Forthcoming chapter in Working Within the Boundaries of Intellectual Property (Rochelle Dreyfuss, Harry First, Diane Zimmerman. Oxford University Press 2010).

Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact

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Multiple and diverse intellectual property management strategies are required to deploy university research results for maximal social impact and accessibility. University technology transfer offices have traditionally been judged by the number of patents they hold, the number of licenses signed, startup company data, and license revenues. Universities, however, perform early-stage research and serve to accelerate innovation; they are lead-off runners in a multi-party relay race to commercial endpoints. New definitions of success in the industry contracting office at the University of California, Berkeley (Berkeley) have engendered new models of industry-university contracting including those that benefit the developing world, such as our Socially Responsible Licensing Program. Industry partnerships are indispensable to the achievement of our goals and our approach to industry contracting is relationship-based. Universities and companies interact in myriad ways and for many different reasons. Based on a range of needs and desired outcomes in campus interactions with industry, we continually draft new contract types to implement a spectrum of intellectual property (IP) management strategies. To assess the impact of our strategies a combination of traditional and non-traditional metrics must be employed. New metrics to measure social impact rely in part, on external data that are outside of the purview of our office, and in part, on outcomes and externalities that occur over many years.

As a denizen of the San Francisco Bay area, Berkeley is part of a vast innovation crucible containing extensive private capital networks, venerable academic research institutions, companies and foundations, industrial parks, and a risk-taking, entrepreneurial culture. An ever-renewing crop of start-up companies populate the region, hundreds of which spun out of Bay-Area universities.[1] Companies from around the globe form research alliances with Berkeley to access fresh talent, obtain IP rights, and leverage their own R&D budgets.[2] Companies also receive R&D tax credits in California when they sponsor research at the U.C. campuses.

According to a recent study Berkeley ranks seventh worldwide in biotechnology patenting.[3] Formal university-industry interactions and partnerships requiring contractual agreements to property

[1] Including 100-200 from Berkeley to date.

[2] *Assessing the role of the University of California in the State's Biotechnology Economy: Heightened Impact Over Time*. Cherisa Yarkin, Andrew Murray. University-Industry Cooperative Research Program. IUCRP Working Paper 02-4. March 24, 2003. http://ucdiscoverygrant.org/pdf/UC_Role_in_CA_Biotech_Economy_March2003.pdf

[3] *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization. The Milken Institute*. Ross DeVol and Armen Bedroussian. September 2006. http://www.milkeninstitute.org/pdf/mind2mrkt_2006.pdf

rights are the purview of Berkeley's IPIRA (Intellectual Property and Research Alliances), Berkeley's management office.[4] Transactions in IPIRA must be varied and flexible to achieve a variety of outcomes that match the mutual goals of industry and the University along an entire relationship continuum. As a service organization, not a business, IPIRA reports to the research side of the campus administration. It supports Berkeley's research enterprise and its goal of deploying research results for social impact and public benefit.[5] When universities elect to make academic discoveries proprietary by obtaining IP rights, and when we license IP and property rights, we must demonstrate good stewardship. Responsible deployment of public sector IP rights involves retaining public sector access to the properties for public sector use. Good stewardship of public assets and public outcomes involves consideration of all potential avenues of technology deployment and all consequences of making research results proprietary through university ownership of IP. Personnel in IPIRA bring a combination of business, law and science backgrounds to accomplish these critical goals. They are encouraged to take risks and to create win-win solutions for a given situation, not force a given situation into preexisting templates.

The intellectual property (IP) management approach at Berkeley is rooted in the certainty that the research university is a powerful innovation accelerator and engine of economic growth.[6] IPIRA is organized to serve the needs of an eminent research university that plays an integral role not only in the innovation ecosystem in the San Francisco Bay area, but globally.

Cutting edge academic research laboratories typically create early-stage, "embryonic" technologies that are far from being actual commercial products. Nevertheless, academic discoveries at Berkeley have spawned some of the most important economic drivers of the state of California such as the biotechnology industry and the information industry.[7] Berkeley discoveries continue to accelerate the alternative energy industry through an innovative, $500M public-private alliance with oil giant BP that established a new Energy Biosciences Institute to research alternative fuels, especially biofuels;[8]

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[4] See http://ipira.berkeley.edu.

[5] See *The Role of University Research in California's Future*, CITRIS Symposium 2006: Engineering a Better World (Dec. 14, 2006) <http://www.siliconvalley.um.dk/NR/rdonlyres/50DE4982-8CBD-4420-8486-79EFFF75B79B/0/141206_CITRIS_SYMPOSIUM.pdf>.

[6] See ICF Consulting, *California's Future: It Starts Here: UC's Contributions to Economic Growth, Health, and Culture* (Mar. 2003) <http://www.universityofcalifornia.edu/itstartshere/report/fullreport.pdf>.

[7] *U.C. Berkeley's Economic Impact and Social Benefits* <http://www.berkeley.edu/econimpact/>.

[8] *BP Selects UC Berkeley to Lead $500 Million Energy Research Consortium with Partners Lawrence Berkeley National Lab, University of Illinois* (Univ. of Cal. Berkeley News Media Press Release issued Feb. 1, 2007) (available online at <http://www.berkeley.edu/news/media/releases/2007/02/01_ebi.shtml>); Rick DelVecchio, *Cal Sees BP Deal as Landmark: Research Could Lead More Quickly to Making Alternative Fuel a Reality*, S.F. CHRON., Feb. 2, 2007 at <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2007/02/02/BAG1GNTL911.DTL&type=printable>; *Energy Biosciences Institute Begins Ground-Breaking Research into New, Cleaner Sources of Energy* (Energy Biosciences Inst. Press Release issued Nov. 14, 2007) (available online at <http://www.energybiosciencesinstitute.org/index.php?option=com_content&task=view&id=110&Itemid=120&date=2009-05-01>.

and through its participation in the Joint Bioenergy Institute,[9] funded by the U.S. Department of Energy as a Bioenergy Research Center.[10] "Green/Clean tech" startup companies from Berkeley are vital contributors the local alternative energy innovation ecosystem,[11] for they perform the essential role of translating laboratory discoveries into commercial goods and services.[12] They are funded in part, by a strong network of local sources of private capital including venture capital companies.[13]

Innovation can be expedited at the university when resources and effort are coordinated, such as through large, interdisciplinary projects and programs focused on a given technological field with multiple funding sources. The California Institute for Quantitative Biosciences, in Stanley Hall at Berkeley, is architecturally and functionally designed to encourage and facilitate cross-disciplinary biophysical research "that may one day lead to new treatments or preventions for diseases, more environmentally friendly sources of energy and better ways to clean up pollutants."[14] It is one of four California Institutes for Science and Innovation[15] that leverage state funding with industry support to catalyze the creation of new industrial sectors and markets that spur economic growth in California, and through a ripple effect, to deliver benefits worldwide.

Given that the mission of the university is teaching, research, the dissemination of information, and public service, where does the university IP rights contracting office fit in, and what is its proper role? Most knowledge transfer to and from the university occurs in informal ways, and that is appropriate. By far, the most prevalent forms of transfer from universities involve knowledge dissemination through publication and teaching, training of a work force to perform new employees for today's technical business sectors, and public service.[16] All of these informal forms of knowledge transfer usually occur without university contracts and are efficacious. For example, San Francisco Bay area firms hire workers in computer, engineering, and math jobs at twice the national average[17] and

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[9] *Bay Area's Joint BioEnergy Institute Gets Financial Kick-Start from DOE* (Berkeley Lab Press Release issued Sept. 28, 2007) (available online at <http://www.lbl.gov/Science-Articles/Archive/PBD-JBEI.html>).

[10] See http://jbei.org/.

[11] *East Bay Green Corridor Grows, Cash Pours In*, San Francisco Chronicle June 27, 2009. http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/06/26/BUEH18EP14.DTL

[12] Bay Area Science and Innovation Consortium, *Report on Innovative Energy Solutions from the San Francisco Bay Area: Fueling a Clean Energy Future* (June 2007) at <http://www.bayeconfor.org/basic/media/files/pdf/FuelingACleanEnergyFuture.pdf>.

[13] *Venture Capital Investment in Greentech and Renewable Energy Exceeds $2.5B in Q4*, REUTERS (Jan. 2009) at <http://www.reuters.com/article/pressRelease/idUS140478+05-Jan-2009+PRN20090105>.

[14] *Stanley Hall Dedication Heralds New Era of Bioscience Innovation* (Nanotechnology Now Press Release issued Sept. 26, 2007) (available online at <http://www.nanotech-now.com/news.cgi?story_id=25236>).

[15] See http://www.ucop.edu/california-institutes/about/about.htm.

[16] Dissemination also includes consulting, which is commonly performed under personal service contracts at Berkeley.

[17] U.C. Berkeley News Center, *U.C. Berkeley's Economic Impact and Social Benefits* (Sept. 13, 2007) <http://www.berkeley.edu/econimpact/>.

Berkeley graduates fare well in that pool.[18] Berkeley faculty and staff publish prodigiously. Hundreds of degree programs are offered through seven colleges and schools.[19]

There are, however, many instances in which contracting is the most appropriate form of knowledge transfer. Property rights contracts, including IP rights licensing, represent one form among many of industry-university engagement types. The campus constantly adapts to match needs and motivations for interacting with industry, with the right forms of engagement. Gift funding from industry is a welcome method of engagement, as it comes with no strings attached. Corporate donations to campus have increased dramatically in recent years. We attribute this in part, to flexibility that we have demonstrated in our IP management strategies (including resisting the temptation to overvalue every innovation as though it were the next Google[20]) particularly, those that address global health and poverty,[21] and thus benefit the developing world.[22] Our Socially Responsible Licensing Program (SRLP) deploys Berkeley innovations to induce investment in technology, tropical and neglected diseases. [23] It creates breakthrough business models and contracts to alleviate health disparities and poverty in low- and middle-income countries.[24]

Part I of this Chapter describes various IP management strategies and contract approaches in our "relationship-based" perspective to transferring results, knowledge, rights, materials and personnel, both to and from the private sector, in order to stimulate uptake of Berkeley innovations, research collaborations, and to catalyze commercialization. Part II describes implementations of socially responsible principles in IP licensing that can address pressing societal needs, including global health. Part III provides details of how the IP management office is structured, and why organizational structure and appropriate staffing helps to align campus goals with activities at the industry-university interface.

I. Industry-University Collaborations, Partnerships in Innovation

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[18] Cherisa Yarkin, Andrew Murray & Sam Chou, *The Role of University of California Scientists and Engineers in the State's R&D-Intensive Communications Industry*, Industry-University Cooperative Research Program Working Paper 03-1 (Apr. 10, 2003) at <http://ucdiscoverygrant.org/pdf/UC_Role_in_CA_Communications_Economy_April2003.pdf>.

[19] *University of California, Berkeley Statistics*, CAL STATS (Dec. 2008) <http://metrics.chance.berkeley.edu/CalStats.pdf>.

[20] See Carl Schramm, *Five Universities You Can Do Business With*, INC.COM (Feb. 2006) <http://www.inc.com/magazine/20060201/views-opinion.html>.

[21] See, e.g., Kathleen Maclay, *Richard Blum Gives $15 Million to Fund Center to Alleviate Poverty*, U.C. NEWSROOM (Apr. 19, 2006) <http://www.universityofcalifornia.edu/news/article/8076>.

[22] See, e.g., Amy DerBedrosian, College of Letter and Science University of California, Berkeley, *$1.8 Million Gift Will Advance Health Research* (July 2007) <http://ls.berkeley.edu/?q=node/499>.

[23] Carol Mimura, *Technology Licensing for the Benefit of the Developing World: U.C. Berkeley's Socially Responsible Licensing Program*, 18 J. ASS'N U. TECH. MANAGERS 15 (2006) (reprinted in 21 Industry and Higher Education 295 (2007)).

[24] See http://ipira.berkeley.edu.

Industry-university collaborations accelerate innovation and foster translational research that fuels economic growth.[25] In a survey of California biomedical companies, Pricewaterhouse Coopers found that:

> "20% credit a California academic or research institution for playing a central role in the creation or growth of their company, 39% have at least one technology transfer agreement with a California private or public academic institution, 57% have at least one clinical research or sponsored research agreement with a public or private academic institution in California, and 97% plan to either broaden (57%) or maintain (44%) their current level agreements with their academic partners."[26]

Berkeley interacts with companies in myriad ways. Most common are collaboration; sponsorship of research; material, knowledge, and personnel exchange; consultation and other public service; IP licensing; donations of cash, equipment, and in-kind services; and membership-based industry affiliate programs. Companies are also invaluable and strategic members of our innovation network, acting as service providers, sources of capital for investment in university start up companies, and in entrepreneurship programs. To accommodate these various arrangements, we have developed a spectrum of IP management strategies and corresponding agreement types that are based on a range of needs and desired outcomes. The spectrum ranges from points of engagement where IP matters very much to those where IP matters are completely moot. Similarly, at the IP-centric end of the spectrum, a corporate sponsor often expects to receive the first opportunity to license IP rights on an exclusive basis, whereas at the polar extreme, IP licensing is nonexclusive, or open, or IP rights are not perfected at all.

A. Philanthropy: No strings attached

Unlike many for-profit institutions that develop intellectual property and amass IP rights for commercial aims, universities are often the beneficiaries of charitable donations, some of which support our research activities. Gifts are bestowed by companies and are granted without a *quid pro quo*. They occupy one polar extreme of the spectrum because as a charitable donation, contracts do not exist and IP rights are irrelevant. Results funded solely with gift funding are not subject to sponsor obligations, enabling many possible routes to dissemination, including open dissemination. Unrestricted gift funding is used at the sole discretion of the campus, but donors can stipulate that the funds be directed, such as when "research" gifts are bestowed to support a specific laboratory. We encourage gift relationships whenever an industry partner does not require contractual terms and conditions.

B. Open Collaboration Model: Playing beautifully together in the sandbox

The Intel-Berkeley Open Collaborative Research Agreement typifies another contract model that can be placed towards the end of the spectrum where IP rights are not relevant to the parties. Intel is a leader in the semiconductor industry and embraces "open innovation" principles to stay abreast of

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[25] See David L. Gollaher & Tracy Lefteroff, California Healthcare Institute & PriceWaterhouseCoopers, *California's Biomedical Industry: 2004 Report* (June 23, 2004) at <http://www.law.berkeley.edu/institutes/bclt/stemcell/articles/gollaher_ca_biomed_report.pdf>; The University of California, *Industry-University Cooperative Research Program Annual Report 2003* <http://ucdiscoverygrant.org/AnnualReport.pdf>.

[26] California Healthcare Institute & PricewaterhouseCoopers, *California's Biomedical Industry 2008 Report* 55 (Jan. 2008) <http://www.chi.org/uploadedFiles/2008_CA_Biomedical_Industry_Report_FINAL.pdf>.

leading-edge academic research.[27] The Intel Berkeley research laboratory "lablet" operates under this contract model in a space near the Berkeley campus that is rented and managed by Intel.[28] This type of university-industry open collaboration model is motivated by the mutual desire to foster research collaborations in a noncompetitive environment, in which University researchers gain access to company proprietary resources, and where research outcomes are disseminated early and broadly. Academics work on industry projects, learn from Intel's expertise, and use their equipment. Intel benefits not only from academic expertise in leading computer science and engineering departments, but also from having the freedom to innovate in areas of speculative, high-risk research, outside of near-term corporate profit pressure and time scale, and in cross-disciplinary areas that do not fit neatly into existing corporate product programs. Moreover, students receive valuable experience, including the opportunity to consider the commercial potential of their academic research projects, and importantly, Intel establishes relationships with a talent pool from which it can hire. The open dissemination framework advances the field, stimulates exchange, identifies areas of synergy, and helps to bridge the so-called "valley of death"—the funding and resource gap that lies between early-stage innovation and commercialization, which is typical in many technology areas, including networked systems. Other companies may participate, but to date, none have elected to do so.

The Intel-Berkeley agreement provides a streamlined mechanism for Berkeley and Intel to propose projects of mutual interest. Projects are approved based on a description of the scope of work and who will do what, and where. Each party funds its own research. IP ownership is expected to follow inventorship as it is defined in U.S. patent law.[29] While IP rights on results generated under the agreement may be filed or registered by either Berkeley or Intel (or jointly), patents are expected to be rare and any patent licenses issued are expected to be nonexclusive. Indeed, as of Fall 2008 both parties reported that no patents had been filed on a lablet project *per se* in the first seven years of operation. If either party elects to obtain patent rights, then the other party receives a nonexclusive license (on reasonable and nondiscriminatory, or "RAND" terms) to use the rights for research purposes, and/or a commercial use license on RAND terms. The above may also be accomplished through cross-licensing. Of course, Intel may take any lablet outcome in-house, into its closed and proprietary environment to invest in follow-on proprietary R&D. Conversely, Berkeley may further innovate in-house to develop IP improvements.[30]

This IP management strategy facilitates an environment of true collaboration while protecting the University's obligations to third parties, most notably its federal sponsors of research.[31] Intel's openness,

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[27] See HENRY CHESBROUGH, OPEN INNOVATION (Harvard Business School Press 2003); HENRY CHESBROUGH, OPEN BUSINESS MODELS (Harvard Business School Press 2006).

[28] Intel Research Berkeley, <http://berkeley.intel-research.net/intel-brochure-2009.pdf>.

[29] See 35 U.S.C. § 116.

[30] The strategy of outsourcing early stage research is not at all unique to this arrangement. Indeed, David Tennenhouse, who conceived the lablet concept as Intel's Research Director (at its inception) knew better than most the power of distributed R&D outsourcing. In a previous position at DARPA, he fostered the development of many disruptive technologies in the information technology field through external funding of projects to both the nonprofit and for-profit sectors.

[31] Each party funds the research of its own employees. If an invention is made using U.S. Federal funding agency grant, then the invention will be subject to the terms of the Bayh-Dole act, which U.S. government will receive a nonexclusive, royalty-free license to the invention.

flexibility and accessibility under this model establish it as an involved, as opposed to arms-length, research partner. It attracts current and constant input from some of Berkeley's best and brightest in the field and avoids insular, top-down research directives. One of the most inspiring outcomes of research from the lablet is a health initiative in India, that has established several wireless communication-based eye care clinics to perform remote telemedicine eye exams. The poor, in remote areas without access to medical care, receive ophthalmic exams via computer connections and can find out if they must make an arduous and long journey to a medical center or hospital.[32] This outcome could not have been achieved, or would not have been achieved in the short timeframe in which it was developed, without the collaborative input of both parties.

This contracting model facilitates uptake of the outcomes of open collaboration, by encouraging broad and early dissemination of exploratory research results. Furthermore, it avoids some of the transaction barriers that have stymied potential collaborations in the electrical engineering and computer science fields. The basic agreement has engendered several contract variations: it serves as a starting point for drafting and a frame of reference for discussions about expectations and outcomes. We are currently constructing an enhanced collaboration sandbox contracting model, drawing on the principles of open collaboration, but this time involving several companies in a focused product development alliance.

Software created in the lablet is primarily disseminated under the Berkeley software distribution (BSD) open source license, in keeping with the desired outcome of broad dissemination. The BSD license is popular and used widely in part, because it is simple and "ready to sign," thereby reducing transactions costs. It grants one type of permission to use the code without extracting a fee, and shields the provider from risk. Of course, if software used in a lablet research project is subject to other restrictions, such as when a portion of the code has been obtained under a different license, then derivative software developed by the collaborators is distributed accordingly.

Similar low transaction cost, "use" or bailment agreements (that do not transfer ownership but grant permission to use the provider's property) are frequently employed to transfer biological tangible materials to and from the University for research purposes. Most commonly such agreements, including material transfer agreements, are also transacted on a fee-free or very low cost basis. As a group, they can be placed on the IP management agreement-type spectrum in the direction of the polar terminus where gifts reside, and where broad dissemination for research use is the norm.

C. Industry Affiliate Programs: Join our club

In the middle, the IP management spectrum is populated with agreements that achieve intermediate amounts of IP management and IP rights, including so-called industry affiliate program membership agreements. Industry affiliate programs are formed around areas of specialized expertise.[33]

The contracts focus primarily on access to information and personal relationships as the ultimate deliverables. Since industry membership funds are pooled, when IP rights are developed with the

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[32] Research at Intel, *Enabling Eye Care in Rural India* (2006) <http://blogs.intel.com/research/eyecareindia_%20Final.pdf>.

[33] At Berkeley, several programs currently exist such as sensors and actuators, computer security, hybrid embedded software systems, earthquake engineering, architecture and design, analytical biotechnology, and synthetic biology.

funding, they are usually deployed to the membership on a nonexclusive basis. IP rights are not, however, the primary driver in such contracts. Berkeley establishes such industry affiliate programs in specialized research areas to promote programmatic strengths, including fields emerging at the leading edge, and to attract industry contacts, interest, and input into program research directions. Companies join such programs (through payment of a membership fee) to receive valuable information about the newest developments in the sector, to learn who is performing research of interest, whom to hire (either as an outside consultant or internally, as a full time employee), and to advise top notch research units on the types of problems to be solved in the industry sector, including how and where academics can help.

Industry affiliate program membership fees can provide resources to the programs for research areas that are not well funded by federal granting agencies, including those that fall *between* disciplines. Such funding for cross disciplinary research can have a high impact, as many breakthroughs arise from the interstitial spaces between biology, chemistry, engineering and physics.

D. Corporate Sponsored Research: Bridging the gap

At the other polar terminus of the IP management strategy spectrum (opposite gifts), corporate sponsored research agreements are decidedly IP-centric. Industry commonly sponsors research under this model when it wishes to fund a project at the University and then license the corresponding IP rights, usually under an exclusive license. Corporate sponsored research agreements therefore describe in great detail the manner in which IP rights to inventions developed under the sponsored project are managed and deployed.

The University retains ownership of IP rights made by its employees and those arising from use of University facilities. In exchange for funding the project (which includes an appropriate indirect cost rate), the corporate sponsor typically receives the first right to obtain an exclusive license to commercialize the rights.[34] The contracting process starts when the industrial sponsor and the laboratory to be funded mutually agree on a "scope of work" for an appropriate project to be performed, along with its corresponding budget. Given that students, faculty, postdoctoral fellows, and other research personnel perform the research using University facilities and resources, the funding supports basic, academic research that will be published in peer reviewed journals. Furthermore, the University will own the IP rights and data that arise from the sponsored work, but sponsors will typically receive a time-limited publication preview window in advance of public disclosure. This preview right (usually 30 days) is allowed solely for the purpose of requesting that the University file patents, and to request removal of any confidential information of the sponsor, that may have inadvertently been included in an intended public disclosure. It does not include the right to edit or to suppress publications in any way.

Although, as noted, corporate sponsors will usually obtain the first right to exclusive licenses, some corporate sponsors, especially in the information technology field, are not interested in *exclusive* rights to commercialize project outcomes. This is especially likely when the products to be commercialized will be short-lived[35], and/or when the project IP constitutes an incremental

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[34] Biotechnology and pharmaceutical licenses are typically exclusive; the information technology industry frequently desires and receives nonexclusive rights, on RAND terms.

[35] When product development times are short, and when a given product life cycle is short, a primary market advantage comes from early market entry. Such a non-exclusive license strategy allows any of the sponsor's competitors to obtain the same license rights, but when this strategy is elected, the sponsor has determined that it does not require an exclusive license

improvement over substantial prior art. Nonexclusive licenses are also preferred in many industries when the project IP will be used in a manufacturing process that is not itself a commercial product to be sold under license, including software. Rather, these sponsors are interested in freedom to operate, i.e., in not being blocked by the IP created in the project. In those cases, the sponsor is well served with a *non-exclusive*, and even a non-exclusive, royalty-free (NERF) license.[36]

Corporate sponsorship of research at the University is a good value for industry, compared to the cost of resourcing the same work internally, or outsourcing to a contract research organization. For example, a sponsor with an interest in next-generation nanotechnology materials gains access to world class expertise, obviating the need to try to replicate the equipment and expertise in-house at the company, where wages and overhead rates will likely be higher than on campus. The University of California's matching grant program,[37] which matches the sponsor's contribution dollar-for-dollar, sweetens the pot even more. Since it is available to California companies, this arrangement helps to ensure that the State's investment spurs economic development in California's knowledge economy.[38]

These arrangements can be made even more efficacious. Sponsored research "master" agreements are utilized when a single corporate sponsor wishes to fund research in a technological area in multiple laboratories but at different times, and in support of different sets of employees. Master agreements obviate the need to negotiate new contracts for each project. The terms of the master agreement are triggered when a new project scope of work (and its budget) are approved by the sponsoring company and the university. The master agreement approach reduces transaction costs and saves time by normalizing certain variables such as report and accounting procedures for a given sponsor. For example, a single, master (investigator-initiated) clinical trial agreement helped to establish a new clinical optometry research center at Berkeley, and master agreements with companies in the automobile and chemical industries have supported laboratory research that had not been funded by corporations in the past.

As with all University contracts, corporate sponsored research agreements must preserve the mission and goals of the University, while providing an appropriate *quid pro quo* for the corporate sponsor. From the company's perspective, this means receiving timely research and accounting reports, and the opportunity to commercialize products based on IP developed in the project. When research outcomes are not relevant to commercial products *per se*, the corporate sponsor still derives a commercial benefit from the project, such as an enhanced manufacturing technique that increases efficiency, or a process that eliminates or modifies one or more steps along an entire value chain.

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with all of the attendant costs, specific diligence and comprehensive commercialization requirements, and obligations, nor does it need an exclusive market position.

[36] When NERF licenses are granted the following factors are considered: a) written consent of the inventors and authors, b) the nature of the invention and the potential market, c) ensuring public benefit, such as by retaining shop rights to practice the invention on our own behalf and to allows in the nonprofit sector to do the same, and by appropriately defining the licensed field-of-use and licensed territory, d) university patent costs (avoidance of an obligation to perfect IP rights that are granted under a NERF license unless costs are reimbursed), e) possible tax-exempt bond funding considerations and f) fair valuation, which is not limited to cash remuneration.

[37] The University of California Discovery Grant, <http://ucdiscoverygrant.org/welcome.asp>.

[38] The Discovery Grant currently funds research projects in the fields of: biotechnology, communications and networking, digital media, electronics manufacturing and new materials, information technology for life sciences, energy, health and wellness, and nanotechnology.

From the University's standpoint, the paramount issues are retention of the right to continue to perform research in an open, academic environment and to publish its findings. The manner in which IP rights can be granted to the sponsor in keeping with our principles is also important.[39] When exclusive IP licenses are granted to an entity, we always reserve specific shop rights for the University and for others in the private sector, to practice the invention for our own purposes. Exclusive licenses also require diligent commercialization of the licensed rights in the licensed field of use, in sufficient quantities to meet the market demand. Thus, even the act of granting an exclusive license under this contract model preserves academic freedom and the terms are consistent with our overarching goal of deploying IP rights for societal benefit.[40] IP rights management in the academic sector is multifaceted because scrupulous drafting and unambiguous definitions are required to preserve options for future funding for the laboratory; protect students; preserve the university's tax-exempt status; fulfill our obligations to other sponsors (including the federal and state government when federal or state funding is utilized); inform affected researchers of the terms and conditions of the award; address public benefit concerns, such as providing access to results created by a public institution; and administer the award effectively and efficiently. Complexities also arise from the need to consider export control issues and such other aspects of research administration as conflict-of-interest management, animal care and use, human subjects protection, and environmental, health and safety concerns. These issues must be addressed before a contract can be signed, potentially lengthening the time to execution. When projects are collaborative, involving an industry visitor, or when more than one site is performing the work (through subcontracts), complications can arise as well. None of these is insurmountable, but all nevertheless take time, require coordination, and occasionally, require written exceptions to university policy in order to implement.

Industry-university sponsored research agreements as a transaction type, have been criticized as being arduous and time-consuming to transact, resulting in frustration, loss of good will, and implicating huge opportunity costs to research, including redirection of corporate support overseas.[41] Initiatives such as the University-Industry Demonstration Partnership, which is sponsored by the National Academies and the Government-University-Industry Research Roundtable, are working on a national level to streamline and add value to collaborative partnerships between industry and academia by developing contract negotiation tools. At the very least, these should accelerate time to agreement, and could also serve as a training tool and a repository of solutions that have been efficacious in the past. The Bay Area Science and Innovation Consortium (BASIC)[42] has been pursuing similar goals under strong leadership by Hewlett-Packard.[43]

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[39] University of California Technology Transfer, *Principles Regarding Rights to Future Research Results in University Agreements with External Parties* (Aug. 26, 1999) <http://www.ucop.edu/ott/genresources/082699a.html>.

[40] Carol Mimura & Beth Burnside, *How Academic Freedom and Academic Principles are Preserved in Sponsored Research Agreements with Industry* <http://academic-senate.berkeley.edu/pdf/Academic_freedom_sponsored_research_final1.pdf>; *University of California Technology Transfer Program: Mission* <http://www.ucop.edu/ott/genresources/ttprog.html#A>.

[41] Marrilea J. Mayo, *White Paper: Introduction to the UIDP* <http://sites.nationalacademies.org/pga/uidp/PGA_049074>.

[42] See Beth Burnside & Lou Witkin, *Forming Successful University-Industry Collaborations: Replacing Adversarial Dialogue with Engagement can Bridge the Cultural Divide*, 51 RES.-TECH. MGMT. 26 (2008).

[43] See Wayne Johnson, *The Collaboration Imperative*, *in* UNIVERSITIES AND BUSINESS: PARTNERING FOR THE KNOWLEDGE SOCIETY 99 (Luc E. Weber & James J. Duderstadt, eds., 2006). "Over the past 3 years, HP Labs' Wayne

At Berkeley in IPIRA, when complicated contract negotiations arise that will certainly require significant deviation from the norm, snippets of text can be excerpted from existing agreements, to be spliced as a substitute clause, but *de novo* drafting by creative, broad-minded, and solution-oriented staff from diverse professional backgrounds will always be essential to fuel the research enterprise. It will always be necessary to tailor a contract to fit a deal, not the other way around. Boilerplate approaches and a static menu of contract choices can serve as basic model agreements, and help map a scenario to a location along a continuum of *engagement types*, but new and innovative contracts at the industry-university interface must continue to evolve to address innovations in the partnership landscape. At the end of the day, we have as many variants in contracts and in industry alliance types as the nature of collaboration produces. Certainly, transactions could be largely automated, obviating the need for negotiations, but if that were the strategy, no one would be served. Unquestionably, personal interaction and cultivated relationships are crucial to the contracting process. Projects cannot be reduced to words without first communicating and understanding the underlying research, the big picture and the ideal outcome. Investment in appropriate staffing of university contracting is foundational to the innovation cycle. From a management perspective, leaders must create and nurture a culture of flexible and creative forms of industry-university contracting. They must facilitate disruptive breakthroughs such as novel public private partnerships and product development partnerships. The future vitality and interconnectivity of the innovation ecosystem depends on bold advancements in contracting.

E. Corporate Sponsored Research on a Grand Scale: "Corporate labs disappear, academia steps in"

Even further along the IP management spectrum is a new public-private alliance model, as exemplified by the ground-breaking agreement between oil giant BP and Berkeley.[44] Berkeley teamed with stellar research collaborators, the Lawrence Berkeley National Laboratory (LBNL) and the University of Illinois at Urbana-Champagne (UIUC), to win a global competition for the award. Funding and obligations flow down from the agreement to LBNL and UIUC through subawards.

The deal, creating a new Energy Biosciences Institute, (EBI),[45] brings an unprecedented amount of funding and resources to the university-industry interface in order to advance alternative energy research.[46] The agreement is drafted to implement a common goal of stimulating exploratory research in

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Johnson has led a regional effort sponsored by the Northern California Bay Area Science and Innovation Consortium (BASIC) to address intellectual property (IP) issues hindering research collaborations between industry and universities. Through these efforts, the BASIC IP team has developed various models, practices, and frameworks to enable timely, successful contract negotiations. An example of this work is the Sponsored Research Interaction Process (SRIP) model, which is designed to help companies and universities navigate the complex landscape of IP contract negotiations. This model may be found at www.hpl.hp.com/research/ur/images/srip.pdf." HP Labs Open Innovation Office, <http://www.hpl.hp.com/open_innovation/collaboration/ip/basic.htm>

[44] See Bonnie Abzab Powell, *"Our Generation's Moon Shot": Announcing the Energy Biosciences Institute*, U.C. BERKELEY NEWSCENTER (Feb. 1, 2007) at <http://www.berkeley.edu/news/media/releases/2007/02/01_EBI_press.shtml>.

[45] Energy Biosciences Institute Begins Ground-Breaking Research Into New, Cleaner Sources of Energy (Berkeley NewsCenter issued Nov. 14, 2007) (available online at <http://www.energybiosciencesinstitute.org/index.php?option=com_content&task=view&id=110&Itemid=122>). See also <http://www.energybiosciencesinstitute.org>.

[46] Eli Kintish, *BP Bets Big on UC Berkeley for Novel Biofuels Center*, 315 SCIENCE 747 (2007).

all aspects of energy bioscience. Results are to be taken up expeditiously and commercialized by industry, including by start-up companies. Discovery is hastened through cross-disciplinary collaboration. The EBI is structured to allow scientists from diverse fields to work in close proximity to one another so that everyday interactions will encourage physicists to solve problems of biology and chemists to solve engineering dilemmas.[47] Agricultural economists, lawyers, as well as public health and public policy experts also have a role to play in future commercial approaches, as they will determine everything from the effect of feedstock selection for biofuels on food crops and land-use considerations world wide, to economic implications of biodiesel, and the socioeconomic impacts of creating a new bioenergy industry hub in Northern California.[48] The multi-pronged research approach in the EBI is evident in some of the results from the first year of funding.[49]

The contract is essentially an oversized sponsored research agreement with a governance structure and a real estate component (a lease).[50] The parties are BP and Berkeley, UIUC and LBNL receive funding through subawards. It operates as a master agreement under which individual projects commence when specific, simple "implementing letters" documenting the scope of work and its budget are signed.[51] The agreement allows the EBI executive committee, a predominantly academic body, to recommend funding for selected projects through a grants-making program involving peer review. Project proposals are invited through an open call for proposals at all three academic collaborator sites. The entire slate of recommended projects is proposed to the governance board. The governance board either accepts the slate as a whole, or rejects as a whole, along with its corresponding budget. The board has no power to cherry pick from the crop.

Possibly as a bellwether of what the industry-university interface will increasingly resemble as collaboration models continue to be engineered to accelerate innovation, the EBI consists of both an open and a proprietary component.[52] This structure acknowledges that inventions conceived by academia are a far cry from being a commercial product. The process by which publishable results are

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[47] *EBI Annual Report 2008: Bioenergy* <http://www.myvirtualpaper.com/doc/Institute-for-Genomic-Biology/EBIAnnualReport2008/2009030902/>.

[48] Lisa Margonelli, *Start-Up U*, CAL. ALUMNI (2007) at <www.alumni.berkeley.edu/california/200709/margonelli.asp>.

[49] A recent "life cycle impact" study from the EBI's Life-Cycle Environmental and Economic Decision-Making for Alternative Biofuels programs calculated that replacement of gasoline with biofuels as a transportation fuel will lower toxic emissions and improve human health, especially in cities. Improved health in this study was calculated using disability-adjusted life years, or DALYs. Despite having legions of engineers on staff at BP, and BP's long experience in the oil and gas sector, partnering with institutions that can bring the full range of academic expertise to bear on the sustainable development of biofuels was necessary and strategic. See Lynn Yarris, *The Coming of Biofuels: Study Shows Reduced Gasoline Emissions Will Benefit Human Health*, Berkeley National Laboratory News Center (May 27, 2009) at <http://newscenter.lbl.gov/feature-stories/2009/05/27/biofuels-and-human-health/>.

[50] *Energy Biosciences Institute: Highlights of the Master Agreement*, UC Berkeley NewsCenter (Nov. 14, 2007) <http://www.berkeley.edu/news/media/releases/2007/11/14_ebi-contract.shtml> and the full contract is available at <http://www.energybiosciencesinstitute.org/images/stories/pressroom/FINAL_EXECUTED_11-14.pdf>.

[51] Carol Mimura, *Intellectual Property and Contract Considerations in the EBI*, EBI Forum Presentation (Mar. 19, 2007) <http://www.energybiosciencesinstitute.org/dmdocs/3-19-07-EBI-Forum-Mimura.pdf >.

[52] G. Pascal Zachary, *Corporate Labs Disappear. Academia Steps In.*, N.Y. Times, Dec. 15, 2007 at <http://www.nytimes.com/2007/12/16/business/16ping.html>.

brought to the point of practical application is not trivial–the road to commercialization is long, steep, and full of dead ends, switchbacks and obstacles. Huge investments of time and capital investment are required to meet the energy needs of even a small portion of energy consumers. A key hypothesis in the EBI is that such juxtapositions will shorten time to commercial uptake and deployment. Real-time feedback can avoid dead ends and create synergies of a scale that cannot be attained under conventional funding arrangements, including series of traditional, bi-lateral contracts. The beauty of the strategy is that funding an emerging discipline under an open call proposal approach ensures that unexpected outcomes will arise. In this paradigm, speculative, disruptive research will not be summarily dismissed by entrenched or top-down notions of how to achieve outcomes. Each party has much to learn from the other, each understands that the long, 10 year term of the agreement means that the overarching relationship is crucial to staying on track for the duration of the award.

The EBI is headquartered at Berkeley and has a satellite facility at the University of Illinois (through real estate leases). In the open component, basic, academic research takes place as usual, results are owned by the relevant university, and all results are published. In the adjacent proprietary component, BP operates an applications laboratory in rented space, staffed by its own personnel. Results in the proprietary component are owned by BP, and may be kept confidential, at BP's sole discretion. BP employees in Berkeley, Lawrence Berkeley National Laboratory and University of Illinois space (outside of the proprietary component) are subject to the visitor agreements of those institutions.

The academic institutions own inventions made by their employees with BP funding. However, BP will receive no less than a non-exclusive, royalty-free license to project IP rights in the energy field. BP may instead elect to negotiate an exclusive license, but the fee is capped and cannot exceed $100,000 per year.[53] Under a "bonanza clause," which applies in the event that a truly exceptional invention arises that is an extraordinary commercial success, the parties agree to enter into good faith negotiations for an adjustment to the license consideration. IP created in an approved and funded project by at least one employee of BP, and one or more of the academic institutions, is to be jointly owned. Background IP rights (to the extent they are available) are also to be licensed to BP to the extent these rights are needed by BP to practice project IP under license.

EBI funding is also being used to create seven new faculty positions at Berkeley and three at the University of Illinois as well as educational programs and symposia on many aspects of energy biosciences.[54] Cumulatively, the award delivers much more than the typical *quid pro quo* for the University (and its academic research partners) under a sponsored research agreement and illustrates the vast impact that BP's vision and largess can bring to the field. The agreement was recognized as a "Deal of Distinction" in 2008 by the Licensing Executives' Society, an international professional organization. The Society praised it as "unique in scope and represent[ing] an innovative model for collaboration between academia, government labs and industry."[55] Such triple helix collaborations

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[53] By way of comparison, fewer than 4% of all inventions in the UC system earn over $100,000 per year.

[54] These faculty positions receive Berkeley's standard $1M in startup funds and $500,000 in renovation funds. The positions are created, searched, compensated, and managed by the hiring departments and the academic Senate, as would be the case for any new faculty position.

[55] *Licensing Executives' Society Announces 2008 Deals of Distinction™ Awards* (Oct. 22, 2008) <http://www.docstoc.com/docs/2079049/Licensing-Executives-Society-Announces-2008-Deals-of-Distinction>.

between the government, academia and industry sectors represent one model that should prove invaluable in maintaining U.S. competitiveness and reinvigorating state and national commitments to innovation.[56]

II. Socially Responsible IP Rights Management Program: Helping the World's Poor

Berkeley's Socially Responsible Licensing Program (SRLP) has yielded some insights into additional ways that nuanced IP rights management can achieve surprisingly fruitful outcomes.[57] In contrast to the previously described contract models, contracts in the SRLP map to multiple positions along the IP-rights spectrum.

The SRLP promotes widespread availability of technology and healthcare in the developing world at affordable prices.[58] The program strives to maximize the social impact of Berkeley-generated innovations, frequently on a royalty-free or at-cost basis to induce investment in a variety of high-impact projects, such as therapeutics or diagnostics for tropical and neglected diseases, and technological solutions, such as water purification and crop disease resistance in low- and middle-income countries.[59] To date, the program includes IP contracts in the fields of therapeutics, diagnostics, vaccines, sanitation, agricultural biotechnology, and even consumer electronics.

One goal of the program is to create combinations of contract levers *and* business models that deliver solutions to underserved populations both directly, and by stimulating investment by others. The negotiation and drafting challenges are more complex than in the contract models described above because in those situations, the business model is a given, or it is, at the least, well understood. Contract approaches used to date, include the following strategies (in various combinations): nonassertion of IP rights, royalty-free licensing, forbearance of patenting outside potentially lucrative markets (Japan, Canada, Europe, Australia and the United States), mandatory sublicensing to address unmet needs and/or to achieve a price point, field-of-use and licensed territory restrictions, segregation of for-profit from non-profit markets and geographies, tiered pricing within a given country, license conversion options, royalty sharing provisions, attribution, and diligence provisions. The program relies on common mechanisms for implementing the contracts, such as informed consent from inventors and authors, and provisions for third party rights, such as those of the federal government.

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[56] *EBI Named Tech-Transfer "Deal of Distinction* (U.C. Berkeley Media Relations Press Release issued on Oct. 22, 2008) (available online at <http://berkeley.edu/news/media/releases/2008/10/22_mimura.shtml>).

[57] See THERESA WIZEMAN, SALLY ROBINSON, & ROBERT GIFFIN, FORUM ON DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION, BREAKTHROUGH BUSINESS MODELS: DRUG DEVELOPMENT FOR RARE AND NEGLECTED DISEASES AND INDIVIDUALIZED THERAPIES: WORKSHOP SUMMARY 57-61 (2008) at <http://www.nap.edu/catalog.php?record_id=12219>.

[58] Carol Mimura, *Technology Licensing for the Benefit of the Developing World: U.C. Berkeley's Socially Responsible Licensing Program*, 18 J. Ass'n Univ. Tech. Managers 15 (2006) (reprinted in 21 Industry and Higher Education 295 (2007)).

[59] See Barry Bergman, *Research Patently in the Public Interest*, BERKELEYAN (Dec. 6, 2005) at <http://www.berkeley.edu/news/berkeleyan/2005/12/02_licensing.shtml>.

In drafting contracts under the SRLP, we face the perennial challenge of finding strategies and drafting contracts that are effectual, in terms of access and benefit sharing, and that will survive challenge. The University interposes specific requirements in these contracts. We have, however, been cautioned by industry (and others) that some of these obligations can have adverse consequences.[60] The NIH's experience with Cooperative Research And Development Agreements (CRADAs) in the 1990's is instructive in this regard. It revealed that adding teeth to contracts upfront—such as by alluding to a future obligation to provide products at "reasonable cost"—can deter investment.[61] We have found that crafting text during each negotiation, and insightful negotiation, is better than stating in advance exactly what the text will/should look like. This is not surprising, since an alignment of goals and the articulation of a win-win scenario for both/all parties, must precede the act of putting pen to paper.

The SRLP initiative has demonstrated that when nontraditional metrics are employed to measure the efficacy of transactions under the program, the opportunity cost in granting royalty-free IP rights in favor of the world's poor is low in comparison to the impact that is achieved.[62] Moreover, direct benefits accrue not only to *Berkeley* in ways that can be measured by traditional metrics such as licenses, patents, research funding,[63] and gifts[64]; they also accrue to the *licensees* that are diligently commercializing Berkeley inventions, including start-up companies.[65] The SRLP has also had a modest effect in the public policy arena.[66] Its influence can be discerned in the IP policy the State of California

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[60] These include reaching a negotiation impasse leading to no deal at all, and thus no drug; as opposed to a "standard" contract that is devoid of pricing and distribution safeguards for the ultimate consumer. Industry pipelines are littered with drugs that fail in clinical trials, or even after approval. If there is no value proposition to justify investment, or if prospects are marginally attractive and will be made even worse due to the imposition of licensing terms that exceed a threshold of uncertainty, then we have little leverage, indeed. In that case, we can at least abstain from filing for IP rights in developing countries and strive to find a compelling combination of incentives and the right partnering structure.

[61] *The NIH "Reasonable Pricing Clause" Experience*, *in* POLICY AND GUIDELINES DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH (July 2001) <http://www.ott.nih.gov/policy/policy_protect_text.html>.

[62] Bennett Daviss, *Malaria, Science and Social Responsibility*, 19 THE SCIENTIST 42 (2005) at <http://www.the-scientist.com/2005/3/28/42/1/>.

[63] Robert Sanders, *$43 Million Grant from Gates Foundation Brings Together Unique Collaboration for Antimalarial Drug*, U.C. Berkeley Media Relations (Dec. 13, 2004) <http://berkeley.edu/news/media/releases/2004/12/13_gates.shtml>.

[64] *Richard Blum Gives $15 Million to Fund Center to Alleviate Poverty* (UC Berkeley Media Relations Press Release issued on Apr. 19, 2006) (available online at <http://berkeley.edu/news/media/releases/2006/04/19_blum.shtml>); Amy DerBedrosian, College of Letters and Science UC Berkeley, *$1.8 Million Gift will Advance Health Research* <http://ls.berkeley.edu/?q=node/499>.

[65] See, e.g., The Sustainable Sciences Institute, *The Immunosensor – Low-Cost Disease Diagnostic Platform* <http://www.ssilink.org/index.php?option=displaypage&Itemid=84&op=page&SubMenu=>; *Aquaya to Conduct Study of End-User Preferences and Usage of Household Water Treatment Technologies in Rural Western Kenya with UC Berkeley* (Aquaya Press Release issued on Mar. 15, 2007) (available online at <http://www.aquaya.org/news.php#031507>); Two Blades Foundation, http://www.2blades.org/; *OneWorld Health, Amyris Biotechnologies and Sanofi-Aventis Announce Development Agreement for Semisynthetic Artemisinin* (Joint Press Release issued on Mar. 3, 2008) (available online at <http://www.artemisininproject.org/documents/PR_030308.pdf>); Kelly St. John, *UC Berkeley Samoa Makes Deal with Researchers. University Will Share Profits if Cloned Gene Works in AIDS Fight*, S.F. CHRON., Oct. 1, 2004.

[66] See Ericka Check, *Universities Urged to Do More for Poor Nations*, 444 NATURE 412 (2006); Declan Butler, *Neglected Diseases Lost in Translation*, 449 NATURE 158 (2007).

adopted in its Stem Cell Research and Cures Initiative,[67] and also in the advice a core group of universities issued in a White Paper on the licensing of university technology:

> "Point Nine: Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world."[68]

To stimulate and support investment by licensees and philanthropic foundations with humanitarian goals, certain contracts forgo royalty payments to Berkeley on sales in defined regions. This strategy has allowed, for example, the Sustainable Sciences Institute to raise R&D funding from the Acumen Fund for Social Investment, the Doris Duke Charitable Foundation, and others, to develop a portable diagnostic for dengue fever.[69] Two Blades Foundation is developing pesticide-free crops under license, including subsistence crops with durable disease resistance, to benefit "less developed" agricultures. The license waives royalties on sales in "least developed countries" but royalties will be paid on sales in other regions. Licensees that are willing to provide licensed products for free or at minimal cost in the poorest countries may expect to be able to sell products in countries with large middle classes at a profit under tiered pricing structures.[70] Tiered pricing is consistent with the goals of the program as long as the neediest target populations receive the lowest prices or the negotiated prices. An existing example of contract language to address tiered pricing involves a definition of economically disadvantaged population "strata" within a given country according to income level (that is distinct from the definition of economically disadvantaged countries); coupled to a conversion option right (that would allow the licensee to convert from one pricing obligation to another, if a given group graduates from one income level to another). This construct allows both parties to acknowledge the need to preserve market incentives for the licensee, while mutually agreeing on a target market that will be entitled to the lowest prices.

Royalty-free licenses that are associated with research funding have also attracted investment, for example, to engineer more nutritious "biofortified" sorghum with Africa Harvest Biotechnology

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[67] *Joint Informational Hearing of the California State Health Committee Senate Subcommittee on Stem Cell Research Oversight "Implementation of Proposition 71: Options for Handling Intellectual Property Associated With Stem Cell Research Grants* (Oct. 31, 2005) <www.law.berkeley.edu/institutes/bclt/stemcell/articles/israel_prop_71_ip_transcript.doc>. See also Heidi Ledford, *IP: Ideas for Purchase?*, BERKELEY SCI. REV. (2006) at <http://sciencereview.berkeley.edu/articles.php?issue=10&article=IP>.

[68] *In the Public Interest: Nine Points to Consider in Licensing University Technology* (Mar. 6, 2007) <http://otl.stanford.edu/industry/resources/whitepaper-10.pdf>.

[69] *Berkeley Intellectual Property Office Calls SSI "Model"* (Sept. 14, 2005) <http://www.ssilink.org/index.php?option=news&task=viewarticle&sid=13&Itemid=101>; Maleeha Mohiuddin & Omer Imtiazuddin, *Socially Responsible Licensing: Model Partnerships for Underserved Markets* (Mar. 2007) at <http://www.acumenfund.org/uploads/assets/documents/Acumen%20Fund%20-%20Socially%20Responsible%20Licensing%20-%20July%202008_kYAIb8kF.pdf>.

[70] This is an issue in every negotiation when Brazil, Russia, India, and China are discussed in the context of affordable pricing.

Foundation International for charitable objectives,[71] and in the area of sanitation, to bring clean water to areas of need with the Aquaya Institute.[72] They have also been granted to address pernicious diseases of the developing world where there are no profit drivers to motivate commercial investment.

For example, a public-private product development partnership between U.C. Berkeley, Amyris Biotechnologies, Inc., the Institute for One World Health (iOWH) and sublicensee sanofi-aventis is close to deploying a low-cost malaria drug. With $42.6M in funding from the Bill and Melinda Gates Foundation, this initiative has created semi-synthetic artemisinin from microbial fermentation, to stabilize the world's supply of this malaria drug component that heretofore, had been purified from a botanical source. The synthetic-biology derived artemisinin, will reduce the cost of existing artemisinin-based combination therapy, and will treat up to 200 million malaria sufferers worldwide.[73] The initial contract structure underlying this partnership consisted of a three-party collaboration agreement between Berkeley, the iOWH, and Amyris Biotechnologies, Inc, and two IP license agreements from Berkeley to each of iOWH and Amyris. Berkeley's license to the iOWH was field-of-use limited to malaria therapy only, and the licensed territory included approximately 90 malaria-endemic countries (i.e., the developing world). The license to Amyris granted the malaria field of use and all other commercial applications of the same IP right (to make isoprenoid compounds using "synthetic biology for a variety of uses); and its licensed territory includes all countries outside of the iOWH licensed territory (i.e., the developed world). The license structure enabled Amyris to follow a dual commercialization strategy; a short term, non-profit strategy under the malaria field-of-use (with foundation funding), and a long term for-profit strategy under all other fields of use (with venture capital funding). Its contribution to the malaria project ended in December, 2007. In the performance of that project, Amyris was exempt from payment of royalties to Berkeley, but it will pay a fair royalty on products outside of the malaria field-of-use.[74] Amyris reduced the invention to practice by making artemisinin for the malaria drug with its non-profit hat on, and then applied the same platform technology to pursue for-profit commercial goals, including biofuel applications with its commercial hat on.[75]

Through a sublicense from iOWH to sanofi-aventis, sanofi-aventis will run the anchor lap in a multi-party, 6.5 year relay race to a cure, as the partner that ultimately commercializes the drug. Unlike the iOWH, however, sanofi-aventis is a for-profit multinational pharmaceutical company, thus this deal

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[71] African Staple Crop Gets a Boost (U.C. Berkeley News Press Release issued on Apr. 10, 2006) (available online at <http://www.berkeley.edu/news/media/releases/2006/04/10_sorghum.shtml>); *Africa Harvest Projects: Africa Biofortified Sorghum (ABS) Project*, AFRICA HARVEST <http://africaharvest.org/files/projects02.pdf>.

[72] *AQUATEST: low-cost water quality diagnostics* <http://www.aquaya.org/impact_aquatest.php>.

[73] *OneWorld Health, Amyris Biotechnologies and Sanofi-Aventis Announce Development Agreement for Semisynthetic Artemisinin* (Joint Press Release issued on Mar. 3, 2008) (available online at <http://www.artemisininproject.org/documents/PR_030308.pdf>)

[74] *Improved Production of a Natural Product Treatment for Malaria: OneWorld Health, Amyris, and the University of California, Berkeley*, *in* EXECUTIVE GUIDE TO INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 46-49 (2007) at <http://www.iphandbook.org/handbook/case_studies/csPDFs/casestudy20.pdf>.

[75] *Jay Keasling Receives Inaugural Biotech Humanitarian Award* (Biotechnology Industry Organization Press Release issued on June 1, 2009) (available online at http://bio.org/news/pressreleases/newsitem.asp?id=2009_0520_02); *Amyris Biotechnologies, Inc. Honored by the World Economic Forum as a Technology Pioneer for 2006*, PR NEWSWIRE, Dec. 5, 2005 at <http://www.biospace.com/news_story.aspx?NewsEntityId=4061>.

furnishes an opportunity to analyze the business incentives underlying "Big Pharma's" commitment to commercialize a neglected, tropical disease therapy that does not have a market in developed countries. Sanofi-aventis's support shows that an enlightened and socially responsible pharmaceutical company can derive an economic return on its investment in at least the following ways:

a) by receiving a "priority review" voucher from the U.S. FDA;[76]

b) by receiving assistance in navigating the drug regulatory systems in endemic countries from agencies and officials that are motivated to address unmet needs (these experiences are inherently valuable as many drug regulatory systems are opaque and formidable to outsiders);

c) by establishing in-country market presence once the drug is approved (market presence and market entry into a given country are inherently valuable, and will scale, as additional products find demand there);

d) by extracting value in the category of social return on investment (enormous and valuable goodwill, including reputational gains, are bestowed on any company that invests in neglected tropical diseases).

Employee satisfaction and retention can also motivate companies to invest in neglected diseases. Valued researchers increasingly request the opportunity to devote their "free time" to projects that will not make a profit for the company, but will benefit the world's poor. We have recently learned that two drug development companies in our innovation network are motivated to allow their researchers certain time allotments and company laboratory resources to work on a neglected disease target. Management in these companies expect to resource the projects on a "no profit, no loss" basis.

U.S. antitrust considerations have been a frequent concern to various collaborators and licensees, but to date, we have not had to reengineer a basic deal structure solely to address that point. In this context, legal counsel typically analyzes whether or not pre-determination of price constraints to achieve broad access in the developing world, would be deemed to be anticompetitive. Since our goal is to provide access in areas where the licensed product is not currently available or is too expensive, our impact in that region is likely to be found pro-competitive. We carefully craft specific licensed fields of use and define licensed territories in our contracts so as not to fix prices where sales occur under developed-world norms.

As a licensor, Berkeley is faced with the challenge of stimulating uptake and ensuring dissemination when we are neither involved in the end-user transaction, nor in a position to dictate how every business decision that affects pricing is made, after an agreement is signed. In nearly all of Berkeley's exclusive license and option agreements (and most in the SRLP) a "mandatory sublicensing" or "comprehensive commercialization" requirement allows us to ensure that if new and possibly unanticipated uses of a licensed technology are discovered, a given exclusive license does not prevent

[76] These vouchers, which are granted to companies that invest in prevention or treatment of a neglected tropical disease, permit the recipient to expedite Food and Drug Administration's review of a drug application. They may be used by the recipient for the review of a future application (for a new chemical or biological process) or they may be sold to another entity. It is estimated that the value of reduced FDA approval time (and earlier introduction to the market) can be worth hundreds of millions of dollars, see Food, Drug, and Cosmetic Act § 524, 21 U.S.C. §360n (2008).

future investment to fill an unmet need. The underlying motivation is that when the university grants a broad exclusive license we must have a mechanism to ensure that the comprehensive market demand is met. As future, perhaps unanticipated, new uses arise we have an obligation to address new market niches for the public good. This is especially important when our inventions are developed using U.S. federal funds and when an enabling technology has many potential applications. The clause essentially states that if we become aware of a new use that our licensee is not addressing, or if a third party approaches us for the (licensed) rights in order to develop "a new use for the licensed IP right or other unmet need," then we ask our licensee to inform us within 90 days if it will: (a) develop the new application on its own, or (b) grant a sublicense to the third party. If the licensee chooses to develop the new application then it must diligently undertake the new development and report such progress to us. The clause has also been used to drive a licensed product to the lowest possible price, by replacing the trigger of a "a new use or unmet need" with "*for free or at cost*" Under the latter trigger, a third party that can offer prices lower than those of the existing licensee may be granted a sublicense—unless the licensee is willing to lower its prices to the same level.

Since 1996 we have found that most licensees share our desire to meet the market demand, and view the approach as being tantamount to free and ongoing market research regarding the invention's full commercial potential. We have agreed to many variations of the mandatory sublicensing clause to fit various situations. It exists in at least four agreements with large companies, including three large multi-national corporations. We have invoked the clause in at least two situations with different outcomes. It is impossible to opine as to whether we would have been able to negotiate access to a technology application covered by the previously licensed rights if the clause had not been present from the start.

Open source principles and licenses such as those that have been used extensively in the information technology industry can also speed delivery of our discoveries to the global community and assure that they remain accessible. This is especially true for software and research tools that do not require substantial industry investment to actualize. For example, Creative Commons offers a menu of flexible copyright licenses (including analogues of those under Science Commons) under which copyright protected creative work may be disseminated quickly and easily.[77] Open publishing services such as the Public Library of Science provide free and broad access to medical publications.[78] Public databases, such as the biological data repository created by a worldwide consortium called the haplotype mapping project provides unrestricted access to data.[79] Other peer-production strategies include the Rosetta software commons,[80] under which high-resolution protein prediction and protein design software is shared openly to accelerate collaborative research including drug design, and ThinkCycle,[81] which designs engineering solutions for health and environmental projects in underserved regions by drawing from a global network of online contributors. These strategies can complement and can be

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[77] See http://creativecommons.org; http://sciencecommons.org/.

[78] See http://www.plos.org/.

[79] *A Haplotype Map of the Human Genome*, 437 NATURE 1299 (2005) at <http://www.nature.com/nature/journal/v437/n7063/abs/nature04226.html>.

[80] See http://www.rosettacommons.org/.

[81] See http://www.thinkcycle.org/.

synergistic to IP license strategies. Commons-based IP sharing models, including patent pools,[82] or technology trusts should continue to be advanced to promote healthcare and alleviate poverty in the developing world.[83]

Of course, another strategy to address global access is to refrain from claiming IP protection for particular discoveries, or to patent only in the developed world. For example, the Drugs for Neglected Diseases initiative (DNDi), a product development partnership, and sanofi-aventis, have successfully employed a no-patent strategy in certain drug development projects.[84] We are patenting and licensing under the SRLP when IP rights are required to induce or justify investment, or to provide other value for a licensee, such as freedom to operate and cross licensing opportunities. As stated above, we believe open source and commons-based innovation can coexist with more "closed" IP and contract-based transactions to achieve common goals. Neither extreme view of how to impose constraints on discovery (entirely "open" vs. entirely "closed") is good for innovation. For example, the agricultural biotechnology industry has been hampered by patent thickets,[85] yet agricultural traits can be destroyed by misuse in a commons. Traits can benefit from preservation efforts, including limited access such as by traditional IP licensing. Moreover, more than a few licensees under our SRLP have surprised us by requesting that Berkeley obtain patent rights when we had expected the opposite; their reasoning is that having IP rights that are licensed under socially responsible terms prevents others from patenting around their invention and deploying those rights under restrictive terms without regard for the world's neediest.

III. Organizational Structure and Philosophy of the IP Management Office

IPIRA was established in 2004 through reorganization of Berkeley's industry contracting units. It was charged with streamlining industry transactions and increasing corporate sponsored research at Berkeley. The restructured unit combines two formerly separate functions. As restructured, IPIRA consists of the Office of Technology Licensing (OTL) and the Industry Alliances Office (IAO), each operating as peer divisions under common management. IPIRA transacts out-licensing of IP rights through the OTL, and through its Industrial Alliances Office, "incoming" transactions, such as corporate sponsored research agreements under which industry provides research funding to the campus. Where under the former system, projects were often regarded as in competition with one another, or one project was seen as achieved at the expense of another, the current system eliminates silos and reconciles goals, thereby encouraging and enabling more and better outcomes.[86] IPIRA promotes success in all aspects of

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[82] *MSF Welcomes UNITAID Patent Pool Endorsement* (Campaign for Access to Essential Medicines Press Release issued on July 9, 2008) (available online at <http://www.msfaccess.org/media-room/press-releases/msf-welcomes-unitaid-patent-pool-endorsement/>).

[83] World Health Assembly, *Global Strategy and Plan of Action on Global Health Innovation and Intellectual Property*, WHA61.21 (May 24, 2008) at <http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf>.

[84] See, for example, the collaboration between sanofi-aventis and DNDi, *Combination Therapy in Global Strategy for Treatment of Malaria* (DNDi Press Release issued on Apr. 7, 2005) (available online at < http://www.dndi.org/press_dossier01.asp>).

[85] *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174 (2003).

industry relations (not just IP licensing) campus-wide by creating a paradigm that offers new definitions of success and new metrics for measuring it. We thus implement a holistic view of what "TT" (technology transfer) means and what it does.[87]

Traditional definitions of "TT"[88] are not consistent with our approach in IPIRA. To us, TT is an ongoing relationship continuum, not just a single transaction. A relationship continuum spans many years. It results from many points of contact, and many engagement types. It is akin to building a pyramid or climbing a staircase, or contributing different sectors of a pie to create a whole. Our networks are essential. We cannot accelerate innovation on our own; rather, our public-private partnerships and product development partnerships demonstrate that we can expedite translational research and bridge funding gaps through creative partnering and flexible contracting.

Success under the relationship model consists of rights transfer and knowledge transfer in both directions (into and out of the university) to enable innovation acceleration, deployment, uptake, and translation. By many measures, the relationship model has borne fruit. By valuing corporate relationships more than any single transaction, utilizing our networks to advantage, and valuing research support as highly (if not more highly) than license revenue, the overall industry dynamic has changed. Cultural and negotiation biases have been reduced, industry and foundation funding have risen dramatically, collaboration types and numbers have increased, barriers to gifting into the university have been lowered, and greater numbers and types of contracts and strategic alliances have been formed. We have also enjoyed reputational gains as a campus that has improved its corporate relations and contracting units.

If the outcome of IPIRA's support of the campus research enterprise is measured only by the numbers of patents, IP license revenue and other forms of licensing remuneration such as equity, then licensing practices will be skewed to favor those outcomes. Under that regime, non-remunerative transactions and free licenses (such as NERFs) would be deemed to be less desirable. Moreover, provision of service to faculty would be relegated to a lower priority, even though it should remain paramount. To avoid that result, we define success differently—we look to the social impact that our innovations have locally and globally, translational efficiency, innovation acceleration, global outreach, uptake, collaboration, sharing, gifts, reputational gains, affiliation, and the numbers and types of partnerships and strategic alliances. This model more easily accommodates industry-sector specific needs and makes available a broad spectrum of IP management strategies. "Alternatives" to traditional IP management strategies (patent pooling, dedication to the public domain, open source licensing,

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[86] Beth Burnside & Carol Mimura, *Re-Engineering the Partnership: Summit of the University-Industry Congress*, The National Academies: Hosted by the Government-University-Research Roundtable (Apr. 25, 2006) <http://www7.nationalacademies.org/guirr/Burnside_Presentation.pdf>.

[87] And we are not just a "tech transfer" office as that term is commonly used. IP Management and Industry Alliances are apt descriptors. Our IP management strategies are designed to promote and support the campus research engine and to deploy our research results for public benefit. Our strategies and philosophy seek to maximize the impact of Berkeley research, with licensing revenue being merely, a secondary outcome among many.

[88] Having an emphasis on IP rights out-licensing.

royalty free licensing, dedication to a technology trust, and various forms of affiliation[89]) are no longer alternative; to us, they are part of the mainstream.

What are the appropriate metrics for measuring research impact when success is defined in this way?[90] We employ a double bottom-line accounting approach in which the social impact bottom line is equally as important as the financial bottom line. In the financial category, we report traditional metrics including numbers of IP licenses, patents, license income, equity and startups. In the social impact category, we report through vignettes such outcomes as reputational gains, neglected or tropical disease research projects funded at the university and in industry, medical costs reduced, lives saved, software distributed under the BSD open source license, research tools shared, collaboration enabled, services provided, knowledge and expertise transferred, and economic impact measures. Because these "soft" metrics are both difficult to capture and quantify and because we do not have an appropriate baseline to which current results can be compared, we obtain help from our many colleagues in economics. For example, they provide estimates of the induced investment in a therapy that cures a tropical disease that, for lack of market incentives in developed nations, cannot attract investment by the biotechnology industry; the value of health improvements conferred by a given therapy;[91] healthcare savings; and savings of other resources.

Still, these calculations are incomplete. While we certainly know that enhancing Berkeley's reputation as an institution that regards social impact is valuable—perhaps more valuable than forgone (speculative) licensing revenue—we cannot readily quantify that value. From a purely practical standpoint, until better metrics are devised, vetted, and adopted by the broader technology transfer community, we will continue to face the problem of how to parlay alternative, "soft" metrics into actual funding for the office transacting social impact licenses. Even if good metrics were devised, there will be difficulties. Entire categories of success will not materialize for many years and they may enter the campus through another portal. For instance, a future gift that is bestowed to advance the campus's dedication to alleviate health and poverty in areas of law, business, health sciences, IP management and public policy, and ethics would fall into this category. Separated both temporally and spatially from a given impetus, attributing such benefits to a particular campus unit would neither be feasible nor productive. At Berkeley, the tracking problem is acknowledged: to compensate for it, IPIRA's operations are supported, in part, by gifts given to the broader campus. But we are in the vast minority of tech transfer offices to be treated in this way.

Furthermore, tech transfer offices cannot unilaterally declare that they are in pursuit of new goals, and henceforth are to be measured according to new metrics. Support must come from the top down, lest conflicting expectations result in failure even before changes are made. We are truly

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[89] Ben Butkus, *Tech Transfer White Paper Authors Hope to Spur Debate, Socially Responsible Licensing*, BIOTECH TRANSFER WEEK (Mar. 19, 2007) <http://www.genomeweb.com/biotechtransferweek/tech-transfer-white-paper-authors-hope-spur-debate-socially-responsible-licensin>.

[90] Good approximations of what we should be collecting by way of appropriate metrics of research impact are reported in UC Berkeley's Economic Impact and Social Benefits, http://www.berkeley.edu/econimpact/, and Better World Project, http://www.betterworldproject.net/index.cfm, a publication of the Association of University Technology Managers. Also the monograph, JIM COLLINS, GOOD TO GREAT AND THE SOCIAL SECTORS (HarperCollins 2005), has a discussion of alternative metrics for the social sciences.

[91] Such as disability-adjusted life years (DALYs) or quality-adjusted life years (QUALYs).

fortunate to have enlightened leadership at Berkeley, a strong tradition of public good research and an *esprit de corps* that encourages social innovation.

Policies are also evolving at the University of California at the system-wide level. This is important, because by one estimate, the collective campuses in the University of California system generate 7% of R&D in the state of California; together, these campuses are a research powerhouse not only in the state, but worldwide.[92] Broad authorities to grant non-exclusive, royalty-free licenses have recently been delegated to the individual campuses and importantly, the historical University system-wide Office of Technology Transfer now reports to the Office of Research within the Office of the President, when formerly it reported to Business and Finance. Impact-driven motivations fueled by the need to contribute, to see the fruits of our labors picked up and used outside of academia, continually challenge us to craft new approaches and solutions and to enable them through policy adjustments and administrative change.

We are not alone in our quest. Other universities are increasingly interested in socially responsible licensing for global health.[93] Thus, we are increasingly sharing approaches and the best practices. Together we can make a difference. We must not fail to try.

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[92] ICF Consulting, *California's Future: It Starts Here. UC's Contributions to Economic Growth, Health, and Culture* (Mar. 2003) <http://www.universityofcalifornia.edu/itstartshere/report/fullreport.pdf>.

[93] Ashley J. Stevens & April E. Effort, *Using Academic License Agreements to Promote Global Social Responsibility*, 43 J. LICENSING EXECUTIVES SOC'Y INT'L 85 (2008).