

UNIVERSITY LICENSING GUIDELINES

(revised 2/1/12)

The purpose of licensing University intellectual property (IP) rights and materials is to encourage the practical application of the results of University research by industry for the broad public benefit; meet our obligations to sponsors of University research; build research relationships with industry partners to enhance the research and educational experience of researchers and students; stimulate commercial uptake and investment; stimulate economic development; and ensure an appropriate return of taxpayer investments in University research. Financial returns from technology licensing provide additional support for research and education, an incentive for faculty retention, and support of the University technology transfer program. Technology Managers (TM) within University authorized licensing offices (ALO) are charged to pursue these objectives in licensing University IP. In carrying out their duties, TMs 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 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 TM finds them applicable. They provide general guidance, and the relevance, irrelevance or weight that should be given to any particular guideline in any specific case is one of the several matters the TM must judge based on his/her professional experience. These guidelines are not intended to include all considerations for all licensing opportunities. For example, inventors' recommendations regarding the disposition of the IP rights associated with their inventions represent one factor among many to be considered. These guidelines are not intended to dictate a particular approach in any situation. Each licensing opportunity is

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unique based on multiple factors including: the nature and stage of development of the technology; the breadth and complexity of the potential fields of use; the product development path and timeline; the extent of intellectual property protection; the relevant markets and market niches; specific campus practices; unique needs of prospective licensees; ethical considerations for the use of future products; and emerging issues, among other elements. All factors require careful consideration in developing a relationship with a prospective licensee, and the TM needs tremendous flexibility to address each of these issues. Further, the result of any one licensing decision may or may not be appropriate to another similar situation, as changes in knowledge and individual factors should be taken into consideration for each case-specific circumstance.

On March 6, 2007, the University endorsed the “Nine Points to Consider” that articulates some key issues that the TM should take in consideration when evaluating a possible licensing arrangement. TMs should familiarize themselves with the Nine Points to Consider. [http://www.autm.net/source/NinePoints/ninepoints_endorsement.cfm]

In its IP licensing practices, the University reserves the right, to the fullest extent permitted by law, to exercise decisions regarding its choice of licensee, the extent of rights licensed, and a refusal to license to 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 whereby the University manages its property as a public trust as a constitutional corporation of the State of California.

GUIDELINES

1. *The primary objective in developing a patenting and licensing strategy for an invention should be to support the education, research, and public benefit mission of the University.*

The University Patent Policy recognizes the need for and desirability of broad utilization of the results of University research, not only by scholars but also for the general public

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benefit, and acknowledges the importance of the patent system in providing incentives to create practical applications that achieve this latter goal.

In addition, with respect to federally-funded inventions (which comprise a large portion of the University's invention portfolio), the Bayh-Dole Act (35 U.S.C. 200-212) 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 without unduly encumbering future research and discovery; 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 TM is responsible for crafting a technology management strategy that supports the education, research, and public service mission of the University, which requires establishing a delicate balance of priorities between the timely transfer of technology to industry for commercialization while preserving open access to research results for use by the University and the research community.

One consideration is whether or not to seek patent protection of the invention and where such protection should be sought. Patent protection may provide the incentive for an industry partner when significant further private investment is necessary to commercialize the discovery, such as expensive regulatory hurdles or infrastructure requirements. Conversely, some industries employ an open access technology

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development strategy through non-exclusive licensing practices in order to stay competitive in the marketplace.

For diseases that disproportionately affect developing countries, one approach might be to seek protection only in developed countries to allow a company to obtain a return on its investment by excluding competition while allowing others in developing countries, including generics manufacturers, to provide the same product without having to enter into a license agreement with the University.

A primary licensing decision is whether to license exclusively or non-exclusively. The TM should consider licensing either non-exclusively, or exclusively within specific fields-of-use when an invention is broad in scope and can be used in multiple industries as well as for a platform technology that could form the basis of new industries. For example, if a technology will create the greatest public benefit if it becomes an industry standard, the TM should consider making it readily accessible to all interested parties unless significant investment or other factors require exclusivity to incentivize the realization of the commercial potential. Alternatively, the TM should (absent any third party obligations) consider foregoing the patent process and put the invention in the public domain by way of appropriate publications.

In general, TMs should consider granting exclusive licenses to inventions that require significant investment to reach the market or are so embryonic that exclusivity is necessary to induce the investment needed to develop and commercialize the invention. Frequently, new drugs or other technologies requiring time-intensive and capital-intensive development require exclusive licensing. Such technologies require a company willing to dedicate financial resources and the additional research to realize the commercial potential.

Alternatively, an exclusive “field-of-use” license is a way to create market incentives for one company while enabling the University to identify additional licensees to commercialize the invention in additional markets. In some cases, a limited-term

exclusive license that converts to a non-exclusive license can be an effective strategy to meet the public benefit objective.

The licensing strategy should ensure prompt broad access to unique research resources developed by the University. For example, where an invention is useful primarily as a research tool, the TM should carefully consider the choice of an exclusive or non-exclusive license because certain licensing practices could thwart rather than promote public access to the invention (See Technology-specific Considerations below.)

2. University must meet existing third party obligations

Research projects increasingly involve a multiplicity of third party agreements and relationships. For some inventions, the University will have existing licensing obligations to a company or other research partner based upon contractual commitments made under sponsored research, material transfer, database access, inter-institutional, or other third-party IP agreements. TMs shall seek to identify all licensing obligations to third parties so that such obligations can be met. While the primary method for identifying these obligations is the inventor(s)' entries on the Record of Invention (ROI) form, the TM is encouraged to verify the completeness or accuracy of the ROI listing. Among the resources that should be pursued to identify such obligations are the TT 100 Form (Inventor/Author Statement Concerning Involvement in Licensing Decisions) and documents filed with the inventor's department [Report of Category I and II Compensated Outside Professional Activities and Additional Teaching Activities (APM 25) and Form 700 Statement of Economic Interests (past and present)].

Direct discussions with the inventor(s) and/or review of systemwide and local contract and grant databases may help determine whether the appropriate agreements are identified (including through the Web-based Operational Tools resources provided through UCOP's Research Policy Analysis & Coordination website). Careful review of these agreements is critical to understanding the nuances of any third party obligations. Copies of any relevant agreements should be retained in the licensing file for future

reference and to document the basis for decisions affecting the status of such third party obligations.

In addition, the TM should evaluate any other factors that may affect the University's right to license the invention. The TM should investigate whether an inventor's disclosed invention entails a possible claim to prior ownership rights by a third party based upon the inventor's previous or current outside activities, for example, consulting arrangements, visiting scientist agreements, inventor start-up companies, and other contract obligations, particularly in light of court decisions (e.g. *Stanford v. Roche*, Fed Cir., 2009).

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

Where no prior licensing obligations exist, or where additional licensing rights remain after prior obligations are met, the TM should seek licensees capable of bringing the invention to the marketplace in a timely manner. While often only one potential licensee comes forward for any given University invention, the TM should nevertheless assess the potential licensee's technical, managerial and financial capability to commercialize the technology. From a programmatic perspective, licensing preference should be given to small business concerns, when appropriate, pursuant to federal law and regulations, provided such small businesses appear capable of bringing the technology to the marketplace.

These guidelines provide the TM with a resource for selecting a licensee for individual inventions. TMs should use care when licensing multiple technologies, invention portfolios, or a single technology with multiple variant applications to a single commercial organization to ensure that the licensing strategy meets the University's desire to maximize public benefit.

For example, in selecting a licensee, the TM, should consider whether the potential licensee:

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- has a general business plan that delineates a clear strategy to commercialize the invention
- has or can secure the technical, financial and personnel resources to develop and commercialize the invention in a timely manner
- has experience relevant to developing and commercializing the invention
- has appropriate marketing capabilities
- possesses a strong desire and commitment to make the product/technology a success
- is able to meet any regulatory requirements needed to commercialize the technology
- has, or can develop sufficient capacity to satisfy the market demand for the technology
- demonstrates commitment to the University's invention in light of other technologies competing for resources in the company
- has goals that generally align with those of the University with respect to public benefit

The TM should obtain and retain documents that address the licensee's ability to bring the technology to the market. In the case of a start-up company, not all factors necessary to commercialize the technology may be present at the outset. The TM should consider whether the start-up has an appropriate level of resources and technical capabilities, given the development stage of the company and the nature of the invention, as well as whether the start-up has the potential to acquire the necessary resources to successfully develop and market the technology in a timely manner.

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

The TM should include diligence provisions in a license agreement to ensure that the licensee develops and commercializes the invention in a timely manner, especially when

an invention is exclusively licensed. The University's commitment to public benefit is not met by allowing an invention to languish due to a licensee's lack of commitment, "shelving" the technology to protect its competing product lines, or inadequate technical or financial resources. Appropriate diligence provisions are invention-specific and will vary depending on the circumstances. Common diligence obligations that a TM should consider include:

- the amount of capital to be raised (for a start-up) or the amount of funding committed (for an existing business) by the company to support the technology's development.
- specific dates by which the licensee must achieve defined milestones, such as: secure levels of regulatory approval; make a working prototype; initiate beta testing of a licensed product; receive formal market/customer feedback; achieve specific prototype performance thresholds (such as efficiency or size); establish a production facility; first sell the commercial product; or achieve a certain level of sales

To ensure that the University continues to manage its technologies as assets for the public's benefit, clearly defined diligence provisions allow verification of the licensee's compliance with its diligence obligations. Therefore, the licensing agreement language should be sufficiently specific so that both parties can determine whether the diligence obligations have been met. Further, the license should provide a remedy for failure to meet diligence obligations, such as termination of the license or, in the case of an exclusive license, a reduction to a non-exclusive license.

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

The TM should ensure that University receives fair consideration for commercial licenses of its inventions (as public assets created using public funds, supplies, equipment, facilities, and/or staff time) to private entities. Generally, the value of the consideration

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received by the University should be based on the licensee's sale or distribution of licensed products or licensed services by the licensee. Other factors that impact the negotiation of the University's consideration may include:

- the type of technology and industry
- the stage of development and market consideration
- the perceived value to the licensee's business and competitive position ("must-have" vs. "nice-to-have")
- the market potential, contribution of the technology to market penetration, and market sector dynamics (i.e. growing, static, declining?)
- the projected cost and risk of product development and marketing
- the competitive advantage over alternative products; is the invention a seminal "game-changing" one or an incremental improvement?
- the likelihood of competing technologies
- the net profit margin of the anticipated product
- comparable prices for similar technologies or products
- the scope and enforceability of the University's patent claims, extent of freedom-to-operate required, and years remaining on patent term
- the projected decrease in the cost of production or R&D expenditures
- the scope of license (exclusive/nonexclusive, narrow/broad fields of use, U.S./non-U.S.)
- the opportunity for accelerated time to market based upon the necessity for meeting a critical public need.

In general, the fair consideration to the University should be in cash, but other forms of consideration may be accepted in partial lieu of cash fee(s) such as equity in the company (discussed below). The form of such consideration negotiated by the TM may vary widely based on case-specific factors.

The TM should consider including some or all of the following elements as part of the consideration:

Reimbursement of University's patent costs:

The licensee pays for domestic and/or foreign patent applications either through an up-front fee that covers past and future costs and/or through a requirement to reimburse past, present and future costs upon invoicing by the University. Where the technology is licensed to multiple parties, reimbursement may be done on a pro-rata basis. Full reimbursement by an exclusive licensee is standard University practice.

License Issue fee:

The licensee pays a fee to the University upon final execution of the license agreement either in a lump sum or on an agreed upon schedule. The amount of this fee should reflect the value of the invention at the time it is made available to the licensee. Such fees range widely, depending on the circumstance. Under some circumstances, the issue fee for small companies or start-ups 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 (or earned) royalty, typically calculated as a percentage of net sales or use of licensed products or services that incorporate the technology. Such royalties should not be "capped" at a pre-determined dollar level, as the University should share fully in the success of any commercial use of technology made available to the licensee. In some rare cases, a running royalty value may be difficult to assess due to the particular market and the type of products being developed. In such cases a fixed amount for each unit of licensed product sold or a one-time or

annual fee may be contemplated, where the fee should reflect the value of the invention over the projected length of patent protection (both U.S. and foreign).

Annual maintenance fee/minimum annual royalty:

The licensee pays an annual license maintenance fee which serves as a form of diligence and represents the licensee's continuing interest in and a financial commitment to commercialize the invention. A minimum annual royalty begins in the first year of commercial sales and serves not only as a diligence obligation but also incentivizes the licensee to achieve sales generating royalties that meet or exceed the minimum annual royalty. Typically, annual maintenance fees cease after commercial sales begin when they are replaced by the minimum annual royalty. Minimum annual royalties, if paid in advance, are generally creditable against the running royalty due that year. The TM may use these fees singly, in combination, or not at all as judgment dictates, however, including such fees not only creates diligence obligations but also provides annual income to support the University's research and education mission.

Sublicensing fees:

Under an exclusive license where the licensee is permitted to transfer rights to third parties (a sublicense), the licensee pays the University consideration for sales or use of licensed products or services by its sublicensees. The University should receive a fair share of all consideration, including royalty and non-royalty income, received by the licensee from the sublicensee. It is University practice not to include sublicensing rights under its non-exclusive licenses as the granting of such rights could place the licensee in direct licensing competition with the University, except in those cases where the sublicensee's activities are necessary for the sublicensor to commercialize the licensed technology (e.g. sublicensee is a contract research organization or contract manufacturer providing a vital component to the sublicensor necessary for the licensed technology, etc.).

Equity:

To encourage commercialization of University technology, the TM may accept equity in a company as partial consideration for invention licensing pursuant to the University *Policy on Accepting Equity when Licensing University Technology*. This option may be particularly useful in working with small or startup companies where financial considerations limit the company's and its investors' willingness to pay cash to the university for licensing costs, such as license issue fees and annual maintenance fees. When accepting equity, TMs should consider the risk-adjusted value of equity and the potential loss of value associated with dilution of equity.

Other:

The TM may negotiate forms of consideration other than those described above, such as milestone payments upon the completion of certain licensed product development events or upon financing or investment triggers (e.g., investment rounds, merger or acquisition, or a public stock offering). Other unique exchanges of value occasionally may be appropriate forms of fair consideration. The TM should note, however, that such non-monetary forms of consideration (other than equity) fall outside the royalty-sharing provisions of the University Patent Policy. The TM should take care to not designate research funding as a form of consideration in a license as license income is subject to the royalty-sharing provisions of the University Patent Policy whereas research funding is not consideration for a license but is fixed at a level to pay for the cost of conducting the research (*Singer v. The Regents*, 1996).

Finally, the TM should be aware that “overly-aggressive” negotiation of financial consideration may impede commercialization of an invention and may not be consistent with certain research sponsor guidelines (e.g., Federal, State, or non-profit extramural sponsorship policies). However, undervaluing a commercial license reduces the additional monetary support for research and education and compromises the principle of seeking a fair return on the public asset that is the University's technology. The TM

should weigh all appropriate factors discussed above in crafting a commercial license to create an optimal structure and fair consideration.

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

The TM 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 limit 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 to support knowledge transfer and maintain an open academic environment that fosters intellectual creativity.

Accessibility for Research Purposes:

The TM should ensure that the license agreement protects the ability of University researchers, including their student and research collaborators, to use their inventions in 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 10). One way in which the University addresses this is through the retention in the license agreement of the University's right to use and distribute inventions to other non-profit research institutions for research and educational purposes.

A more detailed discussion of these concepts can be found under Principles Regarding Rights to Future Research Results in University Agreements with External Parties (<http://www.ucop.edu/ott/genresources/principles.html>).

7. Licensing activities should be carried out within delegated authority.

Licensing of University inventions may be carried out only by University personnel who are operating under a formal delegation of patenting and licensing authority. TMs shall conduct licensing activities within the parameters of that delegation.

In those cases where a licensee wishes to support future research at the University, where the diligence terms of the license agreement addresses such research funding by the licensee, and/or resulting inventions are otherwise addressed in a license agreement, the TM 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.

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

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

In order to ensure that the University has the right to enter into licensing discussion, the TM should ensure that the inventors have signed both a University Patent Acknowledgement (updated 2011) and/or an actual Assignment Agreement that confirms the University's ownership in the invention and that includes a present assignment of invention rights.

In determining the rights that can be granted in a license agreement, the TM should ask the inventors about past and present sponsors of their research, material providers, and independent consulting and other agreements (e.g., visitor, confidentiality, etc.) they have signed that could be related to the invention to determine if conflicting obligations exist between such agreements and the proposed license.

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The TM 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 with regard to legal integrity and consistency, including the following concerns:

Use of Name:

The TM shall ensure that the license agreement prohibits the use of the University's name, or the names of its employees, to promote the licensee or its products made under the license agreement, unless specifically approved by authorized University 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 TM 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 covering the invention. The licensee should assume all responsibility as it has complete control over product development while the University only provides rights under the patents it holds.

Limitation of Liability:

The TM shall ensure that the license agreement contains a provision that limits the University's liability for any damages that may result from the licensee's acts under the license agreement (e.g., intellectual property infringement, lost profits, lost business, cost of securing substitute goods, etc.).

Insurance:

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

Limited Warranty:

The TM shall ensure that the license agreement contains a limited warranty provision stating that nothing in the license shall be construed as (i) a warranty or representation regarding validity, enforceability, or scope of the licensed patent rights; (ii) a warranty or representation that any exploitation of the licensed patent rights will be free from infringement of patents, copyrights, or other rights of third parties; (iii) an obligation for the University to bring or prosecute actions or suits against third parties for patent infringement except as provided in the infringement provision of the license; (iv) conferring by implication, estoppel, or otherwise any license or rights under any patents or other rights of University other than the licensed patent rights, regardless of whether such patents are dominant or subordinate to the licensed patent rights; and (v) an obligation to furnish any new developments, know-how, technology, or technological information not provided in the licensed patent rights.

Patent Prosecution:

The TM shall ensure that the license agreement contains a patent prosecution provision that stipulates the University will diligently prosecute and maintain the patent rights using counsel of its choice who will take instructions solely from the University. The University will use reasonable efforts to amend any patent application to include claims requested by the Licensee. For an exclusive license, all such costs will be borne by the licensee. For non-exclusive licenses, a common practice is for each licensee to pay a pro-rata share of such costs.

Patent Infringement:

The TM shall ensure that an exclusive license agreement contains a patent infringement provision that stipulates that neither the University nor the licensee will notify a third party (including the infringer) of infringement or put such third party on notice of the existence of any patent rights without first obtaining consent of the other party; with additional language that addresses infringement notification process, participation, control and prosecution of the suit, and payment of costs and sharing of awarded damages.

Third Party Obligations:

The TM must assess the impact of third party obligations on the licensing decision as discussed under the second guideline above.

9. *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 TM 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 TMs 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 TM and the inventor must comply with existing University policy and State law concerning such potential conflicts of interest. Under State conflict of interest law, any University employee or representative is 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 with University policy and State law, to allow participation in the licensing process by such inventors. An inventor's

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expectancy of receiving money or equity as inventor share under the University Patent Policy is not a disqualifying financial interest.

For TMs 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 TM 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 TM 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. Some inventor contributions to the licensing process are primarily technical advice and do not constitute "participation in" or "attempting to influence" a licensing decision under State conflict of interest law. They are called "ministerial." An action is ministerial, even if it requires considerable expertise and professional skill, if there is no discretion with respect to the outcome. Thus an inventor can provide technical or scientific information about an invention where necessary without being considered to be participating in a licensing decision. This exception, however, does not apply to technical tasks such as most data gathering or analysis in which the inventor makes professional judgments which can affect the ultimate decision in question.

Therefore, the TM and inventor(s) should discuss: i) the disqualification option; ii) an approach to and level of inventor involvement in the technology transfer process; iii)

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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 TM 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 judgment, 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 TM and make its own independent recommendations concerning those decisions.

The TM 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 TM can help ensure that the inventor may continue to participate in the technology development process while remaining in compliance with University policies and State law in this area. Future issues may arise, such as an inventor's desire to bring technology back to the University for further testing, development, and purchase for use in the lab as the licensee further develops the technology. If the TM becomes aware of such issues, the TM should ensure that other University officials impacted by such activities on the part of the inventor (e.g., procurement, C&G office, Conflict of Interest review board, etc.) are educated about the rationale and processes needed for a successful technology transfer program.

10. Technology-specific Considerations

The following guidance supports a general understanding of the objectives, practices and issues involved in the University licensing program with respect to specific technologies. The licensing strategies described herein are not intended to be applied in an absolute or mechanical manner. Each licensing decision is unique and a matter of professional judgment. The University's ALOs retain complete discretion in choosing the appropriate licensee and technology management strategy for its technologies.

Research Tools

In determining an appropriate licensing strategy for an invention that is used primarily as a research tool, the TM should analyze if further research, development and private investment are needed to realize this primary usefulness. If it is not, publication, deposition in an appropriate databank or repository, widespread non-exclusive licensing, or electing not to file a patent application may be the appropriate strategy. Where private sector involvement is necessary to assist in maintaining (including reproducing), and/or distributing the research tool, where further research and development are needed to realize the invention's usefulness as a research tool, or where a licensee has the ability to enhance the usefulness, usability, or distribution of the research tool, licenses should be crafted with the goal of ensuring widespread distribution of the final research tool to the research community. Any such license should also contain a provision preserving the University's ability to continue to practice the licensed invention and allow other educational and non-profit institutions to do so for educational and research purposes. If carefully crafted, 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.

One particular concern is royalties assessed on sales of products that are developed using (directly or indirectly) a University invention that is a research tool ("reach-through" royalties), rather than assessed on products actually incorporating the University

invention. The TM should note that reach-through royalties may impede the scientific process or create unreasonable restrictions on research and therefore generally should be avoided. Licensing of research tools should encourage prompt and broad access through a streamlined process. For NIH-funded inventions, see the NIH “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.”

[http://www.ott.nih.gov/policy/rt_guide_final.html]

Global Health

While many of the licensing strategies discussed below are presented in the context of global health issues, such strategies are equally applicable to other current and future emerging technologies that can be used to support humanitarian efforts in underprivileged populations (e.g., clean water, sustainable sources of energy, food sources, etc.).

As innovative healthcare technologies are discovered and, after meeting extensive development and regulatory hurdles, introduced as publicly available therapeutic or diagnostic products, the ability of underprivileged populations to access and afford these technologies may be constrained by price or distribution. In particular, healthcare and agricultural products may not be readily accessible and affordable to the world’s poorest people in developing countries and as a public institution striving to uphold its public benefit mission, the University should consider such public benefit and broad societal needs when developing licensing strategies for such technologies.

Developing “successful practices” is an evolving process, particularly for an issue as complex as balancing access by developing countries to biomedical products with ensuring timely and appropriate development and commercialization of the product. Such practices demand creative and flexible rather than rigid approaches. Entirely new business models coupled with nuanced intellectual property management strategies may be needed to produce the desired outcomes. Each situation is unique and must be

addressed based on its own fact pattern to encourage licensees to make the substantial and risky investment necessary to develop biomedical products. Without appropriate and timely investments, the healthcare technology may never be developed into a product, thus eliminating access by all patients. A prescriptive approach may discourage licensees because of a perceived need to overcome too many obstacles in product development. TMs frequently need to balance conflicting objectives and must be able to make compromises in the interest of moving a technology forward.

As part of the University's public benefit mission, the TM should carefully consider patenting and licensing strategies that promote access to essential medical and agricultural innovations in developing countries. Although a multitude of downstream factors may affect the accessibility and affordability of essential technologies in developing countries, e.g. healthcare infrastructure, poverty, food security, international treaties and laws, sanitation, energy, and political stability, it remains possible for the University to impart a profound life-changing impact in the developing countries through humanitarian patenting and licensing strategies.

One patenting strategy that the University and its licensee might pursue is to limit patent protection to those developed countries with a healthcare infrastructure that can afford the healthcare products and not seek patent protection in developing countries thereby allowing other manufacturers to freely practice the technology. Some examples of alternate licensing strategies to consider could be: (i) inclusion in a license agreement of mechanisms to allow third parties to create competition that affects or lowers prices in developing countries, create incentive mechanisms for widespread distribution of the licensed product, or reserve a right for the University to license third parties under specific humanitarian circumstances, (ii) inclusion of license terms requiring mandatory sublicensing to generic or alternative manufacturers in a developing country or a program that requires the distribution of the healthcare product at low or no cost to underprivileged populations with assurance that the licensee will continue to develop, manufacture and distribute the product to all such populations; and (iii) inclusion of uniquely crafted diligence provisions or other creative pricing tied to the patient's ability

to afford the technology that are consistent with sponsor's march-in rights provision (if applicable).

Financial terms for products that address diseases that disproportionately affect developing countries should, where possible, facilitate product availability in the country of need. At a minimum, the financial terms should recognize the low profitability of such products. The University could also consider foregoing royalties on products distributed in such countries or requiring the licensee to sublicense other companies if the licensee is unwilling to invest in the development of a product distribution network within that country.

To be most effective in promoting global health, the TM needs to pursue creativity and consider a wide variety of patenting and licensing strategies, since the most impactful approach in one situation may fail in others. Prescriptive guidelines dictating limited strategies could be particularly detrimental to achieving the University's goals of public benefit. Creative patenting and licensing strategies addressing global health should focus on effectiveness and should aim to achieve the greatest impact worldwide.

Software

Because of the cross-over of software and other digital media between the patent and copyright policies, licensing of these technologies are less straight-forward than simple patent or copyright licenses. In addition, under University Copyright Policy the campuses have the delegated authority to implement procedures and supplementary local policies regarding licensure, disposition of royalty income, and other rights related to copyrights. As such, copyright licensing practices will vary from campus to campus.

Diagnostics

Licensing clinical diagnostics technologies, regardless of type (genetic or otherwise), should balance the need of the licensee to achieve a fair return on investment with the

public's need to have the test as broadly available as possible, including enabling patients to obtain a second opinion by accessing the test from an alternative provider. Licenses should also reserve the right for the academic community to use the diagnostic for research purposes, including studying and independently validating the test and employing it to advance medical research. The TM will need to take into account that licensees can elect to commercialize the technology (i) as an FDA-approved kit sold to end-users, (ii) as a testing service business using an in-house Laboratory Developed Test (LDT) subject to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 administered by the Centers for Medicare and Medicaid Services, or (iii) a sequential combination of (i) and (ii) whereby the licensee initially enters the market to generate near-term revenue with an LDT-based testing service and subsequently obtains market approval via the costlier and lengthier FDA review process to market a kit for sale. Licensors that have academic medical centers need to structure their licenses to take into account the needs of their own clinical laboratories to insure affordable access to the licensee's FDA-approved kit or to have the right to provide an LDT in their CLIA labs (either as a carve-out or an affordable sublicense from the licensee).

For markets that can reasonably support two diagnostics developers (e.g. melanoma), the TM should consider co-exclusive licensing. However, for more limited markets, in order to assure maximum availability and multiple sources, the TM might consider such approaches as (i) a time-limited exclusive license that automatically converts to a non-exclusive license after several years, or (ii) a license grant for the exclusive right to sell and a non-exclusive right to make and use the patented technology. In this way the licensor can be the sole provider of an FDA-approved kit while clinical labs that cannot afford the kit can still serve patient needs with their own LDTs.

Lastly it is important to appreciate that whereas a single-source provider of an FDA-approved kit provides patients with a uniform, consistent product, LDTs developed by different clinical labs (commercial and academic) may vary in performance quality and have different degrees of false-positive and false-negative results. Thus a given patient's diagnostic outcome could vary depending on which CLIA lab performs the test.

However, insuring test availability from more than one source can mitigate the variability from center-to-center.

Genetic Resources/Traditional Knowledge

Country laws or international treaties may influence licensing decisions where inventions are derived from genetic resources or traditional knowledge. The TM should investigate all project sponsored or collaborative research agreements, including material transfer agreements, to identify if any genetic resource or traditional knowledge was used in making the invention and if any specific requirements apply to the use of such resources. In some situations, the requirement may be attached to a collection permit or a visa document.

Even in the absence of such laws, treaties or contractual requirements, the TM should carefully consider biodiversity issues and negotiate individual agreements that recognize the origin or source of the material. Where possible, such agreements should consider benefit sharing arrangements with indigenous and custodial communities or governments in consideration for access to such biological material or traditional knowledge.

Emerging Technologies

Over time, whole new fields of technology and innovation will emerge that will raise new issues for consideration. As with any emerging technology area, the evolution of “successful practices” will require careful and conscientious decisions that may vary from previously released guidance. The TM should thoughtfully consider how best to address these emerging issues so as to optimally manage University-developed technologies for public benefit.