

MEMO
Operating
Guidance

No. 00-05
Supplement 1
October 1, 2001

PATENT COORDINATORS
CONTRACT AND GRANT OFFICERS
VICE CHANCELLORS--RESEARCH ADMINISTRATION

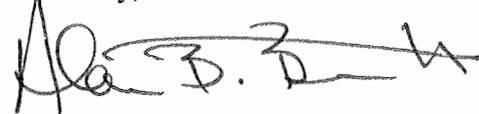
Subject: Supplement Clarifying the University Licensing Guidelines (October 1, 2001)

Since the University Licensing Guidelines were issued, it has come to my attention that they have been inappropriately represented by some entities in dispute with the University as binding or absolute standards, and excerpts have been quoted out of context. Therefore it is necessary to add some clarifying language to the Guidelines by issuance of this Supplement.

These Guidelines were issued to support a general understanding of the objectives, practices and issues involved in the University licensing program. The considerations described in the Guidelines have never been intended to be applied in an absolute or mechanical manner. Each licensing decision is unique and a matter of professional judgement.

The purpose of this Supplement is to make it clear that the University retains complete discretion in choosing the appropriate licensee for its technology. In addition, minor changes have been made to Section 8 of the guidelines to make it consistent with the recently issued OTT guidance on conflicts of interest in licensing. Please replace all copies of the University Licensing Guidelines issued on December 1, 2000 with the enclosed October 1, 2001 revised version.

Sincerely,



Alan B. Bennett
Executive Director
Research Administration
and Technology Transfer

Attachment: (University Licensing Guidelines, October 1, 2001)

cc: Senior Vice President Mullinix
OTT Associate Directors
Administrative Conflict of Interest Coordinators
Academic Conflict of Interest Coordinators

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The purpose of licensing University inventions is to provide a mechanism to encourage the practical application of the results of University research for the broad public benefit; address the needs of sponsors of University research; build research partnerships with industry to enhance the research and educational experience of researchers and students; and generate royalty income for the further support of research and education and as an incentive for faculty retention and support of the University technology transfer program. Licensing Professionals (LP) within University authorized licensing offices (ALO) are charged to pursue these objectives in licensing University inventions. In carrying out their duties, LPs are called upon to make complex licensing decisions based upon a multiplicity of facts and circumstances and by applying their professional experience, in consideration of the following guidelines:

These guidelines describe a framework of the many considerations that go into a licensing decision--and are not a statement of University policy. They may be used in specific cases as part of the complex licensing decision-making process, as the Licensing Professional finds them applicable. They are for general guidance, and the relevance, irrelevance or weight that should be given to any particular guideline in any particular case is one of the several matters the Licensing Professional must judge based on his/her professional experience.

The guidelines are not intended to be an exclusive list of all the considerations that should be taken. For example, University inventors' recommendations and interests regarding their inventions also is sometimes an appropriate consideration. The guidelines are not intended to be sufficiently specific so as to dictate any particular result in any particular situation.

In its intellectual property licensing the University reserves the right to the fullest extent permitted by law in its choice of licensee, the extent of rights licensed, and a refusal to license any party. In part the relevant law includes 35 U.S.C. 271(d) and the Constitution of the State of California, Article IX, Section 9 that the University manages its property as a constitutional corporation of the State of California.

1. *The primary objective in developing a licensing strategy for an invention should be to benefit the public.*

The University Patent Policy recognizes the need for and desirability of encouraging the broad utilization of the results of University research, not only by scholars but also in practical application for the general public benefit, and acknowledges the importance of the patent system in bringing innovative research findings to practical application.

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In addition, the Bayh-Dole Act (35 U.S.C. 200-212, pursuant to which a great majority of University inventions are managed) requires the University's use of the patent system

“to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.”

The LP is responsible for carrying out a licensing strategy that is in the public interest by ensuring that University research results can be made available to the research community to support further inquiry, and transferred to industry for timely commercialization for the public benefit.

A primary determination in developing such a strategy, is whether to license on an exclusive or non-exclusive basis. The LP should consider licensing on a non-exclusive basis inventions that are broad in scope and can be used in multiple industries, or to foster product development in many fields-of-use, or that are so basic that they form the building blocks for new technologies. For example, if a technology will be of greatest benefit to the public if it becomes an industry standard, the LP should consider making it readily accessible to all interested parties.

LPs should consider granting exclusive licenses to inventions that require significant private investment to reach the marketplace or are so embryonic that exclusivity is necessary to induce the investment needed to determine utility. Frequently, these are new drugs or other technologies requiring time-intensive and capital-intensive development or they are technologies that have only a tenuous link between the workbench and production. As such, they require a company willing to dedicate financial backing and the creativity of its own scientists on a long-term basis.

Alternatively, an exclusive “field-of-use” license is a way to protect a market for a company while enabling the University to identify more than one license to advance public utilization of the invention in all markets. In some cases, a limited-term exclusive that converts to a non-exclusive license can be an effective strategy to meet the public benefit objective.

The LP also should ensure that the licensing strategy supports prompt broad access to unique research resources developed by the University. Where an invention is useful primarily as a research tool, certain licensing practices could thwart rather than promote utilization, commercialization and public availability of the invention. (See OTT

Guidance Memo for University guidance related to the National Institutes of Health's "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.")

In determining licensing strategy for an invention useful primarily as a research tool, the LP should analyze whether further research, development and private investment are needed to realize this primary usefulness. If it is not, publication, deposit in an appropriate databank or repository, or widespread non-exclusive licensing may be appropriate. Where private sector involvement is desirable to assist with maintenance, reproduction, and/or distribution of the tool, or because further research and development are needed to realize the invention's usefulness as a research tool, licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product. Exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, could support the University's objectives.

2. The licensee selected should be capable of bringing the invention to the marketplace.

In some cases, the University will have existing licensing obligations to a particular company or other research partner based upon prior contractual commitments for research results made under sponsored research, material transfer, database access, or third-party agreements. LPs shall seek to identify all licensing obligations to third parties so that such obligations can be met. While identifying these obligations is primarily accomplished by the inventor(s)' entries on the Record of Invention (ROI) form, further inquiry may be necessary to verify the completeness or accuracy of the ROI listing. Direct discussions with the inventor(s), review of systemwide and local contract and grant databases (including through the OTT Web-based Operational Tools function) and review of prior research contracts and grants and other agreements may be utilized in a further inquiry.

Where no prior licensing obligations exist, or where additional licensing rights remain after prior obligations are satisfied, the LP should seek licensees capable of bringing the invention to the marketplace in a timely manner. Successful licensing typically includes marketing of the invention by the LP to companies, and the willingness to coordinate patenting strategies and negotiate mutually beneficial licensing terms with a licensee. Marketing may take many forms based upon the nature of the invention, the industry sector involved, and the judgement of the LP. Marketing may include general publication of research results, pursuing LP personal contacts or inventor leads, and electronic or other forms of general notification of availability. While often there is only one available and interested potential licensee for any given University invention, the LP should license such inventions, as assets of the State, only to companies that possess the potential technical, managerial and financial capability to develop and commercialize the technology. From a programmatic perspective, licensing preference should be given to small business concerns pursuant to federal legislation.

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Finally, these guidelines can provide a guide for the selection of a licensee for individual inventions. LPs should use care when licensing multiple technologies to a single commercial organization to ensure that the University's interests in the development and commercialization of an invention for the public benefit is the primary consideration over the needs or interests of the company.

The LP, in selecting a licensee, should consider factors such as whether the potential licensee:

- has or can secure the technical resources to develop and move the invention to the marketplace in a timely manner
- has or can arrange adequate financing of any research or product development required to advance the invention to a marketable condition
- has a general business plan that supports the commercialization of the University's invention
- has relevant experience in developing and commercializing technology comparable to the subject invention
- has appropriate marketing capabilities
- possesses a strong desire and commitment to make the product/technology a success
- is able to meet regulatory requirements for introduction of the technology into the marketplace and to satisfy the market demand for the technology
- is able to integrate the University's invention with other technologies competing for resources and/or commitments of the company
- has access to personnel with understanding of the invention to help ensure successful technical development and commercialization.

The LP should be able to explain how the selected licensee(s) is expected to be able to bring the technology to the marketplace for the benefit of the public in consideration of such factors.

3. *The license agreement should include diligence terms that support the timely development, marketing, and deployment of the invention.*

The LP should include diligence provisions in a license agreement to ensure that University-generated inventions are developed and deployed to the marketplace by the licensee in a timely manner. This is particularly critical when an invention is exclusively licensed to a company, either generally, or in a particular field-of-use. It is not in the best interest of the University or the public to allow an invention to languish due to a lack of commitment of the licensee, a licensee's business strategy to "shelve" the technology to protect its competing product lines, or inadequate technical or financial resources. Appropriate diligence provisions are specific to the invention and will vary widely from case to case. Among the most common diligence obligations that should be considered by the LP are contractual obligations of the licensee regarding:

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- the amount of funding that will be committed to development
- specific dates by which the licensee must secure certain levels of regulatory approval, make a working prototype, establish a production facility, sell the first commercial product, or achieve a certain level of sales
- the amount of investment capital to be raised and committed by the company in support of the technology's development.

Clear diligence provisions ensure that the University retains the ability to manage its technologies as public assets for the benefit of the public. Licensing provisions therefore should be sufficiently definite so that both parties to the license agreement can tell whether they have been achieved. Further, the license should provide a remedy for lack of diligence, such as cancellation of the license, or reduction to a nonexclusive license in the case of an originally exclusive license.

4. *The University should receive fair consideration in exchange for the grant of commercial licensing rights.*

The LP should ensure that University inventions, as public assets (created using public funds, supplies, equipment, facilities, and/or staff time), are licensed commercially to a private individual or company in exchange for fair consideration to the University. The value of the consideration to the University negotiated by the LP should be based on profitability of the expected licensee's product or services. Other factors may include the level of access and exclusivity to the invention granted to the licensee, the strength of patent protection sought/obtained by the University, the respective parties' contributions to the invention and the development of a product to commercial introduction, the contribution of the invention to the ultimate commercial product, the financial significance of the planned commercial activity and other relevant industry standards. In general, the level of consideration to the University that is negotiated should reflect the relative risks and rewards of the commercial pursuit. For example, the LP may consider the following factors in negotiating the value of the commercial license to the extent they are known or reasonably estimated:

- type of technology and industry
- stage of development
- size of potential market and potential success of penetration into market
- the projected cost of product development and bringing the product to market
- utility over alternative products
- the profit margin of the anticipated product
- comparable prices for similar technologies or products
- the amount of commercial risk perceived
- the strength of the University's patents
- decrease in the current cost of production or R&D expenditures
- scope of license (exclusive/nonexclusive, narrow/broad fields of use, US/worldwide).

The form of such consideration negotiated by the LP may vary widely based on case-specific factors. The LP should consider the following forms of consideration:

Reimbursement of University's patent costs:

The licensee pays for domestic and/or foreign patent applications either through an up-front fee for reimbursement of costs or through a requirement to reimburse past, present and future expenses to the University. This may be done on a pro-rata basis where there are multiple licensees. Full reimbursement by an exclusive licensee is standard University practice.

Issue fee:

The licensee pays a fee to the University upon final execution of the license agreement or pursuant to a pre-agreed upon schedule. The size of this fee generally should reflect the apparent value of the invention at the time it is made available to the licensee. Normally, such fees can range from a few thousand dollars to a quarter of a million or more. For small companies or start-ups, the issue fee may be partially postponed until sufficient investment capital is secured, or may be replaced in part by the University's acceptance of equity in the company (see *Equity* below).

Running royalties:

The licensee pays ongoing consideration to the University in the form of a running royalty, typically calculated as a percentage of sales of licensed products or based upon use of licensed methods. Such royalties should not be "capped" at a pre-determined dollar level, as the University should share fully in the success of any commercial exploitation of the public asset that has been made available to the licensee. The licensee also may be required to pay minimum annual royalties. Minimum annual royalties are generally credited against the running royalty due for the year in which the minimum payment is made. The level of a minimum annual royalty is chosen to serve as a diligence provision that the licensee must meet in order to keep the license.

Annual maintenance fee:

The licensee makes an annual payment to the University prior to marketing products or services utilizing the invention. Such fees may serve as a form of diligence in that their payment represents a continuing interest in and financial commitment of the licensee to the licensed invention. Typically, annual maintenance fees stop and are replaced by minimum annual royalties when commercial sales begin or as of the projected date of these sales.

Sublicensing fees:

The licensee pays to the University consideration for sales of licensed products or use of licensed methods by sublicensees of the University licensee. The University should receive its fair portion of consideration received by the licensee (whether in the form of running royalties, fees or other forms) from the sublicensee.

Equity:

To facilitate the practical application of a University invention for the general public benefit, the LP may accept equity in a company as partial consideration for invention licensing pursuant to the University *Policy on Accepting Equity when Licensing University Technology* when the company selected to develop, market, and deliver the technology to the marketplace is not reasonably able to pay license issue fees and maintenance fees in the form of cash. This option may be particularly useful in working with small or startup companies that may find it difficult to commit significant cash outlays for both developmental and licensing costs.

Other:

The LP may negotiate other forms of consideration to the University for access to University inventions other than those described above. Research equipment, other forms of research support, and other unique exchanges of value occasionally may be appropriate forms of consideration. The LP should note, however, that such non-standard forms of consideration fall outside the royalty-sharing provisions of the University Patent Policy.

Finally, the LP should note that “reach-through royalties”¹ and aggressive pricing of inventions that are solely research tools may impede the scientific process (see Guideline 1 above) and generally should be avoided.

5. *The license agreement should support the academic principles of the University.*

The LP should ensure that the provisions of the license agreement support the University’s academic teaching and research mission, including the following concerns:

Open Dissemination of Research Results and Information:

License agreements with external parties shall not abridge the ability of University researchers to disseminate their research methods and results in a timely manner. The most fundamental tenet of the University is the freedom to interpret and publish or otherwise disseminate research results in order to support

¹ “Reach-through royalties” are royalties assessed on sales of products that are developed using (directly or indirectly) a University invention that is a research tool, rather than assessed on products actually incorporating the University invention.

the transfer of knowledge to others and maintain an open academic environment that fosters intellectual creativity.

Accessibility for Research Purposes:

The LP should ensure that the license agreement protects the ability of University researchers, including their student and research collaborators, to utilize their inventions to perform future research, thus protecting the viability of the University's research programs. The University has a commitment to make the results of its research widely available through publication and open distribution of research products for verification and ongoing research. The University also seeks to foster open inquiry beyond the interests of any one research partner, particularly where the invention is a unique research tool (see Guideline 1). One way in which the University may address this is through the retention in a license agreement of the University's right to use and distribute to others inventions for research and educational purposes.

6. *Licensing activities should be carried out within delegated authority.*

Licensing of University inventions may be carried out only by University personnel who have been formally delegated patenting and licensing authority. LPs shall conduct licensing activities within the parameters of their delegation.

In those cases where a licensee wishes to support future research at the University, where the terms of the license agreement require such research funding by the licensee, or where future research and/or resulting inventions are otherwise addressed in a license agreement, the LP must obtain approval of the involved principal investigator(s) or affected inventors and, in the case of prospective research sponsored by the licensee, the appropriate University Contract and Grant Officer.

LPs shall not grant rights to inventions made by University employees at other campuses or national laboratories without appropriate coordination and authority.

7. *The license agreement should be approved as to legal integrity and consistency.*

The LP shall ensure that the provisions of the license agreement are reviewed and approved by the University Office of General Counsel or Laboratory Counsel, and comply with University policies, including the following concerns:

Use of Name:

The LP shall ensure that the license agreement prohibits the use of the University's name to promote the licensee or its products made under the license agreement, unless specifically approved on an exception basis by authorized

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personnel. The license may provide limited use of the University's name where required by law, to give effective legal notice such as a copyright mark, or to make a statement of fact regarding the origin of plant material.

Indemnification:

The LP shall ensure that the license agreement contains an indemnification provision under which the licensee assumes all responsibility for any product or other liability arising from the exercise of the license to patent rights covering the invention. This is essential in that the licensee has complete control over product development.

Insurance:

The LP shall ensure that the license agreement requires the licensee to have sufficient insurance or an appropriate program of self-insurance to meet its obligations to protect the University, and provide evidence of such.

Third-Party Obligations:

The LP shall seek to identify and ensure that the license agreement satisfies all known obligations to third-parties related to the licensed invention, including obligations of the University under prior sponsored research agreements, material transfer agreements, database access agreements, and other agreements impacting rights to research results. Among the resources that should be pursued to identify such obligations are the Record of Invention form, discussion with inventors, and review of systemwide and local contract and grant databases, and the terms of research agreements.

8. *All decisions made about licensing University inventions should be based upon legitimate institutional academic and business considerations and not upon matters related to personal financial gain.*

It is important that the LP conduct the technology transfer process, including patenting, marketing, and licensing in a manner that supports the education, research, and public service missions of the University over individual financial gain.

Because LPs and inventors may have the opportunity to influence University business decisions in ways that could lead to personal gain or give advantage to associates or companies in which they have a financial interest, the LP and the inventor must comply with existing University policy and State law concerning such potential conflicts of interest. LPs and inventors generally are prohibited from making, participating in making or influencing a University decision (including selection of licensees and other decisions made in the course of commercializing University technology) in which they have a personal financial interest. Certain specific actions may be taken, however, consistent

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with University policy and State law, to allow participation in the licensing process by such inventors. An inventor's expectancy of receiving money or equity as inventor share under the University Patent Policy is not a disqualifying financial interest.

For LPs who have a personal financial interest in potential licensees, this situation can be readily managed by having the invention case assigned for management to another LP without a financial interest. For inventors who have a personal financial interest in potential licensees, another individual with appropriate scientific and technical background may be able to carry out the duties and responsibilities typically handled by the inventor. In both cases, personal disqualification requirements would need to be satisfied under University policy and State law.

University inventors, however, may not be able to reasonably remove themselves from involvement in the process under disqualification requirements as their expertise and input may be essential to successful technology transfer. It may be necessary for the inventor to work closely with the LP and with potential licensees, or involve themselves in companies that are potential licensees, with the objective of commercializing University inventions, even when they have a personal financial interest. It is in this context, when the inventor is involved in the process, that the selection of a licensee and other commercialization decisions may have the potential to raise concerns about conflicts of interest.

Therefore, the LP and inventor(s) should discuss: i) the disqualification option; ii) an approach to and level of inventor involvement in the technology transfer process; iii) compliance with University policy and State law concerning potential conflicts of interest; and (iv) where helpful, these University Licensing Guidelines.

In general, the role in the technology transfer process of any inventor who has a personal financial interest in a potential licensee should be kept to the minimum necessary to successfully achieve the University's objectives in patenting, marketing, and licensing. When an inventor has a personal financial interest in a potential licensee and does not fully disqualify him or herself from involvement in the process, an independent substantive review (Licensing Decision Review - LDR) and recommendation concerning the licensee selection and other licensing decisions is required. Thus, both the LP and the inventor should understand that the extent to which the inventor is involved in the technology transfer process may be a factor in the considerations and ultimate recommendations of the LDR body. The LDR body, composed of one or more qualified individuals with appropriate expertise, knowledge and professional judgement, must independently check the original data and analysis upon which recommendations for the selection of licensees and for other licensing determinations were made by the LP and make its own independent recommendations concerning those decisions.

The LP must ensure that disclosure and management of potential inventor conflicts of interest are handled in accordance with OTT Guidance Memo No. 01-02, "Managing Potential Conflicts of Interest in Licensing under the California Political Reform Act." By doing so, the LP can help ensure that the inventor may participate in the technology

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transfer process as necessary, while remaining in compliance with University policy and State law in this area.