

Office of Technology Licensing Intellectual property *newsletter*

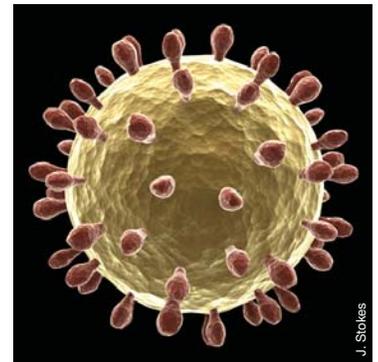
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St. Jude sees chimeric antigen receptor research translate from basic to clinical

Research started over 10 years ago here at St. Jude has now made its way to the clinic in the hot area of cell therapy and immunomodulation. In 2003, Drs. Dario Campana and Chihaya Imai developed a chimeric antigen receptor (CAR) for use in patients with B-cell abnormalities. When expressed in immune cells, this CAR markedly increased the activity of these cells against cancer cells. The Office of Technology Licensing (OTL) filed a patent application on this CAR in 2003 which matured into a U.S. patent in March of 2013, as discussed in the press release available here: stjude.org/immune-cells-patent. Results associated with cancer immunotherapy trials are showing such promising results in clinical trials at multiple institutions that *Science* labeled 'cancer immunotherapy' as the breakthrough of the year in its 20 December 2013 issue. St. Jude recently licensed these CAR patent rights to a company committed to further developing this technology. We also look forward to licensing other related inventions that have also been patented.

New video highlighting St. Jude's work on influenza

St. Jude is internationally recognized for its pioneering research and treatment of children with cancer; however, research of a far more common, yet deadly disease also thrives here. For many years, St. Jude has been a global leader in the study of influenza because cancer patients undergoing treatments that diminish the immune system have an increased risk of death from infectious diseases, like influenza. This video: <http://bit.ly/K74ksV>, located on the OTL web page under the "Success Stories" section, describes the historic global influenza pandemic of 1918 and how scientists from St. Jude began looking for the reservoir in aquatic birds, monitoring annual mutations, and contributing to development of the best line of defense; vaccines.



Artist rendering of influenza virus

The OTL welcomes a new marketing associate



In 2013, the Office of Technology Licensing hired its first Marketing Associate, Chad Riggs. Chad received his MBA from the University of Tennessee in 2006 and founded a technology consulting firm to work with the technology transfer team inside Oak Ridge National Laboratory, with medical and technical start-ups, and venture capital firms. He previously worked on 3D design for video games, TV, medical/surgical simulation, products, and architecture, but is a lifelong fan of science. Chad can address questions about to whom and how your invention can be marketed and looks forward to making sure the information about discoveries made here get to the right partner for commercialization. You can reach Chad at extension 3866 or at chad.riggs@stjude.org.

**Licensing income from St. Jude's portfolio edged past \$4 million in FY 2013
after having been just above \$3 million for the past four years.
As a result, nearly \$1.25 million was allocated to 75 different inventors.**

Supreme court decisions create uncertainty about the type of biotech inventions that can be patented

In 1980, the seminal Supreme Court decision in *Diamond v. Chakrabarty* (447 U.S. 303) ushered in an era of broad patenting in the area of biotechnology by pronouncing that “anything under the sun made by man” could be patented. From that point up until a few years ago, patents were commonly granted to new antibodies, proteins, isolated DNA molecules and diagnostic assays. This was consistent with the broad language used in the statute governing patentable subject matter which states that “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is patentable. 35 U.S.C. §101. The only exceptions courts had found to this general rule of patentability for anything “made by man” were for laws or products of nature, physical phenomena and abstract ideas.

In March of 2012 the situation changed in a significant way when the Supreme Court decided the case of *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. slip no. 10-1150. In that case the Court addressed whether an assay for determining the effect of a particular dosage of a thiopurine drug based on measurement of metabolite levels was patentable. The Court decided that this assay was, in effect, an improper attempt to patent a law of nature. They reasoned that the association between the effect of a particular drug and the levels of its metabolites in the bloodstream was a natural correlation that was equivalent to a law of nature. This reasoning could be used to render a wide variety of diagnostic methods unpatentable, including genetic tests based on a correlation between a mutation or polymorphism and a phenotype or condition of interest. Whether this case will be applied so broadly by lower courts remains to be seen, but the U.S. Patent Office has already begun to reject genetic diagnostic claims in pending applications based on this case. As a result many diagnostic companies are actively considering keeping their methods as trade secrets instead of relying on uncertain patent protection.

A further limitation on patentability in the field of biotechnology was created on June 13, 2013 in *Association for Molecular Pathology v. Myriad Genetics* (the “Myriad case”; 569 U.S. slip no. 12-398). In this case the Supreme Court limited the scope of patent protection for isolated DNA molecules. Prior to this decision, the act of isolating a piece of naturally occurring DNA was generally considered sufficient to deem the isolated DNA to be “made by man” and therefore patentable (assuming other criteria for patentability are satisfied). Addressing this issue for the first time in the decades since such claims had first begun to be granted by the Patent Office, the Supreme Court ruled that this act of isolation was not sufficient to render the resulting DNA molecule patentable. As a result, claims to isolated DNA molecules granted to Myriad which corresponded exactly to BRCA genetic sequences naturally found in the human genome were found to be unpatentable. However claims to isolated DNA molecules which did not have an exact counterpart in the human genome, such as cDNAs in which intron sequences are removed, were found to be patentable.

While it is clear from the Myriad case that isolating a DNA molecule from a genome is not enough to render it patentable, it is not clear how much further modification beyond mere isolation is necessary to consider the resulting DNA molecule to be “made by man” and patentable. It is also unclear whether similar logic will be applied to render isolated versions of other naturally occurring compositions unpatentable, such as proteins and antibodies.

Together these two Supreme Court decisions have created a high degree of uncertainty when it comes to the ability to effectively patent new diagnostic methods and isolated versions of naturally occurring biological compositions. Whether this uncertainty will induce progress by reducing intellectual property hurdles in this field, or impede progress by discouraging the sharing of new research discoveries, remains to be seen.

It pays to work with the Office of Technology Licensing

To encourage disclosure and comply with federal regulations, St. Jude shares about a third of the net license income generated from inventions made here with individual inventors. The remaining license income retained by St. Jude is used to further our research mission. While there is no guarantee that your idea will be pursued and end up being developed into a successful product, the only way to have a chance is to contact the OTL. Any employee can fill out and submit the simple disclosure form available on the OTL intranet site: <http://home.stjude.org/technology-licensing/Pages/forms.aspx> (or via email upon request) to have their idea considered for patenting and licensing. 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.

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 stjude.org/technology-licensing. 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. Stay up to date by signing up for our newsletter: stjude.org/otl-newsletter-signup-form, and encourage others to do so.

Patents issued to inventors in 2013

Patent #	Subject Matter	Inventor(s)
8,309,099	DNA transfection system for the generation of infectious influenza virus	Erich Hoffmann
8,399,645	Chimeric receptors with 4-1BB stimulatory signaling domain	Dario Campana, Chihaya Imai
8,293,247	Modified influenza virus for monitoring vaccine efficiency	Elena Govorkova, Erich Hoffmann, Aleksandr Lipatov, Richard Webby, Robert Webster
8,440,695	Use of chloroquine to treat metabolic syndrome	Michael Kastan, (Semenkovich)
8,470,785	Treatment of retinoblastoma with p53 modulators	Michael Dyer, Kip Guy
8,470,554	DKK2 in <i>E. Coli</i>	Jie Zheng, Youming Shao, Lijun Chen
8,383,793	ALK small-molecule inhibitor resistance mutations	Stephan Morris, Xiaoli Cui, Qin Jiang, Liquan Xue

New US patent applications filed in 2013

Inventor(s)	Department	Title
Suresh Marada, Stacey Ogden	Biochemistry	Targeting tumors with SHH/M2 smoothed mutation
Dario Campana, Yu-Hsiang Chang		NK cell chimeric receptor
Kip Guy, Erin Daly	Chemical Biology & Therapeutics	Aryl amide and urea analogues of "MJC13"
Thomas Webb, Chandraiah Lagiseti	Chemical Biology & Therapeutics	Sudemycin D1 and D6 schemes and protocols
Taosheng Chen	Chemical Biology & Therapeutics	Fluorescent vinblastine analog as PXR binding ligand
Dario Vignali	Immunology	Neuropilin 1 (Nrp1) modulation for immune system control
Richard Smeyne, Amar Pani	Developmental Neurobiology	A novel method for quantitative detection of purines and their metabolites
Yannan Ouyang	Cellular Imaging Shared Resource	Flushable catheter
Jian Zuo, Bradley Walters	Developmental Neurobiology	Combination therapy for hearing loss
Kevin Freeman	Oncology	Combination therapy with DON for Myc-driven cancers
Elaine Tuomanen, Carlos Orihuela, Armand Brown	Infectious Diseases	YLN for cardiac indication

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