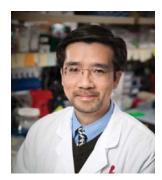


2012 Issue

St. Jude licenses assay to Tennessee diagnostics company



Wing Leung, MD, PhD



Rafijul Bari, PhD

St. Jude is finalizing an exclusive, worldwide license agreement with Insight Genetics, a Nashville-based molecular diagnostics company, for patent rights to an assay developed by Drs. Wing Leung and Rafijul Bari in the Department of Bone Marrow Transplant and Cell Therapy.

Drs. Leung and Bari found that variations in the genetic structure of killer cell immunoglobulin-like receptors (KIRs) found on the surface of natural killer (NK) cells give rise to functional differences in the NK cells. NK cells are a part of the immune system that eliminate virally infected and tumor cells. Those NK cells having an arginine at amino acid position 245 (R245) of KIR2DL1 provided a more effective and longer lasting signal. Thus, a potential transplant donor whose NK cells express the R245 KIR2DL variant would be a better donor candidate than someone with cysteine (C245) at that position.

The patent rights being licensed to Insight Genetics cover an assay useful for identifying optimal donors for allogeneic hematopoietic stem cell transplants (HSCT). Approximately 25,000 such transplants are performed each year for patients with various diseases including acute lymphoblastic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, chronic lymphocytic leukemia, non-Hodgkin's lymphoma, Hodgkin's lymphoma, multiple myeloma, aplastic anemia, sickle cell disease and thalassemia. In addition to providing valuable information about a potential donor, this assay is much more economical and faster than existing high-resolution typing assays.

"We previously licensed diagnostic technology for identifying mutations in two kinases associated with cancer (ALK and ROS1) to Insight," said Scott Elmer, St. Jude Director

of Technology Licensing. "We have been impressed with the company's efforts to develop these assays and are delighted to have the opportunity to expand our relationship into a new diagnostic realm."

Insight Genetics is collaborating with Morris Laboratories LLC, a new company founded in Memphis by former St. Jude faculty member Dr. Steve Morris, in applying for a Small Business Innovation Research contract from the National Cancer Institute in order to further develop the assay and bring it to market. "St. Jude is a leader in determining the major genetic drivers of cancer and other diseases, which is essential to the development of more targeted and effective medical therapies," said Christopher Callaghan, President and COO of Insight Genetics. "As our knowledge and ability to develop targeted therapies grows, similarly targeted companion diagnostic tools also must be created. We are delighted to expand our partnership with St. Jude, and look forward to continuing our work with its team and Morris Laboratories to refine the KIR test and make it available to clinicians and their patients."

New Location

The OTL recently moved its offices from the 305 to the 505 building. We are now located in rooms M1116 – M1121. Our offices can be located by following the signs located throughout the building to "Technology Licensing". You can still reach us at extension 2342.

OTL FY 2008–2012 Activities

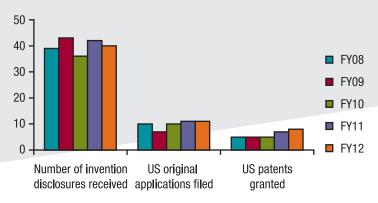


Figure 1 shows OTL activities related to patenting over the last 5 years. The number of invention disclosures, US patent applications filed and U.S. patents granted have all remained fairly stable.

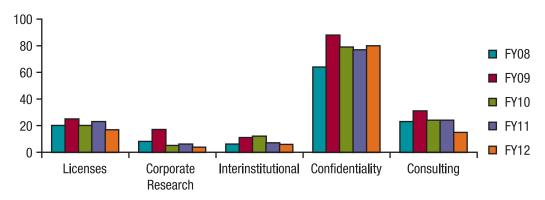


Figure 2 shows the types and numbers of various agreements executed by the OTL over the last 5 years. Agreements shown as "Other" include evaluation before licensing, option to license, service, in-license for software, transfer of clinical data to companies, and access to databases.

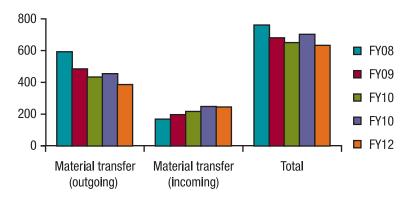


Figure 3 shows the number of outgoing, incoming and total MTAs executed over the last 5 years.

OTL invention marketing

The OTL is trying a new marketing technique with certain inventions generated at St. Jude. Working with BMC, we are making short videos that can be provided to potential licensees. Our first marketing video highlighted the diagnostic assay featured on page 1. The video can be viewed on the OTL internet site along with a video highlighting St. Jude's contribution to Xalkori, an ALK inhibitor, developed by Pfizer. The Xalkori video is on the OTL internet home page and the KIR genotyping assay, which is found under the "Diagnostics and Prognostics" category, is titled Test for Identifying Allogenic Stem Cell Transplant Donors (SJ-10-0024).

Table 1. New U.S. Patent Applications Filed in FY 2012

Inventor(s)	Department	Title
Richard Lee, Robin Lee	Chemical Biology & Therapeutics	Small Molecules to Target Mycobacterium tuberculosis 1-deoxy-D-xyulose-phosphate reducto-isomerase (MtbDxr)
Naoaki Fujii, Michele Connelly	Chemical Biology & Therapeutics	Synthetic PCNA Inhibitor
Jonathan McCullers	Infectious Diseases	Flu Derived Anti-Bacterial Peptides
Kip Guy	Chemical Biology & Therapeutics	Optimized versions of an antimalarial chemotype
Alessandra d'Azzo	Genetics	Association of Neuraminidase Regulated Exocytosis with Cancer Metastasis
Jason Rosch , Jonathan McCullers, Elaine Tuomanen	Infectious Diseases	Live, attenuated, intranasal pneumococcal vaccine
Paul Thomas, H. Alex Brown, Craig Lindsley	Immunology	Antiviral Therapies With Phospholipase D Inhibitors
Wilburn Riddick, Junyu Guo	Radiological Sciences	Multi-slice Myelin Water Imaging
Richard Lee, Elton North	Chemical Biology & Therapeutics	Adamntyl/Isoxazole Ureas as New Drugs for Tuberculosis and <i>M. Abscessus</i> Infections
Stanislav Zakharenko, Laurie Earls	Developmental Neurobiology	Specific microRNAs work in Schizophrenia
Hans Haecker	Infectious Diseases	Method for proliferation and developmental control of hematopoietic precursor cells
Harpreet Singh, Kip Guy, Richard Williams	Academic Programs	Compounds for Treatment of <i>BCR-ABL</i> + Lymphoblastic Leukemias

Table 2. U.S. Patents Issued in FY 2012

Patent #	Subject Matter	Inventor(s)
7,972,843	DNA Transfection System for the Generation of Infectious Influenza Virus	Erich Hoffmann
7,973,034	Carboxylesterase Inhibitors	Philip Potter, Christopher Morton
8,026,097	Expansion of NK Cells and Therapeutic Uses Thereof	Dario Campana, Chihaya Imai
8,030,027	Erp23	Linda Hendershot, Yuichiro Shimizu
8,030,065	Improved Expression of Factor IX in Gene Therapy Vectors	John Gray
8,124,101	Genetically Engineered Swine Influenza Virus and Uses Thereof	Richard Webby, Robert Webster
8,124,393	Mutant Human Carboxylesterase	Philip Potter, Monika Wierdl
8,168,425	Improved Expression of Factor IX in Gene Therapy Vectors	John Gray

Licensing income from St. Jude's portfolio remained above \$3M for the fourth straight year. Over \$850,000 was allocated to 72 different inventors as a result of FY 2012 licensing income.