensed these patent rights to Juno Therapeutics. Juno combined these patent rights with technology from Fred Hutchinson Cancer Research Center, Memorial Sloan Kettering Cancer Center and Seattle Children's Research Institute and raised over \$300 million for further development and testing. Juno's goal is to improve and leverage its cell-based platform to develop new product candidates that address a broader range of cancers and human diseases. Juno retains the ability to sublicense St. Jude's patented CAR technology as well, to ensure broad commercialization and use.



From Left: Morris, Riggs, Noyes

The whole program was a fascinating example of how IP is relevant to the 21st Century economy and a driving force for innovation across many sectors.” - Brian Noyes, Executive Director, Global Intellectual Property Center, U.S. Chamber of Commerce

ST. JUDE OTL RECOGNIZED BY U. S. CHAMBER OF COMMERCE

The U.S. Chamber of Commerce’s Global Intellectual Property Center (GIPC) invited the OTL to participate in their 3rd Annual IP Champions Conference. The event was held April 20 in recognition of World Intellectual Property Day at the Chamber’s headquarters in Washington, D.C.

GIPC recognized St. Jude Children’s Research Hospital with a 2015 IP Champion award for advancing scientific discoveries through the technology transfer process to provide treatments for childhood cancers and adult lung cancer. Chad Riggs from the St. Jude OTL accepted the award along with former St. Jude researcher Dr. Stephen Morris. Dr. Morris and Dr. Thomas Look discovered the anaplastic lymphoma kinase (ALK) gene in the early 1990’s (SJ-93-0002) while searching for genes affected by a chromosomal change common in the cancer cells of pediatric patients with anaplastic large cell lymphoma (ALCL). This discovery led to issued patents that were licensed to develop diagnostics and therapeutics for treatment of cancers driven by activation of the ALK gene.

So far two ALK inhibitor drugs have been approved by the U.S. Food and Drug Administration (FDA):

- Xalkori® (crizotinib) is a FDA approved drug (8/2011) made by Pfizer for use with ALK-positive non-small cell lung cancer (NSCLC). Xalkori was one of the first drugs approved with a companion diagnostic developed to identify patients who would benefit from the drug.
- Zykadia™ (ceritinib) is a FDA approved drug (4/2014) made by Novartis for the treatment of patients with ALK positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Xalkori.

Both drugs have also been used in trials for pediatric patients with ALCL, the population the gene was first discovered in. Watch more about the ALK drug development and diagnostic success story on our [OTL website](#).

OTL CELEBRATES THE INAUGURAL TECHNOLOGY TRANSFER PROFESSIONALS DAY AND TWO IMPORTANT ANNIVERSARIES!

Our office hosted guests from across campus on December 15 in celebration of the OTL’s 20th anniversary as an independent office at St. Jude, the Bayh-Dole Act and Technology Transfer Professionals Day. Over refreshments, we highlighted active St. Jude patents and success stories, explained the licensing process and other types of agreements we oversee, and explored ways to partner and participate.

We set aside this day to recognize the important role technology transfer professionals play in the process of protecting academic inventions and getting them to companies willing to develop them. Technology transfer professionals search for and evaluate new ideas and materials for commercial potential, oversee

the patenting process, market inventions, negotiate licenses, help form start-up companies and perform a myriad of other tasks needed to connect scientists with each other and with business to promote innovation and the development of an idea into an actual product.

OTL celebrates
20th
ANNIVERSARY
as an independent office at St. Jude

A BRIEF HISTORY OF THE OTL AT ST. JUDE

Before 1995, technology licensing activities at St. Jude were handled by Jackie Dulle, the head of Research Administration. Barbara Conta and Regina McKinney established a new, separate office in January 1995 with a total of seven issued U. S. patents and 26 active license agreements. By 2005, our 10th anniversary, the number of active issued U.S. patents had grown to 64, active license agreements totaled 181 and net income had increased to more than \$500,000. As our 20th year came to a close our staff of six looked back on continued growth with 90 currently active issued U.S. patents, 186 foreign patents and 243 active license agreements. Net income in FY2015 totaled more than \$10.5 million.

A list of St. Jude inventions currently available for licensing can be found on our [website](#), where we list antibodies for research, biologics, diagnostics, drugs, drug discovery and development tools, software, vaccines and other technologies invented by those working for or with St. Jude and partner institutions.

OTL staff contacts	Title	Extension	Email address
Scott Elmer, JD	Director	2756	scott.elmer@stjude.org
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Sheila Wilson	Sr. Administrative Assistant	2342	sheila.wilson@stjude.org

WHAT IS THE BAYH-DOLE ACT?

December 12 marked the 35th anniversary of the Bayh-Dole Act, named for co-sponsors Senators Birch Bayh of Indiana and Robert Dole of Kansas, a law that fundamentally changed the nation's system of technology transfer by enabling universities to retain ownership of federally funded inventions and take the lead in patenting and licensing groundbreaking innovations. Prior to passage of this Act, each federal agency retained ownership of inventions arising from its funded projects (with a few exceptions). Under this regime, nearly 30,000 technologies had been patented by the government over several decades but very few had been licensed and developed.

By allowing funded institutions to easily elect ownership of these inventions, the Bayh-Dole Act incentivized these institutions to take control of the technology transfer process. Over time this has resulted in the creation of robust technology transfer operations at just about every major research institution. These offices have actively patented and licensed new technologies, helping to create new products that benefit the public, a new source of income for their respective institutions and thousands of jobs along the way. The technology transfer process has evolved over time as professionals who work in the field continue to make improvements and respond to new markets and market forces.

The Bayh-Dole Act has been a boon for the U.S. economy. It gave U.S. academic institutions and their corporate partners a competitive edge over foreign counterparts and spurred the development of new innovations and job creation. As a whole, technology transfer activities made possible by the Bayh-Dole Act have accounted for hundreds of new startup companies, thousands of new jobs and tens of billions of dollars in annual sales of new products. Results also include hundreds of vaccines, drugs, and new uses for existing drugs, including several from St. Jude.

REGIONAL TECH TRANSFER PROFESSIONALS VISIT ST. JUDE

On November 16, our office hosted technology transfer professionals from the University of Memphis, University of Mississippi, University of Tennessee Health Science Center, and the University of Arkansas for Medical Sciences.

At this meeting we were able to showcase the recently opened Marlo Thomas Center for Global Education and Collaboration, tour the campus and share lunch in our cafeteria. During the visit the group discussed current issues in technology transfer including methods to encourage inventor participation to increase invention disclosure numbers. This tech transfer group meets 2-4 times a year and occasionally tours each other's facilities. In addition to visiting St. Jude last year, the group visited Arkansas State University and the University of Mississippi's start-up incubation and lab spaces.

It pays to work with the OTL

Total inventor allocations for FY 2015 exceeded \$3 million, distributed among nearly 100 current and former St. Jude inventors. The remaining license income retained by St. Jude is used to further our research mission. Keep in mind that the majority of allocations each year are based on invention disclosures submitted more than 10 years ago. While there is no guarantee that your idea will be pursued and be granted a patent, or be developed into a financially successful product, the only way to have the chance is to contact the OTL. Any employee can fill out and submit the simple disclosure form available on the [OTL intranet site](#) to have their idea considered. We are also happy to meet with you if you are not sure if your idea qualifies as an invention or need help with the form.

Multiple patents are filed each year, but only some are granted, often years later.

Here is a list of patents granted in 2015:

Patent #	Subject Matter	Inventor
9,005,629	Treating cancer with an antibody to CD223 protein	Dario Vignali, Creg Workman
8,999,352	Genetically engineered swine influenza virus/uses	Richard Webby, Robert Webster
9,052,324	Controlling Wnt activity	Jufang Shan, Jie Zheng
8,933,043	Regulation of p53 translation and function	Michael Kastan, Masatoshi Takagi
9,068,174	Sensitizing tumor cells to CPT-11 Monika Wierdl	Philip Potter, Matthew Redinbo
8,784,807	Inhibiting interleukin 35 and regulatory T-cell activity Lauren Collison, Kathleen Vignali	Dario Vignali, Creg Workman
8,969,405	Anticancer compounds	Thomas Webb, Chandraiah Lagiseti
8,895,511	Diagnosing and treating learning or mental disorders	Stanislav Zakharenko
9,005,907	Typing molecular subgroups of medulloblastoma	David Ellison

If you are interested in learning about past inventions that have been developed into products and contributed to our licensing success, you can click the ["Success Stories"](#) link on our internet site. These stories may help you envision what is possible when you work with the OTL to turn your idea into an actual product that can benefit the public and perhaps even our own patients.

Inventors listed on new patent applications filed in FY2015 include Rafijul Bari, Taosheng Chen, Pamela Dotson, Jie Fang, Kristy Gibbons, Asli Goktug, John Gray, Christine Hartford, Richard Lee, Wing Leung, Marie Morfouace, Martine Roussel, Heather Smallwood, Karen Smith, Brian Sorrentino, Tal Teitz, Paul Thomas, Stanislav Zakharenko, Jie Zheng, Sheng Zhou, Jian Zuo.

The inventors worked in departments such as Bone Marrow Transplant & Cell Therapy, Chemical Biology & Therapeutics, Clinical Nutrition, Developmental Neurobiology, Hematology, Immunology, Nursing, Radiation Oncology, Structural Biology, and Tumor Cell Biology; disclose your invention so that you and your department might make next year's list!

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