



OFFICE OF Technology Alliances

University of California, Irvine

UCI Is Open For Business: Faculty Perspective

Under the California Master Plan for Higher Education, the mission of the University of California is excellence in education, research and public service.

The University has a positive obligation to ensure that the results of its research are commercialized to benefit the public, which can only be accomplished through industry partnerships. In that context, UC Irvine emphasizes industry research collaborations and technology transfer as the primary means for commercial application of knowledge. Strong university/industry alliances

Our commitment is to make the industry/university partnering process as flexible, timely and productive as possible.

founded on new technology opportunities ultimately expand the research and technological capabilities of both sectors and enhance the economy through new products and services, job creation and new start-up businesses.

Office of Technology Alliances

UCI was delegated authority from the UC President's Office in 1994 to manage its own intellectual property.

The Office of Technology Alliances (OTA) was established to implement this authority. OTA's functions include managing UC Irvine's intellectual property resources (patents, copyrights and trademarks), helping faculty increase research support from the private sector and assisting faculty with various industry-related activities (resource sharing, visiting scientists, start-up companies, consulting arrangements and research material transfers). OTA emphasizes accessibility, timeliness and flexibility in fostering faculty/industry interactions.

Inventions and Patents

The Patent Act of 1980 (also known as the Bayh-Dole Act) gives universities the right to own and to license technology developed under federally funded research, provided that such licenses ensure certain government rights and require substantial US manufacture of resulting products for the US market. It also requires federal reporting and prohibits universities from transferring title to such technology to third parties.

The Bayh-Dole Act applies in all cases where any amount of federal money is used in the development of the technology.

Disclosure and Assignment of Patentable Inventions

To preserve patent rights, faculty should disclose inventions to OTA before making any form of public disclosure, e.g. a paper, poster session or discussion with a colleague. As a condition of UC employment, faculty, staff, and researchers are obligated to disclose all inventions to the University and to assign to UC their

sole or joint rights in any possibly patentable inventions developed within the scope of their UC employment. This includes inventions occurring under UCI industry research collaborations, as well as inventions occurring under consulting arrangements or other outside personal agreements where there is overlap with the areas of research, teaching and publication of the faculty member.

If the University determines it will be unable to successfully commercialize an invention, it may release the invention back to the inventor (or to the federal government, if federally funded). However, once an invention has been released to the inventor, the faculty member will need to further develop the invention without the use of University time or resources. In all cases, new or improvement inventions must be disclosed to and assigned to UC if the invention is within the inventor's scope of University employment.

Inventorship

Inventorship on patents is governed by law and requires that each inventor contribute to the conception of the invention. Unlike authorship on publications, not everyone who contributed to the project is an inventor. For instance, a person who merely carries out the instructions of another (a "skilled pair of hands") in performing experiments does not qualify for inventorship.

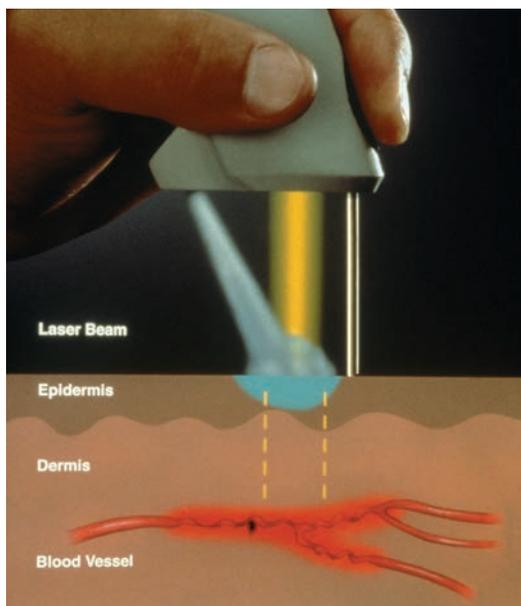
Inventorship determinations are made by the attorney authorized by UC to file the patent application, and this determination is confirmed by the US Patent and Trademark Office (USPTO). A patent can be made unenforceable not only for the omission of a legitimate inventor, but also for the inclusion of a non-inventor.

Royalty Sharing

UC Policy allows faculty inventors to share in net fees and royalties received from licensed intellectual property. For inventors who signed the University Patent Acknowledgement/Agreement after October, 1997, and for all other licensable UCI intellectual property, 35% of net proceeds go to the inventor(s), 15% to the inventor's academic department or research unit (or both if joint support was provided); and 50% goes to the University to cover all other unreimbursed costs and to support University research and education programs. Inventors may voluntarily request that their royalty share distributions go to other entities or request that the royalty distribution reflect relative inventive contributions that may include non-inventors, provided there is unanimous written agreement among the contributing inventors.

Record Keeping

Faculty should keep bound laboratory notebooks up-to-date, signed and witnessed, particularly for significant scientific discoveries. The witness should be someone who can understand the material and who is not an inventor. These notebooks may be essential to obtaining a patent and proving inventorship. The descriptions and dates (properly witnessed) are vital in competitive situations and in legal disputes (see OTA's Web Directory included with this brochure).



The Dynamic Cooling Device selectively cools the outermost layers of human skin during laser surgery allowing higher light dosages, more effective treatment with less pain, and less post operative scarring. Inventors: J.S. Nelson, T. Milner & L. Svaasand Beckman Laser Institute

Variation by Industry Sector

UCI, in its licensing practice, can accommodate the varying circumstances across industry sectors with a range of licensing alternatives. At one end of the spectrum are low-cost, non-exclusive licenses to companies that want to enter a market quickly and where intellectual property protection is less critical. At the other end of the spectrum is an exclusive license for a platform technology that was fully funded by public funds where intellectual property rights are paramount. In the latter case, substantial fees, royalties and diligent commercialization will be required of the licensee. OTA will work with potential licensees to establish terms that are fair and appropriate for the technology, the University and the particular industry sector.

All parties benefit from expert legal scrutiny.

Start-Up Companies

UCI supports faculty entrepreneurship and the creation of start-up companies founded on the inventor's new technology. Such companies represent an important and viable path to product commercialization and

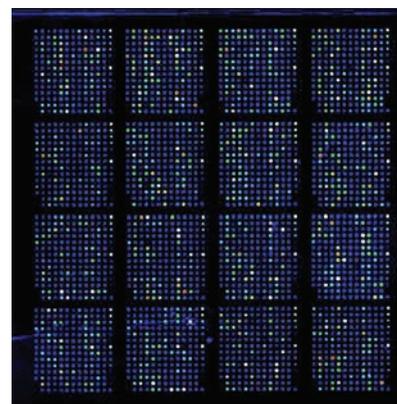
to local economic development and job creation. OTA will seriously consider inventor desires to start companies in its technology licensing decisions, provided that the arrangements conform to UCI's conflict of interest and conflict of commitment policies. OTA will also work proactively with those start-ups that are formed and their investors to optimize the chances of a successful company launch and the attraction of successive rounds of financing.

Licensing UCI Technologies

UCI may issue exclusive or non-exclusive licenses, and may limit licenses by field or by geographic region, depending on the circumstances and the industry sector.

Licenses are negotiated in good faith using appropriate industry standards for fees and royalties. Companies may negotiate options to license agreements to secure the company's commercial position in return for an option fee and reimbursement of patent costs, which is consideration for the value of the right to commercialize publicly funded inventions. Licensees have the following obligations:

- Reimburse UC for patent costs for licensed technology
- Ensure diligent commercialization of licensed technology according to a sound business plan
- Pay a license issuance fee (may be spread out in milestone payments); UCI may take equity in small or start-up companies as part of this consideration
- Pay a royalty on net sales of licensed products, with the rate being adjusted in cases of a jointly owned invention or if multiple technologies contribute to a product
- Accept provisions covering indemnification, insurance, no UC warranty, California law and limitations on the use of the University's name



Antigen Discovery, Inc. is developing a protein microarray based serodiagnostic platform for applications in biodefense and emerging infectious diseases. Inventors: Abraham P. Lee, Armando Tovar, Uland Liao from The Henry Samueli School of Engineering and Philip Felgner, David Davies, Xiaowu Liang from the School of Biological Sciences.

A Winning Strategy for Industry Partnering

OTA has developed a successful strategy for industry partnerships. This strategy focuses on building long-



term corporate alliances founded on new technologies with the goal of helping the company, the faculty inventor and the University achieve their multiple objectives.

UCI's Office of Technology Alliances has a proven winning strategy.

The corporate partner is given the opportunity to acquire commercial rights to an embryonic technology and an incentive to support continued research to further develop the invention in the inventor's laboratory.

Industry-Sponsored Research

Industry-sponsored projects can be supported either by an individual company or by a consortium using the following award mechanisms:

- **Research Contracts** define a scope of work carried out solely by UCI (possibly with subcontractors) and may provide sponsor access to resulting inventions and research results made within the project scope and term. Collaborative Research Contracts involving company and UCI scientists include mutual obligations, and sharing of data, facilities and materials. Contracts can result in joint UC/company ownership of patents jointly invented.

Ampakine molecule that facilitates glutamate receptors and thereby improves communication between neurons in the cerebral cortex. Clinical development is currently underway for a wide range of brain disorders including memory loss in the elderly, Alzheimer's Disease, schizophrenia, and Attention Deficit Disorder. Inventors: G. Lynch et al. College of Medicine

- **Clinical Trials** involve testing of sponsor-owned drugs or devices using the sponsor's protocol, with rights to results and often technology improvements accruing to the sponsor.
- **Gifts** are irrevocable donations to general or specific areas of campus activity that carry no obligations for deliverables or rights to results, although UCI may provide a courtesy report to the sponsor indicating what was accomplished with the funds.

Companies can find additional information on types of awards and model agreements on the OTA web site (www.ota.uci.edu). Additional information for faculty is on the RGS website (www.research.uci.edu).

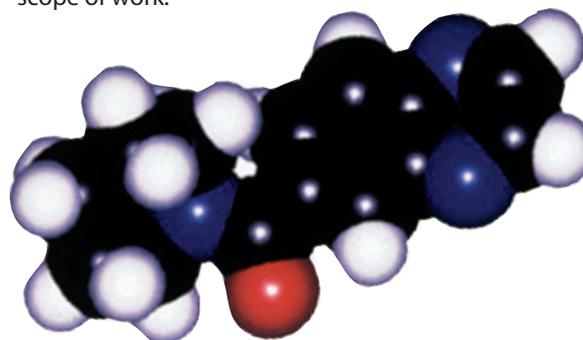
Publications

Faculty must be free to publish the results of research emanating from industry collaborations. However, an industry sponsor can expect the right of prior review (30 to 60 days) and to request removal of proprietary company information inadvertently included in the publication. The sponsor may also request that UCI file a patent (at the sponsor's expense) within an additional 30 to 60 days (total period of delay must not exceed 90 days).

Faculty should contact OTA prior to publishing or disclosing any potentially patentable material to ensure patents are filed before public disclosure. Failing to do so will result in immediate loss of foreign rights and U.S. rights will be lost if a patent is not filed within one year of disclosure. Further, failing to do so may prevent UC from being able to meet its reporting obligation to the federal government or its licensing obligation under a funding agreement.

Confidentiality

As a public educational institution operating in an open academic environment, UCI needs to minimize the amount of confidential material it receives. However, UCI can agree to keep sponsor's defined material confidential for a limited time to the same extent that UCI protects its own confidential information. When unpatented UCI proprietary information is shared with a company, the company should be asked to sign a Non-Disclosure Agreement (NDA), which may be obtained through OTA. This will ensure patent rights are preserved and that the faculty member's proprietary information is protected and secured. UCI does not accept materials covered under export control rules without pre-notification and only where such materials are required in order to complete the scope of work.



Industry Use of University Resources

Accessing Facilities, Equipment and Instrumentation

When a campus unit wishes to render a non-research service or provide goods to a user outside the University for which revenue is collected and for which there is no easily available commercial source, a Sales and Service Agreement is required. This type of agreement is appropriate when the furnishing department incurs expense to make available a product or service that is sold to the non-University user for an established price, or at a price based on an established standard pricing method. A non-University user is either an organization or individual who uses campus services or facilities or purchases goods from a campus unit and who is not a member of the campus community (faculty, staff, students). Sales and Service Agreements should not be used to carry out research relationships. For more information on Sales and Service Agreements, please refer to OTA's Web Directory included with this brochure.

UCI is a broad and respected resource for industry

Visiting Scientists

Anyone using UC research facilities or anyone paid by UC-administered funds (internal or external source) must sign the UC Patent Acknowledgement and agree to disclose and assign to UC any inventions made with UC resources. Contact OTA if there are questions or exceptional circumstances.

Exchanging Tangible Research Materials

UCI may share its tangible research products (TRPs) with other non-profit or for-profit entities, just as third parties may share their own TRPs with UCI, under material transfer agreements (MTAs). MTAs provide for appropriate research, evaluation and testing, and usually impose restrictions on further distribution. Normally each party has the right to use its research results generated from work performed with the materials, and companies may use the results commercially via a license or other exchange agreement.

The purpose of an MTA is to help investigators acquire materials to advance research. However, there is a risk that improper language in an incoming MTA can severely restrict an investigator's future research opportunities and can impose contractual terms that UCI cannot accommodate. The most frequent problematic terms in incoming MTAs: (a) limit academic freedom, (b) assert excessive rights, sometimes even ownership of University research results, (c) ask for inappropriate indemnification, and (d) impose obligations that conflict with those in other funding agreements or federal grants.

For further discussion of appropriate terms in MTAs see the COGR Q&A brochure or NIH Policy on Sharing Research Resources and for further information on MTAs refer to OTA's Web Directory included with this brochure.

Intellectual Property Defined

Patents

Patents grant up to a 20 year right from the date of filing in the U.S. to exclude others from making, using or selling claimed products or services.

In order to obtain a patent on an invention, the invention must be "conceived and reduced to practice", meet the US Patent & Trademark Office standards of novelty and usefulness and not be obvious to someone skilled in the area of the invention.

Patents in other countries must be filed separately within one year of the U.S. patent application filing date. A "Provisional Patent Application" can be filed quickly and inexpensively in order to preserve some patent rights for up to one year on an initial discovery, allowing for publication and further research to be undertaken.

Copyrights

Protect the form of expression of works set forth in a tangible medium. Protection is automatically granted

to authors for their lifetime plus 70 years or 95 years from first publication for a work made for hire.

Copyrighted works may be owned by authors or the University, depending on the circumstances of the work's development.

Trademarks

Protect images, designs, logos, names, sounds and other means of uniquely identifying a product or service. Trademarks derived from UCI programs can be protected by OTA. A Trademark is perpetual but requires the continued use and enforcement of the mark on the part of the owner.

Know-How

UC does not assert rights to faculty skills or knowledge, absent faculty consent in limited cases. Faculty members are free to share this know-how with companies under personal consulting agreements, to the extent that the resulting obligations do not interfere with UCI research and teaching responsibilities.

Negotiation, Review and Approval of Agreements

Agreements with UCI go through the following review and approval process:

- Sponsored and collaborative research agreements are signed by the UCI Office of Sponsored Projects Administration
- Technology options, licenses, non-disclosure, and material transfer agreements are negotiated and signed by the UCI Office of Technology Alliances (OTA)
- Exceptions to University policy must be approved by the UC Office of the President
- All agreements are subject to legal review and, as needed, clearance by Animal and Human Subjects Committees (as well as the Conflict of Interest Oversight Committee for projects where the faculty member has a financial interest in the sponsor)
- For complex industry partnerships, OTA often serves as a focal point for UCI negotiations, coordination and communication with the industry partner
- Important principles that apply to any university agreement include: open dissemination, accessibility of results for University purposes, public benefit, informed participation, legal integrity, protecting student involvement, fair economic value for public assets, and objective decision-making. See the President's Policy: Principles Regarding Rights to Future Research Results in University Agreements with External Parties in OTA's web directory.

UC Policies Governing Personal Faculty/ Industry Relationships

UCI encourages faculty relationships with industry through sponsored research and consulting. Such relationships must comply with UC policies on Conflict of Interest, Faculty Consulting and Leaves of Absence. Both UCI faculty and industry representatives need to be aware of these policies. The following sections provide more specifics.

UCI encourages faculty relationships with industry.

Conflicts of Interest and Commitment

Conflicts of interest and commitment arise when a faculty member's public research and teaching activities converge with his or her private financial interests (e.g. income, consulting, stock ownership, management or board positions) in the same or related subject areas. Provided that the faculty member fulfills all his

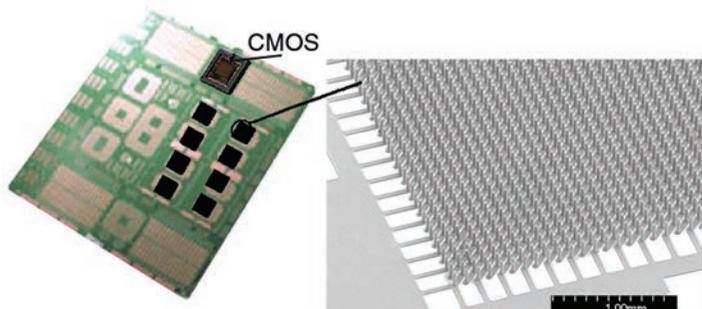
or her University teaching and research obligations, the following conditions apply to the various types of UCI/ company relationships in which the faculty member is required to disclose his/her financial interest in a company:

- Company provides sponsored research or gift funding: Disclosure required and review/ approval by the Vice Chancellor for Research on the recommendation of the Conflict of Interest Oversight Committee (COIOC) is required prior to acceptance of an award. This includes awards from the federal government in the same subject area. In some cases, potentially harmful conflicts can be managed through an ad hoc reporting or oversight committee review process.
- Company licenses UCI technology: Disclosure is required if the faculty inventor has a financial interest in the potential licensee. Inventors should normally not be involved in licensing negotiations. Further, any inventor with such a financial interest should disqualify himself/herself from involvement in any licensing decisions or such decisions would need to be subjected to an intervening substantive review process.
- Company product involved in Human Subjects Research: Disclosure is required through the Human Subjects IRB process, and positive disclosures are referred to the COIOC. The COIOC reviews the case and recommends appropriate actions, and actual descriptive language that will appear in the Human Subjects consent form.

For further discussion of conflicts of interest and commitment, see www.research.uci.edu/ora/coi/. For disclosure and approval processes for all forms of Compensated Outside Professional Activities, please refer to the Academic Senate Policy APM-025.

Faculty Consulting

UCI encourages faculty to engage in consulting outside activities that contribute to their profession and fulfill UCI's public service mission. To the extent that These activities, such as consulting, does should not interfere with teaching and research obligations or use University resources. Consulting agreements are personal agreements to which UCI is not a party. Faculty members should ensure that these agreements are consistent with their preexisting UC intellectual property obligations, which include the obligation to disclose all inventions and may include the obligation to assign inventions to the University (see www.ota.uci.edu/fac_consulting.htm the "Guide to Consulting for UCI Academic Employees" on OTA's web directory).



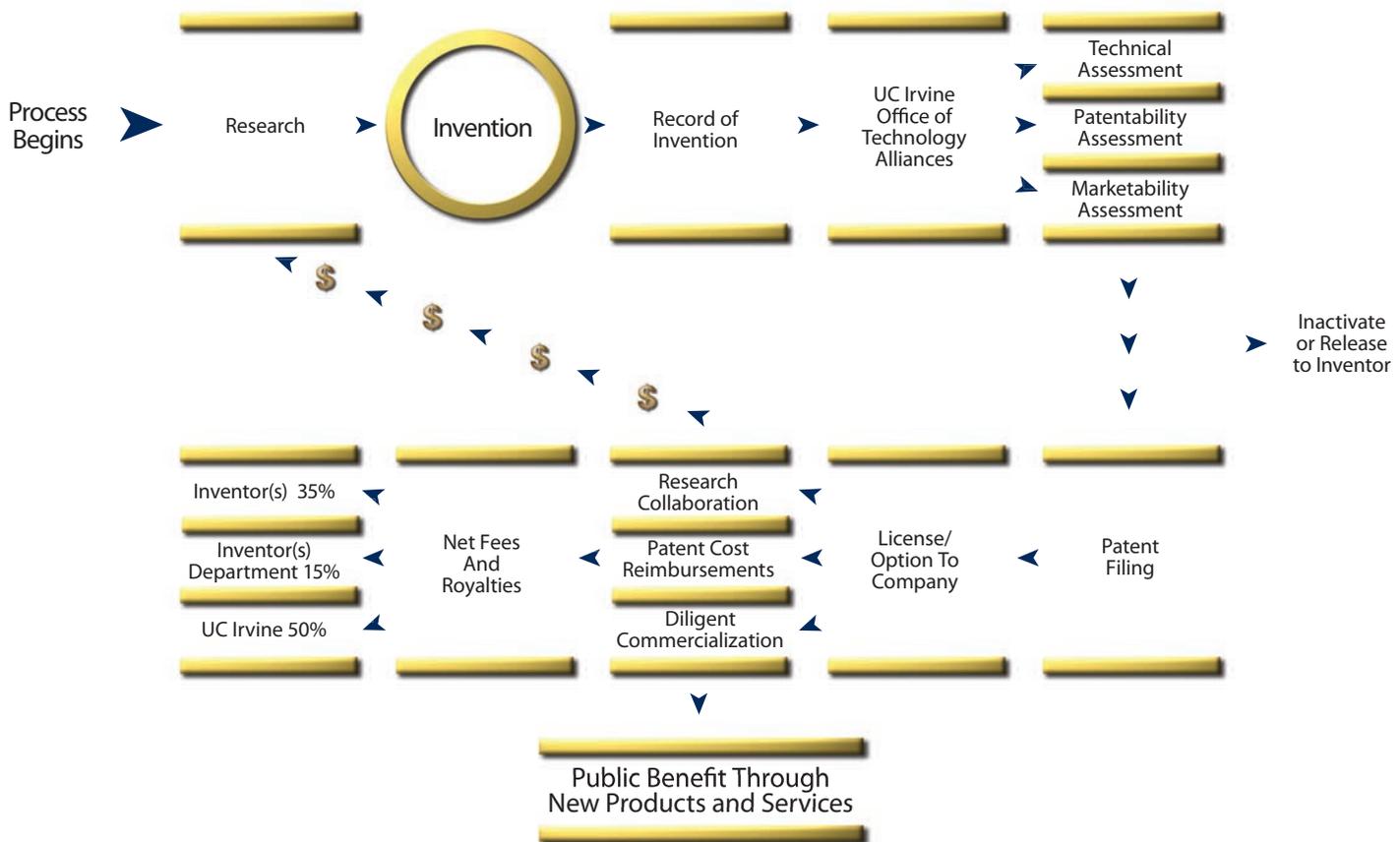
High aspect ratio carbon posts used for three-dimensional C-MEMS Microbattery.
Inventor: Mard Madou, The Henry Samueli School of Engineering

Leaves of Absence

Intellectual property issues may arise when a faculty member desires a Leave of Absence (LOA). Usually leave is without salary to work with or for an outside entity for a defined period of time, and UCI employment status is retained.

OTA can work with the School and the outside entity to frame a Letter Agreement clarifying intellectual property rights that arise during the LOA. OTA will then confirm the implications of the outside arrangements with the faculty member in a Special Investigator Agreement that will also clarify UCI's expectations for appropriate teaching and research involvement of the faculty member while on leave.

UCI Technology Transfer Process



For More Information Contact:

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This brochure is a brief summary and is not intended to be a University policy statement. Reference should be made to relevant University policies, which can change, before relying on the information in this brochure.