

# Portal al Mercado

"Door to the Marketplace"

Volume III (Fall 2004)

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## Message from the President

Welcome to the newsletter from the Science & Technology Corporation @ UNM (STC), the technology commercialization arm of the University of New Mexico. This issue contains information about STC, its services and events, as well as educational material about intellectual property and its management.

STC completed its fiscal year on June 30, 2004 with substantial increases in its commercialization activity. The number of invention disclosures, the new ideas originating from University of New Mexico faculty, students and staff, increased from 46 in the previous year to 67 this fiscal year. Following the trend, the number of patent applications filed and patents issuing to STC increased substantially as well.

STC completed 16 new option and license agreements in the past year, an increase from 9 in the previous year. The agreements included licenses to three start-up companies, based in part of UNM technologies: Avanca Medical Devices, Inc.; Exagen Diagnostics, Inc.; and Attochron, LLC.

Revenues increased by over fifty percent over the previous year to \$327,941 in FY2004, a reflection of increasing commercialization activity.

While STC is still in the early stages of its development, we achieved the type of healthy increases in our metrics consistent with building a substantive technology commercialization program. The significant growth in the disclosure rate is especially important at this stage.

A series of outreach events are scheduled for the fall semester to educate interested UNM community members about intellectual property matters, commercialization and entrepreneurial activities. This newsletter contains a listing of the fall events.

For those interested in learning more about the patent process, the article in this issue, "Exotic Fish Invade Patent Law" will be of interest. It reflects the changing scene for patent prosecution.

We have listed the patents issuing to STC inventors January 1, 2004 through June 30, 2004. Congratulations to our inventors who have patents issuing to them!

Please feel to contact me or other STC staff listed below if you would like to discuss new ideas for commercial potential. As the name of our newsletter indicates, we consider STC to be the Portal al Mercado, or the **Door to the Market!**

Lisa Kuuttilla, President & CEO ([kuuttilla@unm.edu](mailto:kuuttilla@unm.edu)/272-7905)

## Patents Issued to UNM Inventors (1-1-04 - 06-30-04)

*Optoelectronic Circuit for Detecting Changes in Fluorescence Lifetime*

Patent No. 6,673,626 issued 1/6/04

Lopez, Gabriel P.; O'Brien, Michael J.; Rabinovich, Emmanuel

*Nanostructured Devices for Separation and Analysis*  
Patent No. 6,685,841 issued 2/3/04

Lopez, Gabriel P.; Ista, Linnea K.; Brueck, Steven R.J.; Hersee, Stephen D.; O'Brien, Michael J.

*Biochemical Markers of Brain Function*

Patent No. 6,708,053 issued 3/16/04

Brooks, William M.; Jung, Rex E.; Petropoulos, Helen; Sibbitt, William L., Jr.; Yeo, Ronald A.; Friedman, Seth

*Human Kunitz-Type Inhibitors and Methods Relating Thereto*

Patent No. 0726953 issued 3/24/04

Kisiel, Walter; Foster, Donald; Sprecher, Cindy

*Purified Heat Shock Protein Complexes*

Patent No. 6,713,608 issued 3/30/04

Wallen, Erik S.; Moseley, Pope L.; Roigas, Jan

*Fourier Moire Wavefront Sensor*

Patent No. 6,717,661 issued 4/6/04

Berstein, Aaron; Diels, Jean-Claude M.

*Non-Planar Micro-Optical Structures*

Patent No. 6,728,289 issued 4/27/04

Peake, Gregory; Hersee, Stephen D.

*Self-Regulating Body Bias Generator*

Patent No. 6,731,158 issued 5/4/04

Hass, Kenneth J.

*Stimuli-Responsive Hybrid Materials Containing Molecular Actuators and Their Applications*

Patent No. 6,755,621 issued 6/29/04

Lopez, Gabriel P.; Goparaju, Venkata Rama; Atanassov, Plamen B.; Chilkoli, Ashutosh

# Exotic Fish Invades Patent Law

Article by Lorraine L. Greenlee, Greenlee, Winner and Sullivan

Invasive species, fire ants, tamarisk, snakehead fish, etc., have become an unpleasant but familiar aspect of modern existence. Transplanted to a new and unsuspecting ecosystem, these creatures reveal nasty, aggressive traits that spoil the landscape and threaten our health.

There was once a time when University researchers, having made an important scientific advance, could expect to obtain patent coverage, not just for the results of a single experiment, but also for other things made possible by the results of that experiment, things that would be obvious variants to others in the field.

Sadly, the ecology of the patent world has been invaded by a variant legal doctrine which is threatening our cherished assumption that an inventor is entitled to claim embodiments of his invention that would be obvious to those of ordinary skill in the art, following from the teachings of the invention. This "snakehead" variant is known as the Written Description requirement, whose proliferation through the patent system is threatening to severely curtail the scope of patent rights arising from University research.

For years, a benign form of Written Description requirement has existed as a curb on attempts by patent applicants to prevent their claiming priority to inventions not described in their initial filings. In any patent application, Sec 112 of the patent statute requires that the patent specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, ...." In benign form, the written description requirement worked as follows. Professor X, having made an important finding, would file an application, claiming that finding and its obvious variants. Later, further research reveals a new aspect not previously described. Professor X could file a continuation-in-part application, claiming priority from the first application and claiming the new feature. The new feature would not have the benefit of the first filing date because there was no written description of it in the original application. However, the obvious variants claimed in the original application were not affected. Under the new "snakehead" Written Description, even the obvious variants of the original application could be deemed invalid if not adequately "described".

The "snakehead" variant appeared on the scene, appropriately, with litigation over biotechnology patents. A gene encoding insulin was cloned at the University of California in 1977. A patent application was filed. Cloning of the rat insulin gene was disclosed in detail. The patent claimed not only the DNA sequence encoding rat insulin, but also DNA encoding human insulin, although the latter had not been accomplished before the filing date. Litigation with accused infringer Eli Lilly eventually led to a decision in 1997 by the Court of Appeals for the Federal Circuit (CAFC). The CAFC held that the University's claim to human insulin was invalid for lack of adequate written description. That decision might seem reasonable to people in other fields of science, but it dismayed those skilled in the field of molecular biology. Rats are different from humans in many ways, but the structure of their insulin genes is very similar. Having been taught by the inventors how the rat insulin gene was cloned, it would have seemed an obvious application of ordinary skill in the art to use the described methods to clone the human insulin gene. All that the patent lacked was the nucleotide sequence of the gene.

**“Once the neighbors bring their fight out on the front lawn, it's time to call the cops.”**

In the insulin case and in several subsequent cases, the CAFC has stated that to meet the written description requirement, an applicant must "describe the claimed subject matter in terms that establish that the applicant was in possession of the claimed invention, including all of the elements and limitations." "Possession" has never been defined. It could mean sufficient disclosure to enable others to make variant structures or to apply the invention in various circumstances, or it could be restricted to what the inventor actually reduced to practice. The CAFC appears to have adopted the latter (restrictive) meaning, to judge by subsequent decisions. The results have been especially hard on universities and on biotechnologists. University research emphasizes establishing basic operating principles. Patents based on university research tend to lack multiple examples illustrating the basic invention. Under

current written description law, such patents risk being limited to what was actually reduced to practice. In biotechnology, the CAFC continues to demand actual sequences for genes and proteins that in the real world are identified by their functional attributes.

Ironically, while biotechnologists are limited to the exact sequences of genetic information, software developers are not required to disclose code and routinely obtain patents on programs described only in functional terms.



Now, in University of Rochester v. G.D. Searle, the wisdom of releasing snakehead Written Description into the patent law environment is being questioned, and may be heard by the Supreme Court. Rochester scientists discovered the enzyme Cox-2 and its role in inflammation and pain. Cox-2 inhibitors such as Celebrex were rapidly developed as effective and lucrative prescription painkillers. Several patents emanated from Rochester's research including patents to the enzyme itself, the DNA encoding the enzyme, a method for screening candidate inhibitors, and a method for treating pain by inhibiting Cox-2. It was the latter set of claims that the CAFC held invalid for lack of adequate written description. The University was effectively denied the chance to reap any significant profit from the research.

*Invasion continued on page 3*

## STC Website Features

### Draft Manuscript/ Grant Application Upload

[stc.unm.edu/inventors](http://stc.unm.edu/inventors)

Upload your draft manuscript or grant application today for STC to review. We will advise you concerning the patentability of your invention for free.

### "My Technologies"

[stc.unm.edu/inventors/portal](http://stc.unm.edu/inventors/portal)

Log in today and check your inventions' patent status! See activity as it occurs and help us help you. View the marketing efforts being pursued on your inventions in real-time!

## Lobo VentureLab Opens

On July 1, STC officially opened its *Lobo VentureLab*, the venture creation activity of the University of New Mexico's Science & Technology Corporation. The Lobo VentureLab (LVL) is a connection point to link and assist technology inventors, students, faculty, entrepreneurs, venture capital firms, and existing small technology companies. LVL provides a physical location, offering these facilities:

- Market research capability and subscription only databases
- Internet and telephone
- Student intern support

LVL links those with technologies in various stages of development to the resources necessary to commercialize those technologies by facilitating the formation of new companies, based in central New Mexico, and equipping them with the foundation to improve their chances of being successful. LVL does this by utilizing a rigorous venture development process, including:

- Review of venture opportunity
- Assessment of market potential
- Project "gap" funding
- Assistance in preparation of business plan and presentation



Accelerating the Process of New Venture Creation

A part of the Science & Technology Corporation @ UNM

- Matchmaking between scientists and industry entrepreneurs
- Linkages with service providers
- Coordination with TVC and venture capital firms to raise funding to grow ventures
- Facilitation of creation of new companies by project managing the venture development process among the various constituents to assist those without the experience or background, thereby improving the chance for success

Peter Rachor, Director of Venture Development for STC, heads the Lobo VentureLab. "Peter's expertise and experience as an entrepreneur and in new business development makes him an excellent fit to guide emerging companies through the early stages. We are excited to be able to offer this assistance to newly-forming companies," says STC President, Lisa Kuuttila. Those interested in working with the Lobo VentureLab should contact them at 272-7026.

*Invasion* continued from page 2

In the years between the insulin and Cox-2 cases, several CAFC decisions seemed to indicate a lack of unanimity among the twelve judges. The judges divide themselves into groups of three in order to handle their case load. Some three-judge panels have appeared to be less enthusiastic about the new written description requirement than those who decided the insulin case. Their differences spilled into view when Rochester's attorneys petitioned for a rehearing of their case *en banc* (by all twelve judges). The petition was denied, but a significant minority dissented. The majority, agreeing with Judge Lourie, considered the new written description requirement an evolutionary development of existing patent law. The minority view, strongly expressed by Judge Rader, challenged the notion that the new requirement was soundly based in precedent or proper statutory interpretation. Judge Rader also criticized its effects in limiting the scope of patents as being especially harsh for university and biotechnology patents.

Rochester's attorneys plan to petition the Supreme Court to review the case. It is likely that the Court will hear the case because of the deep philosophical divide now evident for all to see. (Once the neighbors bring their fight out on the front lawn, it's time to call the cops.) It is hard to predict how the Court will decide, of course. If it decides to allow valid scope for obvious embodiments and for genetic inventions where sequence information is not needed to carry out the invention, the potential for universities to capture fair value for their contributions to the economy will be restored.

Another case of great interest is a dispute between Pfizer (Viagra) and Lilly (Cialis). Pfizer, like Rochester, discovered a molecular target whose inhibition by an appropriate drug opened a lucrative market. Pfizer, among its many patents for a class of Viagra-like compounds, also claimed a method for treating erectile dysfunction by inhibiting that target. Cialis, while it acts to inhibit the same target, is chemically different from Viagra. The basic issue is whether discovery of a mo-

lecular target, together with a handful of compounds that modify the function of the target, is sufficient to provide reach-through coverage to dominate the uses of all compounds that do the modifying. Will the snakehead still be around when the CAFC decides this case? People are already betting on the outcome. ■

*Lorance L. Greenlee, J.D., Ph.D., a shareholder in Greenlee, Winner and Sullivan, has been in practice for 27 years and is the author of many pioneering biotechnology patents, including those for human growth hormone, recombinant hepatitis B virus, transgenic plants, and Bacillus thuringiensis expression in plants. Dr. Greenlee has significant corporate experience in patent strategy, licensing and technology transfer. Dr. Greenlee focuses his practice in medical science, molecular biology, genetics, immunology, plant sciences, chemistry and biochemistry. In addition to patent preparation and prosecution, Dr. Greenlee provides legal advice on patentability, patent strategy for pioneering fields of science, coordination of business and patent strategy, patent appeals, foreign patent practice, patent infringement and validity, freedom to operate, and licensing matters. Dr. Greenlee has an undergraduate degree in Chemistry from the University of Colorado, a doctorate in Biochemistry from Duke University, and was an associate professor of Biochemistry at the University of Utah prior to entering law school.*

## New STC Board Members

School of Engineering Dean Joseph Cecchi is the new Chairman of the Science and Technology Corporation Board. Vice Chair is Dr. William Schuler, and Secretary/Treasurer is Chuck Wellborn.

The University of New Mexico Board of Regents has recently appointed four new members to the board: Dr. Albert Westwood, Suelly Scarnecchia, Terri Cole and Carolyn Monroe.

For more information, visit [stc.unm.edu/news/news.php?nid=58](http://stc.unm.edu/news/news.php?nid=58)

# Upcoming Events

## Intellectual Property Seminars

### *Recent Developments in Engineering and Physical Science Patents*

Presented by Timothy M. Hsieh, Ph.D. (Min, Hsieh & Hack, LLP)  
October 19, 2004 / 12:00pm  
Student Union Building, Lobo Room B (Third Floor),  
UNM Main Campus

### *Recent Developments in Life Science Patents*

Presented by Donna M. Ferber, Ph.D. (Greenlee, Winner and Sullivan, P.C.)  
November 18, 2004 / 12:00pm  
Basic Medical Sciences Building (BMSB), Room 303,  
UNM North Campus

## Entrepreneurs Forum Series

### *Creating a Partnership Between an Academic Health Sciences University, the State, and the Business Community to Stimulate Technology Transfer and Economic Development*

Presented by Matthew J. Kluger, Ph.D. (Medical College of Georgia)  
September 23, 2004 / 1:00pm  
Basic Medical Sciences Building (BMSB), Room 303,  
UNM North Campus

### *The Critical Steps to Entrepreneurial and Leadership Success*

Presented by Matthew K. Stewart (National Services Group and College Works Painting)  
October 7, 2004 / 12:00pm  
Student Union Building, Lobo Room B (Third Floor),  
UNM Main Campus

### *Raising Capital in New Mexico Today*

Presented by Trevor Loy (Flywheel Ventures, Inc.)  
November 4, 2004 / 12:00pm  
Student Union Building, Cherry/Silver Room (Third Floor),  
UNM Main Campus

### *Concept to Product*

Presented by Kathleen Kelleher and Dr. Bill Sibbitt (AVANCA Medical Devices, Inc.)  
December 2, 2004 / 12:00pm  
Basic Medical Sciences Building (BMSB), Room 303,  
UNM North Campus

Visit our website at [stc.unm.edu/news/events.php](http://stc.unm.edu/news/events.php) to register for any of these events!



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**The technology commercialization arm of the University of New Mexico**