Fall 1999 Newsletter

A Newsletter of the University of California, San Diego Technology Transfer and Intellectual Property Services

From the Director:

What's in a Name?

Since our establishment in November, 1994, the office has been known as the Technology Transfer Office or TTO. Although "technology transfer" is certainly a major responsibility of the office, we do much more. For example, we also manage copyrights of works created at UCSD, file patent applications, register trademarks, and all in all we provide services on matters related to intellectual property issues. To more accurately reflect the broad purview of the office, the Academic Senate and the university administration have approved a name change for the office. The office is now the Technology Transfer & Intellectual Property Services or TechTips.

Your Idea is Safe With Us

In May, the renovation of the office complex for TechTips and the Conflict of Interest Office was completed. The office complex now has one single entrance that channels all visitors directly to our receptionist. The entrance is locked after business hours and the proprietary and confidential information that we routinely handle is more secure than ever. The office complex also has been designed to facilitate work flow. We thank the construction and design folks for their handiwork. We also want to thank all the people in the building for putting up with the noise and the dust during the renovation period. A special thank you is due to External Relations and Conflict of Interest for accommodating our requests for space reassignment.

Another Good Year

TechTips just completed another record year! In FY99 that ended on June 30, we received a record number of new disclosures and executed a record number of agreements which transfer rights to use UCSD intellectual property to the industrial sector. Complete statistics will be available later in our campus and system-wide annual reports.

New Faces

As you walk into our new office complex, the first new and pleasant face you will see is likely to be that of Nikkie. **Nitka Karimi** is our new administrative assistant who is our gatekeeper. Nikkie joined us in April this year from Professional Dental Care. Previously she had experience running her family's business and as an assistant in the UCSD Sports Facilities. Nikkie has a biology degree from UCSD.

Theresa Rotterman joined us in February as our Marketing Assistant. She is responsible for performing market research for our technologies and implementing the marketing activities. Terri has a BS degree in Biochemistry from UCLA and has 3 years of technical research and sale experience with Biocell Laboratories and ICN Pharmaceuticals, Inc.

To help us distribute royalties and pay bills, **Deborah Barber** joined us in January from US Sunbelt Development Company. Debbie has over 15 years of experience in bookkeeping and accounting. She has a bachelor degree in business and accounting from Master's College.

Kristine Cole joined our patent management group in January after spending 2 years in Washington DC and seven

years in Connecticut as a legal assistant in the law firms of Cole, Raywid & Braverman, LLP and Greenberg and Parenteau PC, respectively. Kristine helps us in patent prosecution matters and in reviewing legal bills. Prior to her law firm experience, she spent four years in accounting with the Compass Realty Group. Kristine has an associate degree in accounting and business from Mitchell College.

Our new disclosure assistant is **Quan Nguyen.** Quan has a BA degree in Economics from University of Pennsylvania and has work experience as a portfolio assistant at Prudential Securities, Inc. He helps us receive, process, and review new disclosures that come into the office.

This summer, we also hosted **Claudia Randazzo Amoresano** as a visiting specialist in our office. Claudia visited us from Technopoli (Naples, Italy). Technolopi is a consortium that promotes and manages the Science and Technology Park of the City of Naples with the Missions to foster innovation and technology transfer in the Campania area. Claudia spent the summer with us so that we could share our knowledge and experience.

In August, **Brian Culley** joined the office as our Licensing Assistant. Brian is responsible for providing services to our existing licensees. Brian has a MS degree in Biochemistry from UCSB and a BS degree in Biology from Boston College. He came to us from Neurocrine Biosciences, Inc. (San Diego) where he was a Research Associate for three years.

Alan S. Paau

Director

Who is Really an Inventor When It Comes to Patenting an Invention?

In the United States, a patent is awarded to the first person or persons to invent the claimed invention. Considering the challenges a patent may face during its lifetime**,** identifying the true inventors) is an important issue to resolve when filing a patent application.

Inventorship is a legal determination that is made in view of the claims which define the scope of the invention. An inventor is one who conceives of the claimed invention such that it can be reduced to practice by one of ordinary skill in the art. A patent that does not name the true inventors can be rendered invalid if it is found that the failure to name the correct inventors arose through deceptive intent.

A patent is a legal document, and is not a medium for expressing appreciation or acknowledging assistance. Authorship on a scientific publication is not commensurate with inventorship. Thus, while persons who provide a material, lab space or financial support to conduct experiments, or managers of a group of engineers or researchers that creates an invention, may be named as authors on a publication, these persons are not inventors unless they actually contributed to the conception of the invention. Similarly, persons who performed routine experiments, either independently or under the supervision of another, may be named as authors on a scientific publication, but are not necessarily inventors, regardless of the amount or quality of work they performed.

Where one person conceives of the subject matter encompassed by all of the claims, that person is a "sole inventor." Where two or more persons are named as co-inventors in a patent application, each person can be a sole inventor of different claims, or both can be "joint inventors" of one or more claims. All that is required for joint inventorship is that the two or more persons work together to solve a problem; they need not physically work together or at the same time, and the quality or quantity of their contribution to conception of the invention is not considered. However, if the claims attributable to one of the co- inventors are removed from the application prior to the time a patent issues, that person must be removed from the list of inventors and the patent will issue only in the name(s) of the remaining inventors).

A determination of inventorship can be particularly problematic in an academic environment, where discussions of research take place spontaneously "over coffee" or in the halls, and ideas are "bounced" back and forth in group or even departmental meetings. In determining whether a person is a **j**oint inventor, it helps to ask whether the invention would have been made without the idea contributed by that person. If it would not have been made, then that person likely may be a joint inventor. However, if the "idea" contributed by the person was, for example, a well known alternative method of performing a process such as a purification step where the claim is to a purified product, or an alternate material where the claim is to a structure, the contribution likely would not be considered a contribution to the conception of the invention, and the person would not fit within the legal definition of an inventor.

A brief review of two court cases may help elucidate the considerations that enter into determining whether a person should be considered a joint inventor. In one case, investigators at the pharmaceutical company Burroughs Wellcome believed, based on preliminary experiments, that azidothymidine (AZT) could be effective for treating HIV-infected individuals.' Burroughs contracted with a laboratory at the National Institutes of Health to test the efficacy of drugs against live HIV**,** and provided the NIH group with coded samples of various compounds, including AZT. Burroughs also began to prepare a patent application with claims to methods of treating HIV-infected individuals using AZT. After the results of the assays performed at NIH demonstrated that AZT inhibited HIV replication, Burroughs filed the patent application, and patents issued naming only Burroughs' employees as inventors. The validity of several of the Burroughs patents was challenged, in part, on the basis that none of the NIH investigators was named as a joint inventor. The parties seeking to invalidate the patents argued that the investigators at Burroughs did not have a reasonable expectation that AZT would be effective against HIV until the results demonstrating its effectiveness were obtained by the NIH investigators and, therefore, there could have been no "conception" without the contribution made by the NIH investigators. Although the court recognized that a high level of skill was required by the NIH investigators to perform and interpret the experiments, the court nevertheless held that the work performed by the NIH investigators merely demonstrated that the invention worked as conceived by the Burroughs' inventors, and the patents were held to be valid.

In the second case, two post-doctoral cardiology fellows, Drs. Simpson and Robert, conceived of a design for a balloon angioplasty catheter.' After their initial attempts to select a material suitable for constructing the catheter were unsuccessful, Simpson and Robert solicited suggestions for a suitable material from a plastics engineer, Dr. Hess, at Raychem Corporation. Simpson and Robert explained the principles behind the catheter to Hess, described the materials they had tried, and indicated that none of those materials allowed controlled inflation of the balloon. Hess showed them a Raychem plastic product that was available, described the properties of the material and how it could be used, suggested a non-adhesive method for attaching the balloon to the catheter, and provided them with a sample of the material. After considerable experimentation, Simpson and Robert arrived at a catheter having the desired characteristics. They filed a patent application naming only themselves as inventors, and ultimately were granted a patent.

The validity of the Simpson and Robert patent was challenged, in part, for not properly naming Hess as a joint inventor. In view of the extensive amount o f experimentation performed by Simpson and Robert before the catheter finally was perfected, and on the finding that the information provided by Hess was well known or could have been gleaned from published information, the court held that Hess was not a joint inventor. The court stated that an inventor may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent.

In summary, inventorship is a legal determination that only can be made by consideration of the claims. An inventor is one who contributes to the conception of the invention, and conception occurs when the invention is described with sufficient particularity that one technically competent in the field to which the invention relates can practice the invention as claimed. Careful documentation of experiments, as well as of discussions held with others, can assist

in determining when conception of an invention occurs, and can ensure that a patent application names the correct inventors, thus strengthening the patent against one possible means of invalidation. And one thing is certain - if a patent excludes others from making or using a valuable composition, apparatus, or method, its validity will be challenged.

[Contributed by Rick Imbra and Eleanor Musick of Brown, Martin, Haller & McClain. Reproduced with perMission.]

The Big Hassle with Research Material Transfer

For decades, the transfer of research materials in and out of universities has occurred without much concern or care. While the transfer of most research materials in the physical and chemical sciences and in engineering remains routine and simple, the same cannot be said of biological materials.

With the maturation of the biotechnology industry, the transfer of biological research materials has become quite an onerous process.

It is now routine that when a university researcher requests any research material from a company, the company will *demand certain rights* to the results and the intellectual property that may be developed by the researcher using the material. Further, the company may *restrict the dissemination of the research results.* Such demands have become a big burden to the university in that the university must now keep track of all the materials that move in and out of To tackle these responsibilities at the university.

For research materials that are to come in, the university needs to ascertain that the demands and restrictions of the suppliers are not inconsistent with university policies and state and federal laws, and are reasonable and not in conflict with any prior contractual commitments of the university. For research materials to be sent out, the university needs to ascertain that the researchers and the university indeed have the legal right to send the materials outside of the university and to also address liability issues should any problems arise with the use of the materials by the recipients. One thing in common for all research materials to be transferred, whether they go out or come in, is that a *Material Transfer Agreement* (MTA) should first be executed before the materials can be transferred. The MTA is a contract spelling out the terms and conditions under which the research materials are to be transferred. The contract normally spells out clearly for everybody and for the record:

- the material proposed to be transferred;
- the purpose of the transfer;
- responsibilities relating to compliance with local, state, and federal regulations;
- rights and interests each party may have in the material or in the results derived from using the material;
- disposal of the excess or unused material;
- liability and indemnification;
- warranty, if any; and
- reimbursement for costs associated with the transfer (e.g. costs in producing the materials and for shipping etc.), if appropriate.

UCSD, TechTips and the Office of Contract and Grant Administration (OCGA) share the duties. OCGA will assist you with all MTAs for research materials that are to come into UCSD. For sending research materials out, UCSD researchers should first fill out a Material Transfer Information Sheet to provide some preliminary information about the research materials and send it to OCGA. The Material Transfer Information Sheet is available from OCGA and TechTips and can also be downloaded from OCGA's Web server at http://ocga.ucsd.edu. OCGA will then review the preliminary information to determine whether it should be referred to TechTips. Generally, materials such as patient blood samples and ordinary tissues will not be referred to TechTips. Research materials that are results of UCSD active research activities or programs, especially those related to inventions, are often referred to TechTips and a more detailed disclosure of the research materials will be necessary. The detailed disclosure form is available from TechTips and can be downloaded from our Web site.

In practice, when a UCSD researcher thinks about transferring or receiving research materials and BEFORE a signature is put onto any agreement or shipping any material, the FIRST thing a UCSD researcher should do is to contact Ms. Carroll Ekberg of OCGA at 534-9884, (caekberg@ucsd.edu). If the request is referred to TechTips, you will be contacted by our Intellectual Property Disclosure Manager, Julie McPherson. She and her assistant, Quan Nguyen will help the UCSD researcher with the necessary information and paper work. Julie can be reached by phone at 534-7412, (jamcpherson@ucsd.edu), and Quan can be reached at 822-3275, (qmnguyen@ucsd.edu).

Satellite TechTips Location

As a means of exploring ways to better serve UCSD researchers, we have recently opened a satellite service desk in Muir Hall, Room 4404. Dr. Larry Brand, a Senior Licensing Officer of TechTips, will be there to work with the west campus Biology and other faculty and researchers in the new Center for Molecular Agriculture on new inventions and other intellectual property issues. Larry will be there about 4 hours each on Tuesdays and Thursdays. If this trial proves productive over the next year, we will consider the possibility of opening other satellite service locations to better reach out to our researchers. We are grateful to the Biology department for letting us use the office space for this experiment. For the exact service desk hours, please call Larry at 4-7349 or Nikkie at 4*5815. (Contributed by Larry Brand)*

TechTips Outreach and Professional Activities

TechTips was well represented in the national and regional meetings of the two most recognized technology transfer professional societies - the Licensing Executives Society (LES) and the Association of University Technology Managers (AUTM). TechTips staff attended the LES regional meetings in Napa and Philadelphia, and the AUTM national and regional meetings in San Diego and Berkeley, respectively. Rose Murphy, Marketing and License Manager, and Larry Brand, Senior Licensing Officer, also attended the Biotechnology Industry Organization exposition in Seattle and presented several of our technologies available for licensing. Vanessa Tollefson, Patent Manager, attended the American Bar Association's 25th National Conference on Professional Responsibility. She also served as a panel member for the Patent Law-Intellectual Property Workshop at the Association for Women in Science Conference held at the Salk Institute.

At the invitation of the Chinese Ministry of Science and Technology, Alan Paau, TechTips Director, visited the Institute of Botany of the Academia Sinica (Beijing), the Maize Research Center of the Jilin Academy of Agricultural Sciences (Changchun), and the Nanjing Agricultural University (Nanjing). In each location, Alan lectured on the topics of "Trends in Transgenic Plant Research" and "Commercialization of Transgenic Plants" and learned from the current transgenic plant programs in those institutions.

Technology Transfer & Entrepreneurship:

Genomics Models

Two technologies arising from the work of Prof. **Bernhard Palsson** on the development and application of genomics models in the Department of Bioengineering have been licensed by Genomatica, Inc. (San Diego, CA). The new company focuses on *in silico* functional genomics and modeling. Genomatica Contact: Wain Fishburn, Esq., Secretary (Tel: 858.550.6014)

CUFES TM

The "Continuous Underwave Fish Egg Sampler" was developed by Prof **David Checkley** at the Scripps Institution o Oceanograpyo UCSD. The device has been licensed to Ocean Instruments (San Diego, CA). Fish egg counts are an important predictor of the general health of the ocean's fish stocks, and this device provides for the greatly improved accuracy of those counts. Ocean Instruments Contact: John Hedrick (Tel: 858.291.2557)

Seismic Retrofit

A method using lightweight composite fiber overlays to reinforce earthquake damaged structures or to prevent future damage has been licensed to Composite Solutions, Inc. (La Jolla, CA). This technology was developed by Profs. **Gil Hegemier** and **Frieder Sieble** in Applied Mechanics and Engineering Sciences. Composite Solutions Contact: Tom Burke, President (Tel: 949.261.118 1).

Analog to Digital Conversion

Analog Circuit Technologies, Inc. (San Diego, CA) has licensed an improved method for analog to digital conversion of data based on the work of Prof. **Ian Galton** in Electrical and Computer Engineering. ACT Contact: Ibrahim Yayla, Manager of Analog Sampled Systems (Tel: 858.677.9967 x 105).

Chaos Put to Good Use

The application of chaos theory to pulsed broad spectrum based radio communications has been licensed by the Time Domain, Corp. (Huntsville, AL). This invention arose from the research efforts of Profs. **Henry Abarbanel** and **Larry Larson** and their research groups in the Physics Department and the Electrical & Computer Engineering Department, respectively. Time Domain Contact: Larry Fullerton, President (Tel: 256.922.9229).

Blood Substitute

Sangart, Inc. (San Diego, CA) has licensed a UCSD technology that will form the basis for an oxygen carrying blood substitute. This technology arose from the work of Profs. **Marcus Intaglietta** in the Bioengineering Department and **Robert Winslow,** fomerly of Veteran Administration Hospital. Sangart Contact: Dr. Robert Winslow, President (Tel: 858.455.0966).

Birth Control for Trees

A typical tree expends 35% or more of its energy to produce seeds and reproductive structures. Since forest product companies would rather see this energy be devoted to generate more paper and board feet of lumber, a way to suppress the reproductive processes in growing trees is very desirable. DevTech (Queensland, Australia) and Westvaco Company (Summerville, NC) have each licensed rights to a flower suppression technology developed by Prof. **Martin Yanofsky** of Biology. By linking the expression of a toxic protein to floralspecific transgenes that control the onset of flowering, the emerging flowers are selectively killed without harming other tree tissues. The result is an eunuch-tree that spends more of its energy making wood and not love. DevTech contact:

Beryl Morris (Tel: 61.73.87.05888); Westvaco contract: Edwin Owens (Tel: 843.871.5000).

Drug from the Sea

The experimental anticancer drug, Brytostatin, is derived from a marine bryozoan, *Bugula neritina.* Research at Scripps Institution of Oceanography by Dr. **Margo Haygood** has discovered that the drug is actually made by a bacterium that lives as a symbiont within the bryozoan. Inventions describing how to grow this organism in pure culture and to express its cloned biosynthetic genes in other organisms have been licensed to CalBiomarine Technologies, Inc. (Carlsbad, CA). CalBiomarine contact: Dominick Mendola (Tel: 760.431.2214).

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Information

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