Harnessing the Power of Academic Medicine

The UCSD School of Medicine is one of the nation’s top-ranked academic institutions devoted to medical research, education, and health care services. The school is notable for outstanding faculty and students, research, and its strengths in academic medicine.

Professor C. Lowell Parsons, M.D., is an outstanding example of the power of academic medicine. His understanding of a certain disease led him to search for a solution to develop a new clinical product. Since 1977, Dr. Parsons has been a faculty member in the surgery/urology department at the UCSD School of Medicine. He is an internationally recognized specialist in interstitial cystitis (IC), which is also known as Lower Urinary Dysfunctional Epithelium (LUDE). IC is a long-term, yet treatable, inflammatory medical condition of the bladder. As many as 9 million women and 6 million men in the U.S. suffer from pain in the pelvic area that lasts longer than 6 months. Over the past 25 years, Dr. Parsons has been an active clinician, treating more than 6000 women and men who have IC/LUDE at his clinic at UCSD.

Dr. Parsons realized that mucus regulates the permeability of the bladder wall and that this mucus becomes defective in people with IC. This defect also allows the urinary potassium to leak from the mucus into bladder wall thereby causing tissue injury and the symptoms of IC. Harnessing this knowledge, Dr. Parsons developed novel treatments for IC with his studies that led to the discovery of the drug, Elmiron® (pentosan polysulfate sodium). This innovation, licensed to a US pharmaceutical company, was issued US Patent No. 5,180,715 – Irrigation of internal bladder surfaces in mammals with sodium pentosanpolysulfate. Elmiron® is thought to act by creating an artificial mucus layer in the bladder. In Dr. Parsons’ experience with over 6000 IC patients, Elmiron® helps most of them.

In addition to his clinical work, Dr. Parsons conducts ongoing research into the causes of IC as well as in the development of new therapies for this condition and has developed the first new test for IC in 70 years, the Potassium Sensitivity Test (PST). The PST has been reproduced and validated by many medical centers around the world and Parsons has received numerous federal and private grants for his research studies.

Sharing his knowledge and experience with the scientific and medical communities, Dr. Parsons has published over 200 scientific articles and book chapters, including over 150 peer-reviewed manuscripts on IC. In addition, he travels widely to train physicians and other health professionals in how to recognize and treat IC/LUDE.

(Parsons continued on page 2)
Export Control: Part 2

Export Control laws prohibit the unlicensed export of certain materials or information for reasons of national security or protection of trade. Most exports do not require government licenses. Only exports that the U.S. government considers “license-controlled” under the Export Administration Regulations (EAR) and/or International Traffic in Arms Regulations (ITAR) require licenses. Export controls usually arise for one or more of the following reasons:

* The nature of the export has actual or potential military applications or economic protection issues
* Government concerns about the destination country, organization, or individual, and
* Government concerns about the declared or suspected end use or the end user of the export

Generally, an export includes any: (1) actual shipment of any covered goods or items; (2) the electronic or digital transmission of any covered goods, items or related goods or items; (3) any release or disclosure, including verbal disclosures or visual inspections, of any technology, software or technical data to any foreign national; or (4) actual use or application of covered technology on behalf of or for the benefit of a foreign entity or person anywhere.

The term “export” can mean not only technology leaving the shores of the United States (including transfer to a U.S. citizen abroad whether or not it is pursuant to a research agreement with the U.S. government), but also transmitting the technology to an individual other than a U.S. citizen or permanent resident within the United States (a “deemed export”). Even a discussion with a foreign researcher or student in a campus laboratory is considered a “deemed export.” Export controls preclude the participation of all foreign nationals in research that involves covered technology without first obtaining a license from the appropriate government agency.

When an item is controlled, a license is required before the technology can be exported, unless it qualifies for exclusion as “fundamental research” as discussed below. This requirement relates not only to tangible items (prototypes or software) but also to the research results themselves.

There are certain countries where it is the policy of the United States generally to deny licenses for the transfer of these items. These countries are currently Afghanistan, Armenia, Azerbaijan, Belarus, Cuba, Iran, Iraq, Libya, North Korea, Syria, Vietnam, and the Former Republic of Yugoslavia (Serbia and Montenegro).

What is the fundamental research exclusion for universities?

Even if an item appears on one of the lists of controlled technologies, generally there is an exclusion for fundamental research (as long as there are no restrictions on publication of the research or other restrictions on dissemination of the information) or, in some cases, as long as the research or information is made public or is intended to be made public.

Fundamental research, as used in the export control regulations, includes basic or applied research in science and/or engineering at an accredited institution of higher learning in the U.S. where the resulting information either is ordinarily published and shared broadly in the scientific community or where the resulting information has been or is about to be published. Fundamental research is distinguished from research that results in information that is restricted for proprietary reasons or pursuant to specific U.S. government access and dissemination controls. University research will not qualify as fundamental research if (1) the institution accepts any restrictions on the publication of the information resulting from the research, other than limited pre-publication reviews by research sponsors to prevent inadvertent divulging of proprietary information or to insure that publication will not compromise patent rights of the sponsor; or (2) the research is federally funded and specific access or dissemination controls regarding the resulting information have been accepted by the university or the researcher.

What is considered published information as used in the definition of fundamental research?

The EAR and the ITAR approach the issue of publication differently. For the EAR, the requirement is that the information has been, is about to be, or is ordinarily published. The ITAR requirement is that the information has been published.

Information becomes “published” or considered as “ordinarily published” when it is generally accessible to the interested public through a variety of ways. Publication in periodicals, books, print, electronic or any other media available for general distribution to any member of the public or to those that would be interested in the material in a scientific or engineering discipline. Published or ordinarily published material also include the following: readily available at libraries open to the public; issued patents; and releases at an open conference, meeting, seminar, trade show, or other open gathering. A conference is considered “open” if all technically qualified members of the public are eligible to attend and attendees are permitted to take notes or otherwise make a personal record (but not necessarily a recording) of the proceedings and presentations. In all cases, access to the information must be free or for a fee that does not exceed the cost to produce and distribute the material or hold the conference (including a reasonable profit).

What is public domain?

Public domain is the term used for “information that is published and generally accessible or available to the public” through a variety of mechanisms. Publicly available software or technology that is which already is, or will be, published.

To find out more on federal guidelines for export control, please visit these websites:

http://w3.access.gpo.gov/bis/ear/ear_data.html
http://www.pmdtc.org/docs/ITAR/22cfr121_Part_121.pdf

Parsons (continued from page 1)

In 2004, Dr. Parsons was recognized as “UCSD Outstanding Innovator” with an award from UCSD Chancellor Marye Ann Fox at the TechTIPS’ 10th Anniversary celebration event. Even with his prior success, Dr. Parsons, a Yale University School of Medicine graduate, continues to work on new treatments developing a new therapeutic solution (derived from his clinical and basic research) that can be instilled into the bladder several times a week to reduce and suppress symptoms. The solution, which contains an anesthetic, can provide immediate relief of symptoms and may be used as part of an overall IC treatment plan that includes Elmiron®. His most recent innovation is the founding technology of a new company, Urigen. Dr. Parsons is working with Urigen to commercialize this novel treatment for pelvic pain of bladder origin. Urigen recently obtained FDA approval to conduct a clinical trial with this product and a multicenter, randomized trial began December 2005.

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TechTIPS Hosted International Colleagues

September 2005: TechTIPS hosted a visit from the economic mission of the French Consulate in San Francisco. While France has a strong pharmaceutical industry, they are also looking for ways to further economic development through potential partnering with the San Diego region’s vibrant life sciences industry. Our office discussed ways to identify areas of potential collaboration between the university and interested French companies. The French government is providing support to the biotechnology industry through several avenues including R&D tax credits, creation of a new National Agency for Research, and establishment of a strategic committee for health industries.

October 2005: Dr. Robert Gruetzmacher, Director of Technology Commercialization of the DuPont Center for Collaborative Research and Education along with the Universidad de Oviedo (Spain) were accompanied by Jim Sheu of External Relations when they visited the tech transfer office. The representatives from Spain are interested in developing a technology transfer program to promote their region’s economy.

November: Dr. Wilfried Prewo, Chief Executive of the Hannover Chamber of Industry and Commerce visited our office during his recent trip to the US from Germany. Dr. Prewo is interested in promoting industry and economic development in his region and is looking at what San Diego has done, especially UCSD, in promoting economic development through university technology transfer.

December: TechTIPS hosted a delegation from the Korea IT Industry Promotion Agency (KIPA) of Seoul S. Korea. This group came to study UCSD’s tech transfer model and the biocluster that has developed around the university.

Technology Tours to China Tech Centers

September: Dr. Alan Paau (pictured below), assistant vice chancellor of UCSD TechTIPS was an invited speaker at the International High-Level Forum on Bioeconomy in Beijing, China.

October: TechTIPS representatives, Drs. Alan Paau, Bill Decker, and Jack Zhao, presented UCSD technologies in tech centers in China. The itinerary included, among others, the Shanghai Zhangjiang Hi-Tech Park, TEDA Hi-Tech Park in Tianjin, City of Changchun Technology Park in Jilin, and the Guangzhou Institute of Biomedical and Health Sciences in Guangzhou.

November: TechTIPS members, Drs. Alan Paau and Jane Moores, were invited guests to the US-China Intellectual Property Tour sponsored by the China State Intellectual Property Office (SIPO) and supported by a grant from the US State Department. Delegates from the US included representatives from the US Department of State, MIT, UCSD, Texas A&M University and the George H. Bush Foundation and Presidential Library and were part of a larger delegation invited to attend the conference on “China-US Relations: Trade, Diplomacy and Research” held in Beijing. Delegates met with SIPO officials, officials of the Ministry of Science & Technology, the Ministry of Education, the Chinese Academy of Sciences, and major Chinese research universities in Beijing, Xian, and Yunnan.

Up Front with Celiac Disease

A scientific symposium on celiac disease, “Genetic and Immune Mechanisms in Celiac Disease,” was held at the University of California, San Diego (UCSD) School of Medicine this month. The symposium was held at the university’s Center for Molecular Genetics was hosted by UCSD’s newly established William K. Warren Medical Research Center for Celiac Disease. When this research center was founded last November, UCSD TechTIPS assisted in drafting agreements in securing $2.5 million of funding over a five-year period.

The center is comprised of research in celiac disease being conducted by several investigators at UCSD. Future plans also include developing a clinic at San Diego Children’s Hospital and Health Center, San Diego, planned for early 2006 and, ultimately, an adult celiac disease clinic at UCSD. The funding will support basic and translational research programs for a disease that often goes undiagnosed in patients.

Celiac disease, a digestive condition triggered by consumption of a common protein called gluten, affects one in 100 Americans. Currently, the only treatment for celiac disease is a change in diet.
US Patents

Recent patents from UCSD research

6,906,240 (6/14/05)
Martin Yanofsky et al.
Reduction of lignin biosynthesis in transgenic plants

6,907,017 (6/14/05)
Anthony Acampora et al.
Mobility management in wireless internet protocol networks

6,908,918 (6/21/05)
Trevor McMorris et al.
Antitumor agents

6,911,309 (6/28/05)
Dennis Carson et al.
Nucleic acids encoding MTAse

6,911,324 (6/28/05)
Fred Levine et al.
Induction of beta cell differentiation in human cells

6,911,466 (6/28/05)
Edward Koo et al.
Ab42 lowering agents

6,929,925 (8/16/05)
Charles S. Zuker et al.
Assays for sensory modulators using a sensory cell specific G-protein beta subunit

6,930,101 (8/16/05)
Dennis Carson et al.
Thiazolopyrimidines useful as TNFa inhibitors

6,933,384 (8/23/05)
Roger Tsien et al.
Synthetic molecules for labeling histidine-rich proteins

6,946,132 (9/20/05)
Dennis Carson et al.
Treatment for rheumatoid arthritis

6,951,845 (10/4/05)
Dennis Carson et al.
Method for treating allergic lung disease

6,960,457 (01/01/05)
Lawrence Goldstein et al.
Reversible immobilization of arginine-tagged moieties on a silicate surface

6,960,457 (01/01/05)
Lawrence Goldstein et al.
Reversible immobilization of arginine-tagged moieties on a silicate surface

6,987,193 (01/17/06)
Trevor McMorris et al.
Illudin analogs useful as antitumor agents

6,987,027 (01/17/06)
Sung Ho Jin
Microscale vacuum tube device and method for making same

6,989,146 (01/24/06)
Salvatore Albani et al.
Stress proteins and peptides and methods of use thereof

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INVENTOR PORTAL: UCSD inventors are now able to access the status of their invention and copyright disclosures online. Using the TechTIPS Inventor Portal, you will be able to check on patents, marketing and licensing status of your disclosures. TechTIPS began sending notices about the new inventor portal to UCSD inventors earlier this year. If you have not received your user id and password and would like to use the portal, please send an email request to invent@ucsd.edu.

Broadcast International, Inc. Acquires UCSD Startup with Technology that Facilitates Video Delivery to Mobile Devices

Broadcast International, Inc. (OTCBB:BCST), a fully integrated communication services provider, announced that it has acquired, in a stock transaction, Video Processing Technologies, Inc., a UCSD startup and a wholly owned subsidiary of UTEK Corporation, (AMEX: UTK) (LSE-AIM: UTKA), an innovative technology transfer company.

Video Processing Technologies, Inc. holds the exclusive license to two patent pending technologies developed at the University of California, San Diego, which provides for smoother motion animations on wireless systems that normally lack sufficient bandwidth to sustain frame rates high enough to avoid jerky movement. This technology was developed by Truong Nguyen, Ph.D., Professor of Electrical and Computer Engineering at UCSD Jacobs School of Engineering. www.utekcorp.com

Heat Shock Protein Derived Peptides Patent Issued

U.S. Patent No. 6,989,146 entitled “Stress Proteins and Peptides and Methods of Use Thereof” was granted on January 24, 2006. The inventors are Dr. Salvatore Albani and Dr. Berent Prakken. The patent is assigned to the University of California and has been licensed to Androclus Therapeutics, a UCSD startup in San Diego.

The patent describes HLA pan DR peptides derived from heat shock proteins (hsp) and methods for using such peptides to modulate, block or inhibit immune responses for treatment of immune mediated conditions, such as autoimmune and inflammatory diseases. www.androclus.com