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Technology Licensing for the Benefit of the Developing World: UC Berkeley's Socially Responsible Licensing Program

Carol Mimura, PhD

Abstract

In the few decades since passage of the Bayh-Dole Act of 1980, university technology transfer success has been measured primarily by traditional metrics such as numbers of patents filed, revenue obtained from licensed patents, and numbers of startup companies founded to commercialize university intellectual property. Intellectual property (IP) managers have often responded to these metrics and expectations by attempting to maximize revenue from commercial IP licenses. In the last several years, the University of California at Berkeley has acknowledged that, while license revenue generation and local economic development are important goals, it is equally important to maximize the social impact of research and, therefore, adopted several IP management strategies, including a Socially Responsible Licensing Program. Several types of agreements have been executed under SRLP, including IP licenses, sponsored research agreements, and collaborative research agreements. All are structured to provide an economic incentive to licensees to develop and distribute goods and services to low- and middle-income countries and/or to other target groups as they are defined in each contract.

Introduction

Increasingly, university technology transfer programs are becoming aware of the need—and the opportunity—to translate their research findings into solutions not only in their states and nation but also in nontraditional markets such as in developing countries. At the University of California at Berkeley (Berkeley), which has long been associated with progressive social

Carol Mimura, PhD, is assistant vice chancellor for Intellectual Property and Industry Research Alliances at the University of California at Berkeley.

policy and student idealism, this trend manifests in countless ways. Not only have entrepreneurial researchers made their mark in Northern California by nurturing the biotechnology and the information technology industries[1]—two important economic drivers in the state[2]—they did so while upholding the university's mission. This trend is also reflected in its Socially Responsible Licensing Program (SRLP), one intellectual property (IP) management strategy of Berkeley's IP management office.

The SRLP was conceived approximately three years ago and has several goals, to:

- promote widespread availability of healthcare and technologies in the developing world,
- maximize societal impact and public benefit of technologies developed at Berkeley,
- share revenue and/or other benefits with those who collaborate with Berkeley researchers,
- give proper attribution to a resource/material provider or collaborator, and
- stimulate additional investment by others to achieve these goals.

The program seeks to address affordability and accessibility of drugs, therapies, diagnostics, crops, and vaccines to the developing world by stimulating investment where it has been traditionally lacking under profit-motivated business models.

This article describes the motivations for the program, the IP management reorganization that enabled its implementation, some examples of contracts signed in the last three years, and selected contract clauses that implement principles under the program, such as access to and affordability of drugs, diagnostics, or crops.

Origins of the Program

The SRLP was conceived when Eva Harris, a professor at Berkeley's School of Public Health, collaborated with colleagues in the department of Electrical Engineering and Computer Science to invent a handheld micro-electro-mechanical systems (MEMS)-based diagnostic for the diagnosis of dengue fever. Harris knew that the campus licensing office would have to consider a radical (at the time) approach to enable her company, the Sustainable Sciences Institute (SSI), to garner investment for its application

in tropical regions, starting with Nicaragua.[3] Not only was the licensing office excited about providing the framework for investment to occur, but it formalized the concept as a program as it became apparent that many university-generated technologies could be commercialized both for humanitarian purposes and to meet unique business approaches such as those adopted by product development partnerships. Harris provided the moral compass that forged a deal structure,[4] and other campus researchers, including Jay Keasling, later provided additional deal flow within the program.

Intellectual Property Management Restructure

About three years ago, IP management on campus was reorganized to consolidate industry-university contracts in a single unit. The reorganization consolidated IP licensing and industry-sponsored research activities under a single umbrella unit called Intellectual Property and Industry Research Alliances (IPIRA), creating one-stop-shop access for industry to Berkeley's research capabilities and research outcomes.[5] This consolidation of incoming and outgoing industry transactions in one unit solidified the unit's goals as a service organization whose outcomes are realized in many ways and often in other units on campus. Moreover, the consolidation changed the metrics by which success in technology transfer is measured.

For example, success for IPIRA is defined as success in all aspects of industry-university partnerships, including those that are tallied and reported in other campus units such as the development office. This, in turn, enabled an entire spectrum of IP management strategies to be adopted, including those that benefit the developing world.[6] For example, in the current organizational structure, the future grant of a royalty-free license is financially detrimental to the revenue bottom line of the IP licensing office, but since that strategy stimulates net funding, gifts, relationships, and recognition to the campus that far outweigh the licensing revenue forgone, the benefit can be tallied in the social-impact bottom line and also (in some cases) as research revenue in the licensing office's peer division (the Industry Alliances Office). Using the new metrics and double bottom-line accounting, as long as social impact is valued as strongly as other outcomes such as licensing revenue, then licensing revenue is merely one consideration among many when multifaceted business decisions are made. In the

previous structure in which silos of activity fostered more competition than cooperation, the licensing office would not have had strong incentive to grant such a free license because campus benefit would have been realized elsewhere on campus and/or the personnel who executed the transaction would not have been acknowledged as the drivers of an outcome that is realized outside of the technology licensing office. The campus has allowed IPIRA to apportion credit derived from one peer office to another so that a given action in a broad IP management strategy is not taken at the expense of another and is consistent with, not in competition with, the common goal of maintaining research excellence and maximizing research impact.

In the first fiscal year of IPIRA's operation, corporate sponsorship of research nearly tripled on campus. Gift funding to the campus and foundation funding also increased. IPIRA's contributions to these outcomes are both direct and indirect. The figures are cited here not to imply that IPIRA can take credit for the results, but to illustrate that some of the measurable, anticipated campus benefits resulting from IP management reorganization have been realized. Berkeley's reputation in the industry-contracting arena has also improved.[7]

Several types of agreements have been executed under SRLP including IP licenses, sponsored research agreements, and collaborative research agreements. All are structured to provide an economic incentive to licensees to develop and distribute goods and services to low- and middle-income countries and/or to other target groups as they are defined in each contract. One contractual mechanism used to induce such investment under the program is the grant of a low-cost or free commercial IP license to sell products or services in the developing world coupled to corporate and foundation support for research at Berkeley. In this way, sponsored research investment and the humanitarian impact of research are maximized at the expense of potential future IP license revenue. However, future revenue from licensing is never assured, and the opportunity cost in giving up potential future licensing revenue from sales in the developing world is low in comparison to the benefits derived. In addition, there is the basic moral imperative to further humanitarian causes. The program also provides a service to campus researchers who are willing to accept research funding in the near term on the condition that the campus (and they) forgo potential future IP license royalties from sales in the developing world.

Examples of Contracts

Some examples of contracts under SRLP include the following:

- A license to SSI granting royalty-free sales to a handheld MEMS immunodiagnostic assay in predefined countries for as long as SSI retains nonprofit status.
- A research collaboration and revenue-sharing agreement with the Commonwealth of Samoa that provides Berkeley researchers with access to native mamala tree bark, the source of an antiviral compound. If an antiviral therapy is commercialized, net revenue will be shared with the commonwealth and other stakeholders in Samoa (including native healers and villages). Moreover, biological tangible materials such as plasmids and genes will be named "in such a way that the connection of the gene, gene sequence, or gene product to Samoa will be clear to other researchers."[8]
- A license to a nonprofit agricultural biotechnology company to commercialize certain disease-resistant crops on a royalty-free basis in "least developed" predefined geographies.
- A tuberculosis vaccine agreement with a for-profit biotechnology company stating that if a vaccine is invented from company sponsorship of research at Berkeley, vaccine distribution will be royalty free "outside of Europe, North America, Japan, South Korea, and Taiwan."
- A three-party research agreement coupled to two license agreements for development of a malaria therapeutic based on a $42.6 million grant from the Bill and Melinda Gates Foundation.
- A research collaboration agreement through Africa Harvest Biotechnology Foundation International (a Bill and Melinda Gates Foundation grantee) for the development of nutritionally enhanced sorghum seed for royalty-free distribution to areas of need.[9]

Inducing Investment Where Profit Drivers Do Not Exist: Free Licenses Associated with Research Funding

The highest profile transaction in SRLP under this model is a product development partnership (PDP) funded by the Bill and Melinda Gates Foundation to produce a low-cost version of an existing malaria drug. Contracts underlying the PDP consist of:

- A three-party collaboration agreement between the Institute for One World Health (iOWH), a nonprofit pharmaceutical company);

Berkeley; and Amyris Biotechnologies Inc. (Amyris), a Berkeley startup company;

- A license from Berkeley to iOWH to distribute the drug in the developing world; and
- A license from Berkeley to Amyris to provide the drug to iOWH. This license also grants Amyris the right to sell patented compounds in the developed world under royalty-bearing terms, since the compounds have commercial applications in the flavors, fragrances, and energy industries.

Funding under the three-party collaboration agreement is administered by iOWH as the prime Gates Foundation grantee. The iOWH retains $22.6 million to fund regulatory activities and product distribution, but distributes approximately $8 million to Berkeley to perform basic research on E. coli to create the synthetic drug precursor and approximately $12 million to Amyris to fund applied research on the fermentation and chemical steps.

The deal satisfies the mutual goal of producing a low-cost malaria treatment in tropical countries and provides benefits to each participant. All of the parties in the PDP are known, and the terms of future licenses have been agreed to in advance. Uncertainty about future contract terms has thus been eliminated and gaps between developmental stages have been closed.[10] The structure obviates the need to find a way through the traditional valley of death in drug development when basic research at the university only takes a project so far, and translational research in a startup company cannot proceed until enough private funding has been raised. Future transaction costs have thus been eliminated as well.[11]

The Bill and Melinda Gates Foundation has praised the contractual structure underlying this PDP and hopes that the model would be adopted by other universities for their applicable projects.[12]

The malaria drug PDP deal structure has also demonstrated a unique way for a university startup company to obtain early-stage funding from a philanthropic source, in essence bootstrapping via philanthropy.[13] The dual-commercialization-track strategy pursued by Amyris makes it possible for the company, albeit a for-profit startup company, to reduce the technology to practice for a nonprofit end use (sales of malaria drug in developing nations), but then to deploy the same technology to enter commercial markets in the developed world. It is as though the company has the luxury of

having both a non-profit-style research institute that doesn't have to worry about turning a profit but that will generate innovations for the for-profit side of the company to sell with a profit motive.

Selected SRLP Contract Clauses

Research agreements under SRLP necessarily grant rights to IP that has not yet been developed, whereas license agreements grant rights to IP that exists when contracts are drafted and, therefore, can be analyzed. Contract clauses in research agreements necessarily differ from those in license agreements.

Research Agreements

A research agreement contemplates the future grant of a license to the sponsor to IP that is expected be developed under research described in a written scope of work and its corresponding budget. Such agreements prospectively describe the terms of a future grant of rights to IP that is expected to be developed under the agreement. Therefore, grant clauses are qualified with phrases such as "to the extent that we are legally able to do so" and/or "if all of the inventors concur with the terms." The former phrase, "to the extent that we are legally able to do so," is necessary to address, for example, IP developed through acts in a research program that—despite the expectations of the parties—incur obligations to a third party. Such obligations can arise, for example, if IP incorporates material received under a material transfer agreement from a third party or through collaboration with an outside entity. Similarly, a second sponsor (such as the federal government) could have IP rights if the laboratory research utilizes more than one source of funding. Such encumbrances to the IP are not expected to arise, and consummate laboratory management is required to prevent them, but they cannot be dismissed as a possibility. The latter phrase, "if all of the inventors concur with the terms," addresses the reality that inventorship is a legal determination that can only be made when patent claims are drafted. At that time, it is possible that a researcher will be named an inventor who has not pre-agreed in writing to the grant of special IP terms in a contract. The contracting office can obtain approval from all contemplated inventors, but the unanticipated, future inventor (such a colleague who contributes through a hallway conversation) is the subject of this clause.

Similarly, the manner in which IP rights will be conveyed in the future

has been addressed in a collaboration agreement by stating that Berkeley will make "reasonable efforts to license resultant IP for public benefit, keeping in mind Berkeley's and the sponsor's mutual goals of providing low-cost therapies for free, at cost, or at minimal profit in the developing world."

Sister institutions are invited to join in the development of appropriate contract clauses to further the goals of the program and those of others where IP and other research outcomes can be deployed for humanitarian purposes in developing nations.

License Agreements

In SRLP, commercial license agreements that convey rights to preexisting IP define geographies and/or a field of use and typically grant either a royalty-free right to sell products and/or services or the right to sell at the cost of manufacture and distribution without paying running royalties. To address the situation that a given transaction has been crafted with the understanding that the licensee shares SRLP's goal of deploying rights developed at the university for humanitarian purposes and to reflect the context in which SRLP performed a legal and policy review of a given transaction, the agreement qualifies a given license grant to be in effect "for as long as the licensee retains its nonprofit status."

Legal and Policy Issues

The program utilizes contractual approaches that deploy Berkeley technologies to induce investment where is it needed. Contracting under PDP structures, such as the malaria therapeutic example, is driven by the nonprofit mission of the ultimate vendor and the humanitarian goals of its sponsors. In the for-profit world, corporate constraints are different. Advance contractual mechanisms that address affordable pricing and widespread access have been tried and abandoned in the past (such as CRADA clauses from the early 1990s), and barriers to market entry that go beyond pricing, such as regulatory hurdles in Africa, parallel importation, protection of brand identity when generics are introduced, and insurance, are equally massive obstacles for drug manufacturers to overcome. However, the creation of a foundation structure as a vehicle through which a for-profit company administers its charitable goals while shielding (and keeping distinct) its profit-driven core business may allow drug manufacturers to

take more risks and/or to entertain more controls from public-sector IP owner licensees in SRLP contracts.

Antitrust implications must be considered in all SRLP agreements when the parties agree in advance to a given price, even when that price is set at zero. Certain SRLP license agreements require one or more companies to sell a drug at cost or at the mere cost of manufacture and distribution in the developing world, but the procompetitive aspects of providing a new technology to the needy where they would not otherwise have broad access to such new technology far outweighs the anticompetitive initial appearance based upon developed-world norms. The licenses that grant rights in developed countries follow the "normal" approach of royalty-bearing sales based upon business decisions of the licensees.

One research collaboration agreement under the program implements two goals of the SRLP. The programmatic goals of revenue sharing with a collaborator and ensuring proper attribution of a resource provider or a collaborator are addressed in a contract that facilitates the isolation and characterization of an antiviral compound from the mamala tree, which is indigenous to Samoa. In this contract, Berkeley agreed to share 50 percent of net revenue with the Commonwealth of Samoa and other stakeholders in Samoa if a drug from the research is commercialized. Shared revenue under this agreement is administered through a foundation. The commitment to share future net revenue in this agreement imposes a duty on the university and its researchers to use nonfederal sources of funding for the project because inventions made with federal funding must be distributed according to the Bayh-Dole Act, which stipulates that resultant net revenue must be used for education and research purposes. While the Commonwealth of Samoa and other recipients might well use their share for education and research purposes, that use was not explicitly stated in the contract. In the agreement, Berkeley also agreed to give attribution to Samoan experts, villages, and other collaborators by naming plasmids to reflect the preexisting expertise and origin of the biological starting material and to acknowledge the collaborative nature of the research.

Written Consent

All researchers whose IP rights are affected by contract terms under the SRLP participate in the program on a voluntary basis, in accordance with the University of California's principle of informed participation. The researchers or inventors are apprised of the humanitarian goals of the contracts, and their written consent to the terms is obtained before any transaction is consummated in which, for example, a royalty-free commercial license is either granted outright or promised in the future or when future revenue will be distributed in a nonstandard manner. Technologies and/or research programs that could further the goals of the SRLP are managed under the program only after consultation with the researchers or inventors and corporate partners, and there is no absolute requirement of research programs that might contribute to the goals of the program to include concessions for humanitarian use in developing nations.

Preserving Access

Most technology transfer from universities and research institutes occurs in traditional ways: through teaching, publications, and other forms of information dissemination; consulting; training of students; and interactions with the private sector. Only a small percentage of a university's collective intellectual output is ever made proprietary through IP protection. Therefore, when SRLP makes its results proprietary by patenting, as IP managers, we must demonstrate good stewardship of the IP rights.

Good stewards of IP rights take care to protect public sector access to research tools for research purposes, and a non-negotiable reservation-of-rights clause is appropriate in this program, as it is when licensing any publicly developed IP right. All IP licenses both inside and outside of the SRLP reserve the right for the university and others in the nonprofit sector to use the licensed IP rights for education and research purposes (and also a right to transfer tangible materials that are required to practice a given invention to nonprofit institutions for the same purpose).

Certainly the strategy of not obtaining IP rights at all, or only in certain geographies, is a mechanism for ensuring access when IP rights are not required as a commercialization incentive. A related strategy is to obtain IP rights but then to grant licenses under open access principles[14] and open licenses.[15] Open innovation in the Intel lab near Berkeley, which operates

under an open collaboration agreement with Berkeley, illustrates the kind of innovation acceleration that is encouraged when IP rights are not contemplated, expected to be rare, and/or ancillary to the research.[16]

License restrictions that grant rights only in a defined field of use can also preserve access. For example, a license granting the right to use a gene sequence for a diagnostic test in one format, such as on a high-density nucleotide array (a gene chip) leaves open the possibility of relicensing that same gene to another company for development into a different diagnostic test.

Nonexclusive licensing is another strategy that can preserve access, but licensees in the biotechnology and pharmaceutical industries often insist on exclusive grants as a condition of investing in costly and lengthy research and development that is required to bring a licensed right to the point of practical application. Mandatory sublicensing clauses in many exclusive licenses from Berkeley since 1998 address the situation where the grant of an exclusive license to a licensee allows future applications of the same technology to be developed, not blocked, by the exclusive licensee. Unmet market needs are addressed through this mechanism by requiring the exclusive licensee either to develop a given new application of the licensed right or to grant a sublicense to a third party who will do so.

If an exclusive licensee does not or cannot provide a drug in an area with an unmet need, a more aggressive reserved right of the university would be to a right to re-license the IP rights to a drug generics manufacturer for the purpose of providing access to such country or region. If the SRLP licensee does not provide the drug for a certain market niche, then there should be a mechanism whereby another provider can serve that market. Unfortunately, this specific enhanced reserved right has not yet been successfully incorporated into an agreement (even though more general mandatory sublicensing clauses have been incorporated into patent license agreements at Berkeley for a number of years). We have been testing such an enhanced clause for acceptability and welcome input from potential licensees. We know that parallel importation, brand preservation, product packaging, and the quality of generic drugs are enormous concerns to for-profit licensees. We welcome a dialogue with biotechnology companies and pharmaceutical companies on appropriate text in a given agreement to further promote drug access and affordability and how we might further segment rights within countries such as Brazil, for example, where there are

many poor, but also significant numbers of middle-class consumers who can afford to pay for drugs. Gilead Sciences Inc. deserves credit for leading by example in this regard, as its Access Program demonstrates the company's commitment to providing HIV/AIDS therapeutics to sufferers in areas of significant unmet need.[17]

Conclusion

In the few decades since passage of the Bayh-Dole Act of 1980, university technology transfer success has been measured primarily by traditional metrics such as numbers of patents filed, revenue obtained from licensed patents, and numbers of startup companies founded to commercialize university IP. Intellectual property managers have often responded to these metrics and expectations by attempting to maximize revenue from commercial IP licenses.[18] In the last several years, Berkeley campus administration has acknowledged that, while license revenue generation and local economic development are important goals of the program, it is equally as important to maximize the social impact of research. The technology transfer program spins off and welcomes partnerships with startup companies, does not value overprotection of research outcomes. The SRLP embraces the sentiment of Mary Sue Coleman of the University of Michigan who stated at the 2005 AUTM Annual Meeting℠, "First and foremost, technology transfer must serve our core mission: sharing ideas and innovations in the service of society's well-being."[19]

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