OFFICE OF TECHNOLOGY LICENSING

INTELLECTUAL PROPERTY NEWSLETTER

2021 Issue

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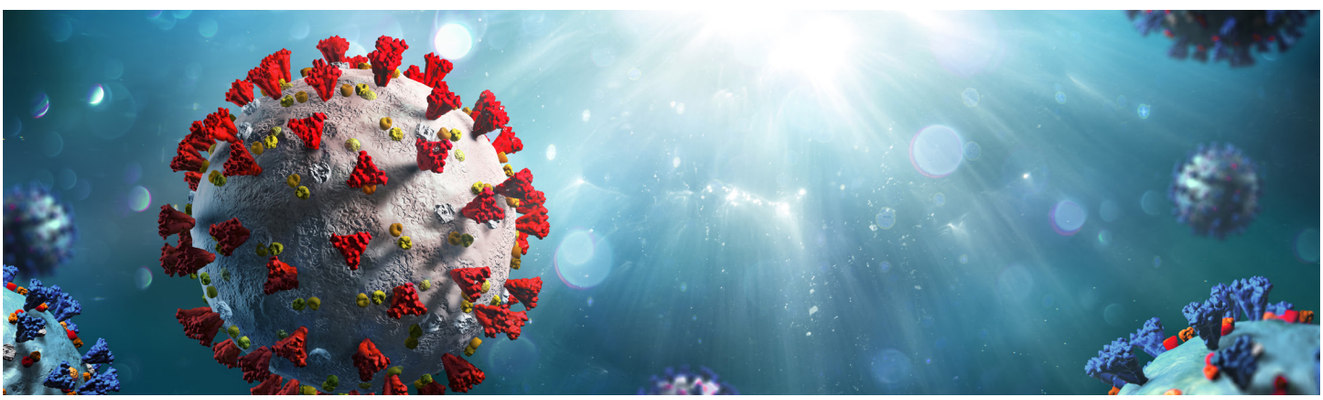
COVID, at the Top of Every Page

Everything, including St. Jude Children's Research Hospital has been impacted by the pandemic. We've leveraged our values to solve problems, volunteer, donate blood, convert labs, and continue our mission. Since March, OTL personnel work mostly remote but keep an office presence, allowing us continued success. St. Jude research produced two licensing opportunities related to COVID involving repurposing existing approved drugs:



SJ-20-0035: Method for treating COVID-19, which uncovered many patients thought to be exhibiting Cytokine Storm Syndrome may instead have strongly elevated levels of a few cytokines (such as IL6); with evidence of excess cortisol signaling, suppressing otherwise protective immune responses. So researchers proposed therapies targeting drugs blocking IL-6(tocilizumab) with any one of the anti-cortisol therapies (including but not limited to ketoconazole, mitotane (Lysodren), metyrapone (Metopirone), mifepristone, and pasireotide).

Related publications:
https://advances.sciencemag.org/content/early/2020/11/13/sciadv.abe3024, Science Advances, Dec. 9, 2020: Vol. 6, no. 50, eabe3024
DOI: 10.1126/sciadv.abe3024
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30317-2/fulltext
https://scienceadvances.altmetric.com/details/94227036
https://www.futurity.org/COVID-19-cytokine-storm-inflammation-respiratory-failure-2476012-2/

SJ-21-0008: New drug combination for treating cytokine storm associated with COVID-19 and other conditions, which uses approved drugs that inhibit TNF-γα and IFN-γγ activity, as well as those that target other molecules in the same pathway (e.g., JAK), which could be repurposed to inhibit cytokine storms. TNF alpha inhibitors are used to treat Crohn's disease, ulcerative colitis, and rheumatoid and psoriatic arthritis (approved TNF inhibitors: infliximab, adalimumab, certolizumab, golimumab, etanercept, thalidomide, lenalidomide, pomalidomide, pentoxifylline, bupropion, or delmitide).

Related publications:
"COVID-19 cytokines and the hyperactive immune response: Synergism of TNF-α and IFN-γγn triggering inflammation, tissue damage, and death." Cell, Nov. 18, 2020. DOI: https://doi.org/10.1016/j.cell.2020.11.025
https://www.stjude.org/media-resources news-releases/2020-medicine-science-news/in-the-lab-st-jude-scientists-identify-possible-COVID-19-treatment.html, https://www.biorxiv.org/content/10.1101/2020.10.29.361048v1
https://www.sciencenews.org/article/COVID-19-coronavirus-immune-system-chemicals-deadly-cytokine-storm

COVID may represent a spectrum of disease states which may require distinct treatments, even in the same individual over the course of the disease; our scientists remain on the case. Several other inventions were also marketed which may prove beneficial to the fight against COVID.

OTL staff contacts	Title	Extension	Email address
Scott Elmer, JD	Director	2756	scott.elmer@stjude.org
Shawn Hawkins	Associate Director	2751	shawn.hawkins@stjude.org
Esther Allay	Senior Licensing Associate	4700	esther.allay@stjude.org
Chad Riggs	Marketing Associate	3866	chad.riggs@stjude.org
Regina McKinney	Coordinator, Departmental Finance	5354	regina.mckinney@stjude.org
Sheila Wilson	Administrative Specialist	2342	sheila.wilson@stjude.org

The OTL turns 25

The week of December 12, we celebrated the Association of University Technology Managers (AUTM) Technology Transfer Professionals Day, the 40th anniversary of the Bayh-Dole Act, and the 25th anniversary of our own office. Over that time, we filed 684 U.S. and 817 foreign patent applications and were issued 225 U.S. patents and 382 foreign patents. We executed 1,335 license agreements, and tens of thousands of other agreements. From those agreements, we collected over $100 million in license income and patent reimbursements.

There were 43 invention disclosures submitted in FY2020, 1 was licensed without patenting, 1 was released to the inventor, 14 were made the subject of a new patent application or added to an existing application, 18 were inactivated based on a determination that the subject matter was not patentable and/or not licensable, and 9 remain open pending further developments.

The OTL negotiated or processed more than 1,000 agreements in FY2020, 10 of which were new licenses. Nine inventions generated net income over $50,000 in FY2020 (table to the right). This year the OTL received net income of over $8 million, $2.5 million was shared with 114 inventors. The table below lists the inventors who received an issued patent in fiscal year 2020. New inventors receiving their first issued patent will receive a special commemorative mug.

IDs	Net Income
9	>$50K
7	>$100K
4	>$250K
2	>$500K
1	>$1MM

Disclosure #	Patent #
Title	Inventors
SJ-08-0039	10,392,431
IL35 Receptor	Dario Vignali, Lauren Collison
SJ-10-0028	10,632,183
Pneumo Fusion Vaccine	Elaine Tuomanen, Elizabeth Mann
SJ-11-0005	10,647,702
Nutlin Analogs	Michael Dyer, Kip Guy, Richard Kriwacki, Donald Bashford, Antonio Ferreira, Yiqun Zhang, Brandon Young, Grace Royappa, Jaeki Min, Lie Min, Nagakumar Bharatham, Kristin Finch
SJ-11-0012	10,533,208
PPCA and Neuraminidase	Alessandra d'Azzo, Ida Annunziata, Shai White-Gilbertson
SJ-13-0002	10,538,739
NK Cell Chimeric Receptor	Dario Campana, Yu-Hsiang Chang
SJ-13-0018	10,441,744
Flushable Catheter	Yannan Ouyang
SJ-13-0035	10,647,997
Anti-GD2 CAR	Dario Campana, Massimo Dominici
SJ-13-0039	10,457,946
CASP1 and GC Resistance	William Evans, Erik Bonten, Steven Paugh
SJ-14-0003	10,676,510
ADEP Compounds As Activators Of The Clpp Endopeptidase	Richard Lee, Ying Zhao, Zhong Zheng, Aman Singh, Elizabeth Griffith
SJ-14-0025	10,428,305 B2
NK Cells Expressing Membrane-Bound IL-15	Dario Campana, David Shook, Masaru Imamura

Disclosure #	Patent #
Title	Inventors
SJ-15-0007	10,457,707
Phosphate Prodrugs	Jiuyu Liu, Richard Lee, Ying Zhao
SJ-15-0009	10,696,972
Adenosine Signaling	Stanislav Zakharenko, Jay Blundon
SJ-15-0025	10,383,873
CDK9 Inhibitors	Charles Sherr
SJ-15-0035	10,441,601
Thalamic microRNA controls the late onset of schizophrenia	Stanislav Zakharenko
SJ-16-0002	10,525,048
DCN1 Inhibitors	Deepak Bhasin, Kip Guy, Brenda Schulman, Jaeki Min, Daniel Scott, Jared Hammill
SJ-16-0011	10,550,091
PXR Antagonists	Taosheng Chen, Wenwei Lin, Yueming Wang
SJ-16-0027	10,570,179
MASA and VRE	Ying Zhao, Richard Lee
SJ-16-0036	10,626,376
Improved AAV Purification	Michael Meagher, Bryan Piras, David McNally
SJ-18-0010	10,526,380
Optogranules	Joseph (JPaul) Taylor, Peipei Zhang, Andrew Davidoff
SJ-21-0002	10,463,718
AAV Factor VIII Vectors	Amit Nathwani, Jenny Mcintosh

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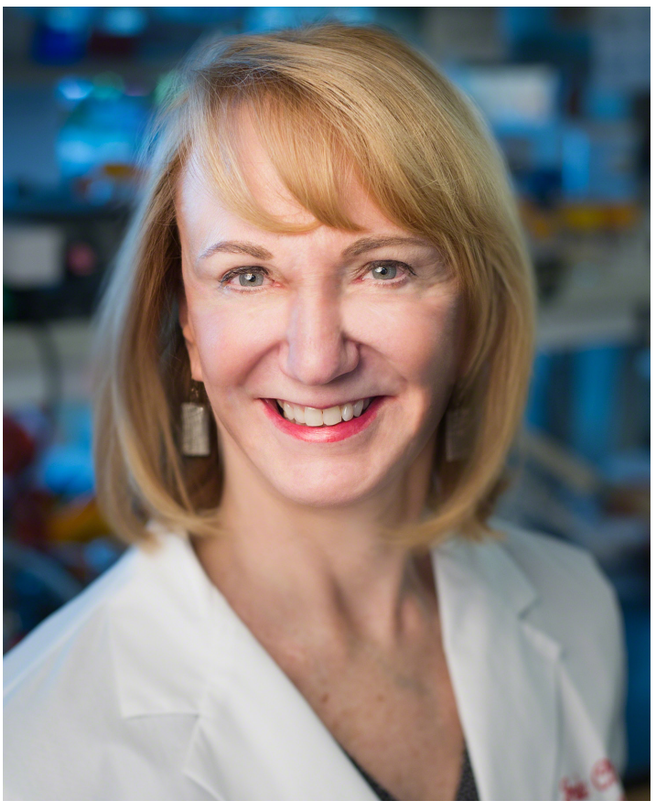
Licensing Successes



Blue Water Vaccine to commercialize a vaccine to prevent ear infections

Five out of six children in the U.S. will have at least one Streptococcus pneumoniae bacterial ear infection before they celebrate their third birthday. It's the number one reason for both pediatric appointments and antibiotics prescription. Ear infections are one of the most common infectious diseases worldwide, with 6 million occurring annually in the U.S. It is also a leading cause of sinus infections and pneumonia—the single largest cause of death in both children and the elderly worldwide. Current pneumococcal vaccines are effective at preventing blood infections (sepsis) and other invasive diseases; but the shots provide limited protection against pneumococcal infections that begin in the upper respiratory track and cause ear infections, sinusitis and pneumonia.

The substantial gap in preventing infection led Jason Rosch, PhD, of the St. Jude Children's Research Hospital Department of Infectious Diseases, to join a project early in his career led by Elaine Tuomanen, PhD, and Jon McCullers, MD, to create a vaccine to close the pneumococcal protection gap. Tuomanen chairs the St. Jude Infectious Diseases department; McCullers was then a member. He now chairs the University of Tennessee Department of Pediatrics.

Those efforts yielded the first effective experimental vaccine against pneumococcal ear infections in animal models. Blue Water Vaccines, an Ohio-based biopharmaceutical company, licensed the technology to develop a human vaccine. They were founded in order to work toward producing a universal influenza vaccine, and have expanded their efforts to include other vaccines

During Dr. Toumanen's leadership, there have been 48 infectious disease inventions disclosures licensed by the OTL to 38 different companies though research license (16), non-exclusive license (29), and exclusive license (12). This is the first of several vaccines Rosch has worked on to be licensed for clinical development. Blue Water Vaccines executives visited St. Jude to discuss next steps to prepare the vaccine for an expected clinical trial beginning in healthy adults.

Other Licensee Activities

- St. Jude and National University of Singapore (NUS) exclusively licensed related inventions made by Dr. Dario Campana first at St. Jude and then at NUS to Nkarta, Inc. in 2016. They are developing two CARs for three indications. In July 2020 they received acceptance of an IND application for a licensed product and went public.
- Licensee Bristol Myers Squib (BMS, who acquired Celgene, who previously acquired Juno) is seeking FDA approval of its CD19 CAR, liso-cel, for adults with relapsed/refractory large B-cell lymphoma.
- In June uniQure announced the sale of its Factor IX gene therapy vector, AMT-061, to CSL Behring. This sale includes the sublicense of St. Jude patent rights that were exclusively licensed to uniQure in 2008.
- The Factor VIII gene therapy for hemophilia licensed by BioMarin was expected to be approved in August but it was delayed by the FDA asking for two more years of data.
- New Equilibrium licensed P27 Inhibitors for Hearing Regeneration and/or Breast Cancer.

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Patient Impact

Through the process of technology licensing, research initiated at St. Jude has contributed to several pending and approved therapies and diagnostics that are improving the lives of our own patients as well as the general population. The following table summarizes the impact of our biggest successes so far:

	Technology	Indication	Patient Impact
Licensed Awaiting Approval	Factor VIII Gene Therapy	Hemophilia	In clinical trials (GO8), 9 total participants; 1 @ St. Jude.
			219 in Biomarin Trials.
	Factor IX Gene Therapy	Hemophilia	In clinical trials (AGT4HB), 14 total participants; 5 @ St. Jude.
	XSCID Gene Therapy	X-SCID	In clinical trials w/adolescents & infants. (12 @ St. Jude & 5 enrolled at collaborating sites). NIAID for 23 individuals from 2-40 years of age.[1,2]
	Respiratory Syncytial Virus Vaccine	RSV	21 treated in completed NIH RSV/hPIV-1 vaccine adult phase I study. A paper describing safety and performance published, so a concept sheet has been submitted for a pediatric study.[3]
			Serum Institute of India is advancing SeVRSV toward a parallel phase I clinical study in the developing world.
Licensed, Approved	CAR T-Cell Gene Therapy	Cancer (ALL, CLL, NHL)	1,000+ treated in clinical trials with therapies that use St. Jude CAR T technology. 15 @ St. Jude, for SJCAR19, in the Treatment phase, as follows: Phase 1: 12; Phase 2: 3 (+2 more in the manufacturing phase); and for Kymriah: 12 (2 who received Kymriah infusion 2x)
			100+ US medical centers are set up and have treated 2000+ with Kymriah[4]
	Plasmid Rescue	Influenza	100 Million+ vaccine doses manufactured/yr.w/additional animal vaccines.[5]
	CYP3A5 Drug Metabolism	Diagnostic	There are 3, which make up 150+/yr.[6]
Past Impact [7]	Thiopurine tolerance & B-cell Test	Diagnostic	Known as TPMT & CD-19 MAb; 500,000+ /yr.
	ALK Drugs based on St. Jude gene discovery & how it causes cancer	ALK+ Non-small Cell Lung Cancer	45,000+/yr. were treated by the 3 approved drugs when the patent expired in 2014. Used here for the ALK+ anaplastic large cell lymphoma (ALCL) pediatric patient population where ALK gene was originally discovered (incl. Xalkori, Zykadia and Alunbrig)
	14 ALK+ Diagnostics		
	Snuggle Restraints	Animal	150+ sold/yr.

1. https://clinicaltrials.gov/ct2/show/NCT01512888
2. https://clinicaltrials.gov/ct2/show/NCT01306019?term=NCT01306019&rank=1
3. https://www.tandfonline.com/doi/full/10.1080/21645515.2020.1779517
4. By FDA approved Kymriah® (As of 3/19/19, ~130 medical centers are set up to offer treatments.)
5. The patent rights are expected to expire around April, 2021.
6. The patent rights are expected to expire around December 2021.
7. Continued invention impact after patent expiration.

BioTN and the Memphis Scipreneur Challenge

The Life Science Tennessee (LifeSciTN) Academic Alliance is still working with LifeSciTN, but through their relationship with the industry group “Bio” this year became The BioTN Academic Alliance to continue providing networking opportunities for graduate students and post-doctoral researchers. Speakers give advice in clinical, research, policy, and biotechnology business areas, and share personal experiences and perceptions from their various paths that often differ from the academic world, providing members a unique insight into professional growth. Check the website for upcoming events in Memphis, or with groups in Middle and East Tennessee.

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