SOCIALLY RESPONSIBLE LICENSING GUIDE FOR TECHNOLOGY TRANSFER OFFICES

Adoption and Implementation of Socially Responsible Licensing Practices

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Foreword

This guide seeks to provide technology transfer offices with some guidelines on how to implement Socially Responsible Licensing practices when carrying out their IP management & commercialisation activities. This is an easy to understand guide with examples of clauses provided in the appendices. The aim is to translate the theoretical concept of Socially Responsible Licensing into a more practical, easy to implement concept. We hope that this guide will lead to increased implementation of Socially Responsible Licensing practices in an effort to alleviate the problem of access to healthcare technologies in poorer countries.

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Introduction

Although some papers have been published on the topic of Socially Responsible Licensing (SRL) and the topic discussed at meetings and conferences, there has been very little practical implementation by technology transfer offices and their licensees to date, with the result that SRL remains largely a theoretical issue. Technology transfer professionals who are familiar with the concept of SRL might therefore struggle in trying to implement SRL practices. This document seeks to provide some practical guidance in such implementation. In this guide, the concept of SRL is explained, the benefits for adopting SRL strategies are discussed and various SRL strategies are provided, and practitioners are encouraged to take into account issues such as institutional culture, policy and varied perspectives of stakeholders in their implementation.

The Concept of Socially Responsible Licensing

SRL is the licensing of intellectual property (IP) so as to ensure access to health technologies or products for underserved populations at affordable cost, while also seeking to encourage dissemination of know-how in all relevant markets. SRL is a way to leverage IP to accelerate the development of solutions in a manner that leads to optimised access to medicines and other health technologies by populations most in need. Optimised access includes availability, affordability and acceptability of such technologies by the populations in need.

The SRL approach is not intended to affect business transactions in developed countries where significant profits can still be achieved, but rather makes use of parallel strategies to promote access in developing countries. Technology transfer offices (TTOs) can therefore adopt SRL practices and still maintain the profit incentive of commercialisation. SRL is a free market alternative to compulsory licensing, in that the parties can voluntarily agree on licensing terms that will promote access to medicines.

Why Should TTOs adopt SRL Practices

- **To address market failures**

In terms of the free market system, everyone is entitled to participate in business, allowing the markets to determine the price. An alternative option is price regulation by government authorities. In the pharmaceutical industry, the market price of drugs takes into account R&D investment, regulatory and marketing costs, quality control and risk, but it has been alleged that in some instances, excessive prices have been charged. The free market system therefore sometimes leads to inaccessibility of some important drugs in poorer countries, which cannot afford to procure the drugs at the market price. Although generic companies produce cheaper versions of branded products, they are also subject to market forces. Time to market for the introduction of generic alternatives may be increased, and quality may be adversely affected in some cases. Also, companies will most likely not enter markets where there is no perceived economic benefit.

A further aggravating factor is that research priorities are often guided by potential commercialisation benefits. This leads to projects with good prospects of commercialisation being selected that are not necessarily addressing the health needs of poorer countries. Consequently certain types of diseases are not given attention and become what is known as 'diseases of the poor' or 'neglected diseases'. The adoption of SRL practices can serve as one of the means to address these market failures. The concept of SRL attempts to balance issues of economic, social and environmental impact, which are important for ensuring the sustainability of businesses while simultaneously meeting the needs of underserved market segments.

- **To ensure that society benefits from the research outputs of publicly funded research and increase the impact of such research**

Universities and other public research institutions access public funds used to carry out research that is relevant to and addresses the needs of their communities. Publicly funded research should, as far as possible, be in line with the needs of society and commercialisation of such research should also be aimed at addressing these needs. Hence, by adopting SRL practices, universities and public research institutions can increase the impact on society of their research outputs by ensuring that they do not only generate revenues for the institutions and their licensees, but also address societal needs.

- **To adhere to legislative requirements and contribute to overall corporate social investment**

Some countries and funding agencies have legislative or policy requirements that seek to promote SRL practices.[1] For recipients of applicable funding, an SRL approach must be followed. Even where such regulation is lacking, one can also argue that considering the needs of society and putting in an effort to commercialise technologies in a socially responsible manner is the right thing to do. It is an ethical imperative which should be adhered to. If the health needs of society are addressed, the quality of life will be improved and there will be a larger and more productive workforce to build economies, thereby increasing the level of sustainability of communities and companies.

- **To create alternative models of commercialisation and increase the uptake of technologies**

A two-pronged approach to commercialisation can be taken whereby IP is licensed to generate profit for certain territories or market segments, and to address health needs in other territories or market segments, typically in developing countries. In this way, institutions will continue to generate income and recover some of their R&D costs, without preventing licensees from pursuing commercially viable business models, while at the same time increasing the impact of the technologies concerned on society. Methods of commercialisation need to be adapted with changing times and needs. By developing and adopting SRL practices, TTOs will be contributing to the shaping of global innovation systems and providing new ways of working together. Collaboration partners and companies with a higher interest in technologies with social impact will be encouraged to enter into licence or collaboration agreements with the institution adopting SRL practices.

- **To create enhanced reputational goodwill for institutions and their licensees and increase sources of funding**

By ensuring that health technologies are licensed in a manner that addresses the health needs of society, institutions will reap reputational benefits and most likely increase their chances of securing more funding from their existing funders and/or philanthropic funding sources. Also, this approach will respond to concerns from student activists and other interest groups trying to promote the public interest. This will further serve as motivation for researchers working for the public good and wishing to see evidence of the impact of their work on society.

[1] One example is the South African Intellectual Property Rights from Publicly Financed Research and Development Act of 2008 (IPPFRD Act).

Potential Benefits to the Licensee

- **Addressing unmet needs and accessibility issues**

Licensees accepting SRL clauses stand to benefit from entering markets where there is an unmet need and can gain a good market share in these territories, creating new distribution channels, which they can use for other products. By making their products more accessible, such licensees are able to increase the awareness of their brand and create goodwill. These companies can, later on, benefit from the increased positive brand awareness by making more products available in the market, which customers will recognise and buy due to the brand reputation. They can provide non-essential drugs at market-related prices and essential medicines at cost plus a small mark-up and continue to reap the benefits of commercialisation of their products in poorer countries.

- **Mechanism for corporate social investment and enhanced reputation**

Companies are increasingly required to take the triple bottom line approach when doing business. This entails taking the economic, social and ecological considerations into account. Hence, a lot of companies have adopted corporate social investment (CSI) programmes. By adopting SRL clauses companies can meet their CSI obligations and build a positive global reputation. Companies adopting SRL practices also stand a chance of developing or strengthening relationships with policy makers in developing countries, enabling them to have an opportunity to make an input in policy issues they would otherwise have not had.

- **New business models**

Adopting SRL practices can provide the licensee with an opportunity to explore and develop new models of doing business which provide the company with a competitive advantage.

- **Access to regional and national disease expertise**

Regional and/or national experts in particular disease areas are likely to be more willing to collaborate with the licensee if they see that the licensee is committed to creating social impact. Such collaboration will be highly beneficial to the licensee, providing valuable know-how in the particular disease areas and a deeper understanding and prior experience of the local context.

- **Affirmation of industry as responsible steward of IP**

By adopting SRL practices, licensees will affirm that industry is a responsible steward of IP and potentially improve the reputation of industry among global society. A lot of criticism has been directed at industry for only pursuing profits and ignoring the needs of the poor. Adopting SRL practices will demonstrate that industry can champion the process of ensuring that IP monopolies are also used to benefit the less advantaged.

Business Models

Academic research is funded primarily by public or sovereign granting agencies in pursuit of their missions of teaching, research and public service. Technology transfer programs of academic research institutions operate within their institutional missions and pursue several goals when managing institutional IP rights, such as:

- Encourage the practical application of research and research results by the industry sector for the broad public benefit,
- Honour commitments to sponsors of research and other stakeholders,
- Build research relationships with industry to enhance education and research opportunities,
- Stimulate translation of research results through commercial uptake, investment, and deployment,
- Stimulate economic development,
- Ensure appropriate returns on taxpayer and other stakeholder investments that support the research enterprise.

- **The virtuous cycle**

The patent system provides incentives for entities to invest in risky and protracted R&D expenditures. Where profits from the investment are both feasible and expected, the traditional approach to licensing IP rights based on academic research involves finding a licensee with the right qualifications, and requiring them to diligently commercialise goods and/or services so that consumers, including taxpayers (who help fund the academic research enterprise) can benefit. The licensor (research institution and IP rights owner) typically benefits under this strategy through financial remuneration (through license fees and royalties) and its stakeholders (inventors, research departments, institution) also receive a portion of net revenues, thus creating a cycle of investment, invention, deployment, and reinvestment.

- **Market failure and models to traverse gaps in translation**

Where traditional profits are lacking, however, market economics do not drive investment, resulting in market failure. For example, the IP system alone does not induce investment in new innovations for neglected diseases (that afflict many who cannot afford to pay for treatment) and rare diseases (that afflict few, thus comprising a small customer base). When consumers cannot pay for a product, investment is lacking and investment in translational research to develop basic discovery into products does not occur.

The gap between discovery and translation of research results (often referred to as the "Valley of Death") can be bridged by push and pull mechanisms, not all of which are sufficient to bring a given technology to those in need.

New business models, including creative financing, and modified IP management strategies can traverse R&D gaps by finding ways to share risk and apportion rewards.

- **Technologies with applications in the developed and developing world**

How can academic TTOs address situations where a new technology can be licensed into a traditional, profit-driven market and a non-traditional market where profits are not possible to achieve? Such "dual use" technologies can have standard terms and conditions covering products to be sold in developed economies, and modified "humanitarian" terms and conditions for low- and middle income countries. Under the traditional "push model" of academic tech transfer it is difficult, indeed, to stimulate and sustain commercial investment in an early-stage technology under the best market conditions, so the addition of "new" and unfamiliar terms and conditions at the time of IP rights licensing can be difficult to insert. Those developed or co-developed under a "pull model" are more applicable to such tailored contract terms, and/or do not require negotiation of the terms, due to prior arrangements in contracts that precede an IP license (such as collaboration and sponsored research agreements and letters of intent).

Contract terms to implement humanitarian use of a technology in developing countries include:

Definitions of licensed field of use (defininig "humanitarian" or "charitable use"):

- royalty sharing,
- attribution,
- selective patent rights coverage (to encourage generic drug manufacture and other forms of competition to achieve competitive pricing),
- "claw-back" terms (mandatory sublicensing to address unmet needs and/or achieve target price),

- » humanitarian reservation of rights,
- » royalty-free sales (requires informed consent of inventors),
- » separate treatment of for-profit markets from non-profit markets,
- » tiered pricing within a given country (including conversion options),
- » favourable pricing (such as "free or at-cost" terms),
- » "no profit, no loss" definitions,
- » non-assertion.[2]

- **Bifurcated business models and dual commercialisation strategies**

Sometimes a single licensee (or a partnership among licensees) serves both markets, under different obligations to the licensor, following a bifurcated business plan pursing different commercialisation strategies. One pursues for-profit sales (in developed markets) and the other operates under an "at cost" or "cost plus" cap on the sale of products, or operates under a "no profit, no loss" basis (in developing markets). Another form of bifurcation or dual commercialisation strategy achieves enough benefit for a commercial investor from one strategy to offset and justify the lack of profit from the other. For example, profits from developed markets can pay for market entry into developing markets with the aim of deriving a long-term benefit. Examples of these include opening of markets, development channels and distribution networks, navigation of in-country regulatory regimes, access to local know-how, receipt of "incentive vouchers" such as the U.S. Food and Drug expedited review voucher and the U.S. Patent and Trademark Office priority review voucher.

In short, two forms of de-linkage can be used to achieve humanitarian objectives such as affordable pricing including:

1. dissociating the cost of R&D from the sales price
2. deriving an ancillary benefit from a "humanitarian" strategy

Some examples of partnerships that have achieved these objectives are described below:

- **Collaborations and partnerships to traverse funding and R&D gaps**

Basic academic research is sometimes not translated due to several reasons, the largest of which is lack of funding. The risk: reward ratio is highly skewed against commercial applications that do not provide sufficient profit incentives, resulting in non-investment as described above in the description of market failure. In recent years collaborations between academics and those in other sectors have improved the risk: reward ratio by advancing R&D projects through public-private partnerships, public-public partnerships and product development partnerships (PDPs) that share and leverage resources, to focus on translational R&D.

[2] See for example, "Guidance and Clauses" at: http://ipira.berkeley.edu/socially-responsible-licensing-ip-management - refer to Appendix B

In doing so, the progression from discovery to development and deployment is advanced, the value proposition is improved, and translation is "de-risked."

- All such partnerships address:
  - » The partnership structure, including, who are the parties and whether they are for-profit, non-profit or both
  - » Financing of the partnership
  - » Alignment of goals, including finding and retaining incentives
  - » Treatment of property rights, including IP rights
  - » The coordination and timing of participation – how do the various partners enter and exit the partnership?
  - » Which partners are involved in which stages?
  - » What are their respective roles?
  - » How many and what types of contracts are needed?
  - » What are the specific terms and conditions?
  - » How are results delivered, measured and put to use?

In recent years PDPs have arisen in the medical field that are focused on medical solutions for developing countries such as therapeutics, vaccines, and diagnostics. Medical PDPs bridge important gaps in translation by partnering "upstream" with academics and "downstream" with biotechnology and pharmaceutical companies. They are primarily funded by public funders and philanthropic foundations and thus, have missions and goals similar to those of academics in basic research institutions. They bring vital funding, drug, vaccine and device development expertise to partnerships, thereby facilitating translation and expediting commercial outcomes. Other PDPs are focused on agricultural biotechnology outcomes, such as improved crops.

To optimise collaborations between academic researchers and PDPs (and other partnerships) support is needed in terms of both organisational structures (infrastructure, policies) and values (aligning benefit outcomes). Academic norms and academic cultures are slowly changing to reflect a growing desire of researchers (and their institutions) to focus their research results with relevance to global health needs, and ultimately help those in need. Streamlined material transfers, data sharing and access to knowledge and know-how through publications and personnel exchange can all facilitate collaborative research and dissemination of good public assets for public benefit.

Constructs such as the Clinical and Translational Science Award (CTSAs) in the US and dedicated translational research institutes light a way to the future. Relevant "needs-based" research involves a "pull model" of innovation as opposed to the traditional IP rights "push model" and requires at a minimum, institutional contracting offices that go beyond licensing and also include expertise in industry sponsorship and collaboration agreements, plus insight into strategic alliances.

Overview of SRL Strategies

- **Technology selection**

SRL is generally appropriate to certain types of technologies. Those most suited to this approach are technologies which offer solutions to problems in underserved markets, including:

- **Healthcare**

  - » Vaccines, drugs, diagnostics, formulations, cold chain distribution
  - » Agriculture
  - » Renewable/distributed energy
  - » Potable water

- **IP management strategies**

An SRL approach should aim to reduce IP barriers in the target markets where the licensor wishes to see the technology made available. Patent filing strategies should therefore be guided by whether patent protection is likely to promote or hinder availability and accessibility of a technology in a particular market of interest.

Motivation for not filing patent applications
In some cases, choosing not to file patent applications in certain territories can promote availability and affordability of products.

1. Often there is little value to be obtained by patenting in least developed countries.
   - » Where markets are unlikely to be lucrative enough to attract developed country producers to enter, domestic companies can then, in the absence of patent protection in their own country, make use of patent information from other countries as well as other literature, to develop the technology themselves (provided sufficient information is publicly available and that the companies concerned have the necessary capacity).

   - » Where local companies do not have the capacity to take a product to market independently, absence of patent protection can then pave the way for importation of affordable generic drugs.

2. Where technologies are 'enablers' for further R&D, and/or can be used without requiring significant further downstream investment (which is likely to be forthcoming only in exchange for exclusive exploitation rights), patents are often not necessary. Examples where this might apply include:
   - » Research reagents
   - » Drug targets
   - » Certain other research tools

Motivation for filing patent applications

However, in many cases (notably in respect of healthcare technologies), lack of patent protection could in fact hinder uptake of technology by industry and prevent it from reaching its intended market.

Where substantial investment is required for further development and marketing of a technology, patents are often essential, to give licensees an opportunity to recoup their investment before competitors enter the market.

» For those developing countries with domestic innovative and manufacturing capacity, patents are often necessary to incentivise local companies to invest in developing and marketing a technology, thus creating a barrier to entry for potential competitors. Where such companies export in addition to serving local markets, patents become even more important.

» Patents can be used as bargaining chips (e.g. via cross-licensing) to gain access to IP belonging to others, which might be necessary to use a particular technology or to add value.

» By licensing patent rights, the licensor is in a stronger position than it would be in the absence of patent rights, to impose conditions on the licensee to make technologies available in target markets, and have a means of enforcing such conditions contractually.

Complementary approaches to consider

1. In those countries that recognise 'petty patents', such protection can be considered for technologies that meet the relevant requirements.

2. Open and proprietary mechanisms can and do co-exist. One can therefore choose to protect certain elements of a technology to provide a necessary competitive edge, while putting associated information into the public domain; this could be of value to other researchers, but would not hinder the ultimate commercialisation of the technology.

- **Licensing frameworks**

SRL licences aim to promote availability and affordability of technologies in underserved (typically developing country) markets. In order to achieve this, a balance must be struck between providing adequate incentives to attract licensees with the capacity and willingness to take technologies to these markets, and building in suitable measures to ensure access of technologies on affordable terms in the markets of interest.

Licence terms to consider

Various provisions may be considered for inclusion in licence agreements to assist in achieving SRL objectives. These should be selected on a case-by-case basis; such decisions to be informed by the business model for taking the technology to market, which in turn will be influenced by the nature of the technology, the stage of development (and by implication the further steps required to achieve a marketable technology), the needs of the licensee, the structure and demands of the market, etc. A range of licensing terms promoting SRL objectives are suggested here, but should not be considered an exhaustive list. Different combinations of terms can be used, as appropriate. Overall, it must be borne in mind that licence terms found to be (individually or in combination) excessively restrictive on licensees could prevent a technology from reaching the market at all, and licence negotiations must ultimately produce a feasible outcome.

1. Market segmentation

Where a dual market business model is proposed, differentiated terms for various market segments can be applied.

Examples of different market segments:

- Developed vs developing countries
- Identification of regional blocs
- Public sector vs private sector
- Differentiated fields of use or industry sectors
- Humanitarian use or charitable objectives
- Appropriate definitions are important to avoid misuse

Examples of differentiated terms, which might apply in the specified market segments:

- Exclusive vs non-exclusive rights vs non-assert provisions/waivers
  - Note that in the case of non-asserts/waivers, liability to IP holders may be reduced, as they do not take on many of the positive obligations of the licensor. However, non-asserts can also raise concern about product diversion from the target SRL market to other markets where exclusive rights are in place.

- Exclusive rights in more profitable markets coupled with guarantees for underserved markets
  - Milestones can be set for the markets of interest e.g. minimum sales, date of first sale

- » Tiered pricing models – favourable pricing in specified markets
  - Subsidisation in certain markets – typically by a not-for-profit third party
  - Sales to be made 'at cost' in certain markets
  - Set limits on allowable mark-up ('cost-plus' pricing)
  - Price reduction facilitated by licensor taking a royalty sacrifice (in whole or in part, subject to prior consent of affected stakeholders, including inventors at a research institution)

2. Diligence/performance clauses

Provisions need to be included to encourage compliance with SRL terms, and to allow for alternative measures to be taken by the licensor to ensure that the SRL objectives are met in the event of non-compliance with the relevant provisions by the licensee.

- In the event of non-compliance with stipulated milestones or other SRL performance clauses, the licensee may require that exclusive licensed rights (which might include those for developed country markets) be converted to non-exclusive rights, or that the license be terminated (in some or all of the licensed territories)

- Mandatory sub-licensing clauses can be included in terms of which the licensee is obligated to sub-license to a third party in the event that the licensee itself is failing to develop the technology and/or satisfy market demand
  - » It should be noted that licensees often view such provisions unfavourably as they are concerned about the extent to which this limits their freedom to do business

- 'Walk-in rights' can be used to allow the licensor or a third party (e.g. a government or not-for-profit funding agency) to take over the licensed rights in those markets that are not being satisfied
  - » These rights may be built into grant and funding agreements from certain agencies under relevant national legislation or funding agency policy

- Performance clauses are of course of little value unless performance can be monitored and enforced and relevant terms should be incorporated to ensure that this can be done, to the extent possible.

3. Research use licenses retained by licensor

Efforts should be made to build in license terms to ensure that further R&D based on the SRL technology is restricted as little as possible.

- At a minimum, the licensor should ensure that it has a royalty-free license to continue its own non-commercial R&D

- Preferably, such rights should also be extended for use by other public research organisations for non-commercial R&D purposes

- In some cases, such rights might be extended even to companies, with appropriate conditions or limitations in place (e.g. for work on neglected diseases and subject to certain undertakings to ensure that ultimately, products are made available in the markets that need them)

4. Benefit-sharing with communities & providers of plant genetic resources and/or traditional knowledge

Where technologies are developed as a result of traditional knowledge and/or plant genetic resources provided by communities or traditional knowledge holders, licence agreements need to build in provisions for benefit sharing with such parties.

- Under the Convention on Biological Diversity, several countries have legislation governing access and benefit-sharing, resulting from bio-prospecting. But even where such activity is not formally regulated, a licence agreement for relevant technologies should provide for this.

- Both monetary and non-monetary benefits should be considered and incorporated wherever possible.

5. Providing for unforeseen or changed circumstances

SRL agreements should attempt to build in some flexibility to allow for unforeseen or changed circumstances (e.g. where a new use for a drug is discovered that addresses unmet needs and could have a substantial impact). Such provisions might not always be binding and are typically difficult to enforce, but nonetheless can assist in creating good faith expectations.

- The agreement can obligate the licensee to consult with the licensor to renegotiate in the event of certain stipulated circumstances occurring.
  - » Depending on the language, this will often be considered 'an agreement to agree' and as such, not be legally binding.

- Wherever possible, license fee and benefit-sharing provisions should be crafted sufficiently broadly to cover all developments enabled by the license.
  - » There are, however, limitations in terms of how far the licensor is able to 'reach-through' to future developments, especially where these are not anticipated at the time that the license agreement is drawn up.

Support for innovation and industry in developing countries as a component of SRL
For TTOs in developing countries, building local innovation capacity and strengthening local industry (particularly innovation-based companies) achieves many social and policy objectives. Local licensing technologies may play a role in creating new industries and employment opportunities and ensure that the benefits of the technologies concerned are harnessed locally. In cases where international licensing ultimately provides better prospects for increasing impact and ensuring that technologies reach their intended markets, provisions can nonetheless be drafted to ensure that benefits to the local economy and to local innovation efforts are achieved.

These may include the following:

- Commitment from the international licensee to collaborate in and/or support further R&D at the licensor organisation and/or other local institutions
- Support for human capital development
  - Exchange programmes
  - Funding of scholarships
  - Hosting and training researchers
- Providing knowledge and technology transfer
- Commitment to manufacture/produce locally (possibly in addition to doing so elsewhere), whether complete products or certain components

Further examples of SRL terms and strategies are provided in the appendices. Also, the Association of University Technology Managers (AUTM) website provides more examples of clauses: http://www.autm.net/AM/Template.cfm?Section=Global_Health&Template=/CM/ContentDisplay.cfm&ContentID=8010

Metrics

Appropriate metrics for measuring the success of such activities include: numbers and types of partnerships, diversification of funding sources, collaborative "fitness" (sharing of data, materials, personnel, reciprocity on IP terms or other property treatment), efficiency of translation, and importantly, the social impact of the activities, including use of research results, enablement of follow-on improvements, inducement of co-investment, recruitment of personnel for public good goals, and humanitarian metrics such as alleviation of poverty, health improvements, and infrastructure (such as sanitation, clean water).

Underlying Considerations

- Institutional culture and top management expectations

To allow easy adoption of SRL practices it is important for technology transfer practitioners to get buy-in from top management. This will ensure that there is alignment between expectations of senior managers and those of technology transfer personnel. If top management expects the TTO to only generate profits for the institutions, this might affect the choice of projects by technology transfer personnel and the type of licenses they may enter into. This could encourage the technology transfer personnel to pursue projects with potentially high financial returns and ignore those with potentially high social impact but low financial returns. Also, the licensing models adopted by technology transfer personnel might be geared to generating high profit margins instead of social impact. Hence, if top management buy-in into SRL practices is not obtained, it might be difficult for technology transfer personnel to implement these practices. Where the culture of the institution is such that it does not support projects with high social impact, this will also make it difficult for the adoption of SRL practices. It is important that TTOs work with other stakeholders to instil a culture inside the technology transfer office, of adopting projects and commercialisation models, which lead to high social impact and advocate broad buy-in within the institution. Incentives to technology transfer personnel should therefore not only be based on the profit generated by the TTO: recognition and incentives should also be provided for the social impact that the TTO has helped facilitate.

- Institutional policies

For effective adoption of SRL practices, institutional policies should explicitly support this type of licensing activity. For example, an institutional IP policy could provide for licensing for social impact. Enshrining SRL practices in institutional policies will provide the TTO with extra ammunition during negotiations with outside parties. Institutional policy promoting SRL will also provide clear guidance and extra motivation for the TTO, whose actions will be supported by policy.

- Multiple perspectives

Since SRL affects multiple stakeholders, both within the institution and externally, there will exist many different perspectives on how things should be done. In adopting SRL practices the TTO will have to effectively manage these different perspectives on technology transfer models and the purpose of the TTO. (e.g. some stakeholders might view the TTO as a vehicle for generating profit and expect it to be self-sustainable. Some inventors might view it as a vehicle to generate their future riches. Others might wish to make their technologies available in the public domain. Potential licensees might fail to see the benefits that an SRL approach might bring them.)

It is important that the TTO is able to handle these different perspectives and manage the expectations of the different stakeholders. For example, the TTO will need to build awareness in order to gain buy-in from the inventors with regard to commercialising technologies for social impact. This will ensure that there are no tensions between the inventors and the TTO when commercialised technologies do not generate income, which might otherwise have been expected by the inventor.

Conclusions

We believe that the adoption of SRL practices by TTOs is critical to improve access to healthcare technologies in underserved markets. By adopting SRL practices, TTOs can address market failures, ensure that society benefits from the research outputs of publicly funded research, increase the impact of publicly funded research, adhere to legislative and/or policy requirements, contribute to overall corporate social investment, create alternative models for commercialisation, increase the uptake of their technologies, create reputational goodwill for their institutions and increase sources of funding. It is clear that there are many incentives for TTOs to adopt SRL practices. Various SRL strategies can be followed when carrying out IP management and commercialisation activities to ensure greater societal impact. Successful SRL will be dependent on obtaining buy-in from top management and ensuring that institutional policies and culture are supportive of and aligned with the implementation of SRL practices. The approaches that have been described here are not intended to be an exhaustive catalogue – instead, technology transfer practitioners are urged to consider crafting new solutions tailored to the circumstances of their own deals, and to share these with the technology transfer community on an on-going basis, thereby helping to expand options in this fledgling field, ultimately increasing adoption of SRL for appropriate technologies.

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Appendix A

Examples of SRL clauses developed by Medical Research Council when entering agreement for intellectual property funded by the South African AIDS Vaccine Initiative (SAAVI):

Company A, 2001

* MRC hereby grants to Company A (i) a royalty-free, non-exclusive license to make, have made, use and sell HIV Collaboration Vaccine and/or Cocktail Vaccine to the Public Sector in Developing Countries, and (ii) a royalty-bearing non-exclusive license to make, have made, use and sell HIV Collaboration Vaccine and/or Cocktail Vaccine to other than the Public Sector in Developing Countries. For the avoidance of any doubt this includes Private Sector in Developing Countries and both Public and Private Sector in Developed Countries.

Company B, 2002

* Company B hereby grants to MRC an exclusive perpetual fully-paid up license to make, use and sell products **within the continent of Africa, without the right to export such products from Africa**, that are covered under any Company B Background Invention and/or any Joint Invention that is utilized with any MRC nucleotide sequences in the Study with the right to sub-license such rights (Company B retains the right of first refusal and the first right to negotiate an exclusive license for North America and Europe).

Institution C, 2002

* Institution C grants the MRC a non-exclusive license under any and all of its intellectual property rights in vector X to manufacture and distribute HIV vaccine which incorporates the said vector or parts thereof together with the MRC HIV gene sequences.
* The license shall be world-wide and royalty-free for Developing Countries (list provided from World Bank classification) for the term of this Agreement.
* For Developed Countries (list provided from World Bank classification) the license granted to MRC shall for the term of this Agreement be world-wide and provide a royalty to Institution C (the royalty is only payable once the MRC has recovered all its reasonable direct costs expended on the development, manufacture and distribution of the HIV vaccine).

Company D, 2003

* Upon the MRC's written request, Company D will, as promptly as commercially reasonable, manufacture and deliver to the MRC up to a maximum of five thousand (5,000) doses (the "Doses") of Vaccine for use solely in clinical trials. The total amount payable to Company D for manufacture and delivery of such Vaccine shall be equal to Company D's Manufacturing Cost (defined) of the Doses plus ten percent (10%). If Company D declines to supply Commercial Product to the MRC (for use in the Territory) on the terms set forth in the term sheet, then the MRC shall be permitted to enter into an agreement with a Third Party on the terms set forth in the term sheet and such other terms and conditions as are commercially reasonable under the circumstances….. Company D shall enter into an agreement with such Third Party Manufacturer pursuant to which Company D will grant a license and transfer its technology to such Third Party (with royalty provision) as required to enable such Third Party Manufacturer to manufacture and supply Vaccine to the MRC…. Company D shall make seed stock of the Vaccine available to the MRC and Third Party Manufacturer and the Third Party Manufacturer shall be permitted to use such seed stock to manufacture and supply Vaccine to the MRC (or its nominated distributor) for use solely within the Territory.
* Territory shall mean the sub-Saharan African countries listed in the exhibit (48 countries).

Appendix B

http://ipira.berkeley.edu
Carol Mimura
Memo: Updated August 17, 2010

Guidance and sample clauses for use in developing strategies, licenses, research and collaboration agreements in IPIRA's humanitarian/ socially responsible licensing program (SRLP) at Berkeley.

Please remember that even before discussing contract terms we should discuss with all parties (including inventors and authors of creative works) not patenting or not patenting in certain geographies, patent pools, technology trusts, commons (such as for software), open source licenses, and other incentives to achieving the goal of social impact, access and affordability through our initiatives.

Licenses grant rights to existing IP. Research agreements and collaboration agreements state our intention to deploy rights when they arise under sponsored research or through joint efforts. When prior IP exists and continuing development is funded under a research or collaboration agreement with charitable purposes, an option to license the original IP can be coupled with the research agreement and access terms under the SRLP can be applied to both.

Sample clauses:
In the recitals:
LICENSEE is capable of developing safe, effective, and affordable new [medicines] for people in the developing world afflicted with [infectious diseases], including [ ]. BERKELEY and LICENSEE wish to have LICENSED PRODUCTS marketed in the LICENSED TERRITORY as soon as possible [and at cost] so that products resulting therefrom may be
available for public use and benefit.

In the definitions section:
PROJECT INVENTIONS are defined in the RESEARCH AGREEMENT. The research underlying PROJECT INVENTIONS is expected to be fully funded by [foundation or other grant source name, or use "LICENSEE" if licensee is the charitable funding source]. If PROJECT INVENTIONS arise, however, that are funded entirely or in part by grants from U.S. Government agencies, BERKELEY will grant to the U.S. Government a non-exclusive royalty-free, non-transferable, and irrevocable license to practice or have practiced the PROJECT INVENTIONS for, or on behalf of, the U.S. Government throughout the world (35 U.S.C. § 203) and this Agreement will be subject to those

rights. (insert as applicable for exclusive license) Moreover, this license will be subject to 35 U.S.C. § 204 (preference for U.S. industry) and March-in rights (35 U.S.C. § 202(c)(4)).

"LICENSED TERRITORY" means countries listed in Appendix A (note: this varies widely but has typically included low and middle income countries and/or least developed countries. Or, Economically Disadvantaged Countries (EDC) vs. non-EDC. See World Health Organization site, Doris Duke Charitable Foundation site for examples) of the RESEARCH AGREEMENT provided that, any development or manufacture of LICENSED PRODUCTS for the purpose of sale or distribution thereof in the LICENSED TERRITORY shall be deemed to have occurred within the LICENSED TERRITORY, whether or not such development or manufacture occurs in the LICENSED TERRITORY.

"HUMANITARIAN PURPOSES" means (a) the use of LICENSED PRODUCTS and LICENSED SERVICES for research and development purposes by any nonprofit organization or other third party, anywhere in the world that has the express purpose of developing the LICENSED PRODUCTS or LICENSED SERVICES for use solely in an EDC, and (b) the use of the LICENSED PRODUCTS or LICENSED SERVICES by any nonprofit organization or other thirdparty for SALE solely in an EDC at or below cost.

Reminder, define "HUMANITARIAN OBJECTIVE" in research agreement and attach GLOBAL ACCESS STRATEGY in addition to the scope of work (corresponding to budget) as an appendix.
Reminder, define Field of Use in research agreement if a present grant such as "means the conduct of the [project] in accordance with the scope of work and the GLOBAL ACCESS STRATEGY and implementation of the HUMANITARIAN OBJECTIVE.
Reminder, define ECONOMICALLY DISADVANTAGED POPULATIONS (EDP) for tiered pricing requirements.

In the Grant clause section:
Subject to the limitations set forth in this Agreement and subject to potential licenses granted to the U.S. Government in the future, BERKELEY hereby grants and LICENSEE hereby accepts an [exclusive/nonexclusive/co-exclusive], royalty-free license [with right to sublicense, if exclusive] under BERKELEYS' PATENT [could be copyrights] RIGHTS to make, have made, use, offer for sale, import, and sell [or for copyrights, reproduce, prepare derivative works, distribute copies, perform publicly, or display publicly] LICENSED PRODUCT(S) and to practice LICENSED
METHOD in the LICENSED FIELD OF USE in the LICENSED TERRITORY.

This grant is further subject to receipt by BERKELEY of written, informed consent of its inventors [or authors]. Written consent for the license terms in this AGREEMENT has been received from BERKELEY employees who will receive funding under the RESEARCH AGREEMENT. If one or more inventors or authors with an obligation to assign his or her patent rights to BERKELEY is named an inventor [author] on a future patent application or patent within BERKELEY's PATENT RIGHTS has not received funding under the RESEARCH AGREEMENT, then this grant will be
subject to that future inventor(s)' written consent.

In termination article:
After typical terms for termination by BERKELEY stating that if a material breach is not cured within six months after written notice has been received by LICENSEE Insert for nonprofits: OR, shall terminate immediately if a) LICENSEE ceases to be designated a 501(c)(3) non-profit organization, or; b) if LICENSEE'S CHARITABLE OBJECTIVE changes.
Sublicensing: consider expansion to geographical unmet need, not just new uses. Note that "free or at cost" can be substituted for "new use" to drive the licensed product price lower.

Mandatory Sublicensing Clause
The concept is that when the University grants a broad exclusive license then we must have a mechanism to ensure that the market demand is met. As future, perhaps unanticipated, new uses arise we have an obligation to fill new market niches for the public good. This is especially important when our inventions are developed using federal funds. 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 or other unmet need then we ask our licensee to tell 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).

Suggested language:
"If REGENTS (as represented by the actual knowledge of the licensing professional responsible for administration of U.C. Berkeley Case No.: xx or if a third party discovers and notifies that licensing professional that the INVENTION is useful for an application covered by the LICENSED FIELD OF USE but for which LICENSED PRODUCTS have not been developed or are not currently under development by LICENSEE, then the REGENTS, as represented by the Office of
Technology Licensing, shall give written notice to the LICENSEE, except for: 1) information that is subject to restrictions of confidentiality with third parties, and 2) information which originates with REGENTS personnel who do not assent to its disclosure to LICENSEE.

Within ninety (90) days following LICENSEE's receipt of REGENTS' notification LICENSEE shall give REGENTS written notice stating whether LICENSEE elects to develop LICENSED PRODUCTS for the application.

If LICENSEE elects to develop and commercialize the proposed LICENSED PRODUCTS for the new application, LICENSEE shall submit a progress report describing LICENSEE's commercialization efforts in developing the new application every six months to REGENTS pursuant to Article xx herein. (this language if this paragraph is used in an option agreement: pursuant to the appropriate paragraph in the LICENSE AGREEMENT).

If LICENSEE elects not to develop and commercialize the proposed LICENSED PRODUCTS for use in the new application, REGENTS may seek (a) third party(ies) to develop and commercialize the proposed LICENSED PRODUCTS for the new application. If REGENTS identifies a third party, it shall refer such third party to LICENSEE. If the third party requests a sublicense under this Agreement, then the LICENSEE shall report the request to REGENTS within thirty (30) days from the date of such written request. If the request results in a sublicense, then LICENSEE shall report it to REGENTS (this language if this paragraph is used in an option agreement: pursuant to the appropriate paragraph in the LICENSE AGREEMENT).

If the LICENSEE refuses to grant a sublicense to the third party, then within thirty (30) days after such refusal the LICENSEE shall submit to REGENTS a report specifying the license terms proposed by the third party and a written justification for the LICENSEE's refusal to grant the proposed sublicense. If REGENTS, at its sole discretion, determines that the terms of the sublicense proposed by the third party are reasonable under the totality of the circumstances, taking into account LICENSEE's LICENSED PRODUCTS in development, then REGENTS shall have
the right to grant to the third party a license to make, have made, use, sell, offer for sale and import LICENSED PRODUCTS for use in the LICENSED FIELD-OF-USE at substantially the same terms last proposed to LICENSEE by the third party providing royalty rates are at least equal to those paid by LICENSEE.

ALSO ADD THIS TO THE REPORTING REQUIREMENT in both an option agreement and a license agreement:
(b)LICENSEE's progress in developing any applications of the REGENTS' PATENT RIGHTS elected for commercial development by LICENSEE pursuant to Article 4.5 of this Agreement.

***

Humanitarian Use Tiered Pricing License Terms
For a Research Agreement or Master Agreement
Summary

The following, sample Humanitarian Use License approach may be included in a research agreement. The terms provide conditions for a non-exclusive, royalty free license to inventions arising in the course of an industry sponsored research project. This sample language may be used in research agreements or in master agreements with separately executable project schedules, as in the case below.

Four concepts are notable in the terms below. First, the terms are oriented toward the information technology sector, while most humanitarian use terms are applied in the biomedical sector. Section 2.E addresses the fact that in the IT sector, many intellectual property rights may be incorporated in a single product, and products may be bundled or merged. Second, the usual country-level definition of licensed territory (usually defined as economically disadvantaged country, or "EDC") is defined more granularly at a population level (economically disadvantaged
population, or "EDP"). Third, to address possible anti-competition issues, a "Conversion" clause is introduced which provides for automatic conversion of a non-exclusive, royalty-free license to a Commercial License if any of three conditions arise, as described in Section 2.G. Fourth, many cases of offering humanitarian use clauses involve a nonprofit licensee with a charitable focus. In the case below, the sponsor and prospective licensee is a multinational, for-profit corporation with a clear commercial purpose even as it exercises its own social impact goals. We recognize this fact in the recitals and in associating the exercise of Humanitarian Use License with the company's Corporate Responsibility unit provided the company has its own social impact goals and criteria related to the university's public good mission. The fourth provision may not be feasible in all cases.

Recital

The Parties agree that provisions for humanitarian use license rights, as further described in Section 2 herein, are intended to address economically disadvantaged populations ("EDPs" as defined Article 1), and to induce investment and create markets for such populations where: i) there is strong potential for social impact in EDPs; ii) Company's business potential for specific University Foreground is unclear and therefore lacks a natural home within a Company business unit except for use by Company Corporate Responsibility; and iii) University's provision of Humanitarian Use License to Company for such University Foreground would motivate uptake and use by Company Corporate Responsibility in EDPs. University supports the social impact goals of Company Corporate Responsibility and encourages Company's offer in EDPs of Humanitarian Products incorporating University Foreground under Humanitarian Use License (the "Humanitarian Objectives").

1. Definitions

"Company Corporate Responsibility" means Company's corporate responsibility program. **"Conversion"** means a conversion of Humanitarian Use License to a Commercial License if Company offers Humanitarian Products: a) at market rate according to GAAP within EDPs, b) at EDP Rate in populations not listed in or added by amendment within sixty (60) days of notice to the relevant license, or c) if a given EDP graduates from its applicable EDP status. Financial terms and diligent development requirements may apply.

"EDP" shall be defined as: a) countries recognized by either the United Nations as "least developed countries" ("LDCs") or by the World Bank as countries with extreme or moderate poverty; and b) populations within a country living below the generally accepted poverty line in non-LDCs. For (b), populations in the United States will be identified using the standard of populations below the U.S. federal government poverty line according to the U.S. Census, and for other non-LDCs, a generally accepted poverty line of the given country which is substantially
similar to the U.S. poverty line relative to the given country.

"EDP Rate" means the offer of Humanitarian Products by Company in EDPs for free, below market rate, or at cost, but not at market rate according to generally accepted accounting practice ("GAAP").

"Humanitarian Objective" means the social impact goals of Company Corporate Responsibility and University and the offer in EDPs of Humanitarian Products incorporating University Foreground under a Humanitarian Use License.

"Humanitarian Products" means Company products and/or services incorporating University Foreground licensed under any Humanitarian Use License granted pursuant to Section 1.

"Humanitarian Use License" A non-exclusive, royalty free license, as outlined in Section ____, for University Foreground which shall be granted to Company when Company intends to incorporate into Humanitarian Products offered within EDPs to meet Humanitarian Objectives and satisfied criteria outlined in Section 1.

"LDCs" means countries defined by the United Nations as "least developed countries."
"OTL" means University's Office of Technology Licensing.
"Commercial License" means a license for commercial use with terms described in Section __[standard IP section].

"Project Schedule" means a project schedule agreement using the form in Appendix 1 to this Agreement that is signed by an authorized representative of each of the Parties, and that describes a research or collaboration project by the Parties. [Note: These terms are part of a master agreement, and a Project Schedule is separately executable under the master agreement.]

2. Humanitarian Use Terms

2. Conditions for Royalty Free, Non-Exclusive Humanitarian Use License. A Humanitarian Use License shall be granted to Company if Company satisfies the conditions outlined below and provides written, supporting documentation to University's OTL. Upon submission of written documentation, University's OTL shall respond in writing to Company within thirty (30) days as to whether it will accept or challenge Company's assertion that conditions for a license granted pursuant to this Section 1 have been satisfied. A license granted pursuant this Section 1 shall automatically be offered, without further documentation, upon such acceptance from the OTL.

A. Company shall manage its exercise of the Humanitarian Use License or offer of Humanitarian Products under its Company Corporate Responsibility unit.

B. Company shall offer Humanitarian Products solely within EDPs, for Humanitarian Objectives. Such EDPs shall be listed in any Humanitarian Use License and anticipated if possible by listing in the Project Schedule.

C. Company's offer of Humanitarian Products shall be made available at the EDP Rate in the EDPs listed in the Project Schedule or license, as applicable.

D. While not limiting Company's exercise of any other rights under this Agreement, Company's offer of Humanitarian Products shall be restricted to populations in which it is presumed Company or its competitors do not expect to make a near term profit under GAAP with respect to such Humanitarian Products, whether or not Company operates in such markets. The probable effect on other markets may be taken into account in determining this exclusion.

E. To satisfy the Humanitarian Objectives, for any (i) offer of products and services incorporating University Foreground under a Humanitarian Use License, and (ii) any Humanitarian Products coupled or packaged with other products or services necessary to use Humanitarian Products, such offers shall be offered together at an EDP Rate.

F. Company shall provide to University's OTL a separate annual report of products and services provided under Humanitarian Use Terms and listed by EDP and EDP Rate.

G. A Humanitarian Use License is convertible upon six months' written notice byUniversity to a Commercial License if Company offers Humanitarian Products: a) at market rate according to GAAP within EDPs, b) at EDP Rate in populations not listed in or added by amendment within sixty (60) days of notice to the relevant license, or c) if a given EDP graduates from its applicable EDP status. In the event of conversion, financial terms and diligent development requirements may apply. The Conversion shall not occur if Company cures the identified event within the six month period and reports such cure to University within at least thirty days before the end of the six month period.

***

Humanitarian Reservation of Rights

Text for license agreement, modify for research contract

x.x "HUMANITARIAN PURPOSES" means (a) the use of LICENSED PRODUCTS and LICENSED SERVICES for research and development purposes by any nonprofit organization or other third party, anywhere in the world that has the
express purpose of developing the LICENSED PRODUCTS or LICENSED SERVICES for use solely in an EDC, and (b) the use of the LICENSED PRODUCTS or LICENSED SERVICES by any nonprofit organization or other third party for SALE solely in an EDC at or below cost.

x.x Nothing in this Agreement will be deemed to limit the right of UNIVERSITY to:

a) publish any and all technical data resulting from any research performed by UNIVERSITY relating to the INVENTION, and to make and use the INVENTION, LICENSED PRODUCTS, and LICENSED SERVICES and practice LICENSED METHOD and associated technology for its educational and research purposes, and to allow other educational and non-profit institutions to do so for their educational and research purposes, and;

b) license the UNIVERSITY PATENT RIGHTS to any third parties solely for HUMANITARIAN PURPOSES. Such licenses for HUMANITARIAN PURPOSES shall (i) expressly exclude the right of the third party licensee to export or SELL the LICENSED PRODUCTS from an EDC into a market outside of the EDC where LICENSEE has introduced or will introduce a LICENSED PRODUCT and where UNIVERSITY PATENT RIGHTS exist (such markets, the "LICENSEEMARKETS") and

(ii) require the third party licensee to create and maintain distinctive trade dress and trademarks ("EDC Trademarks and Trade dress") that clearly distinguish third party LICENSED PRODUCTS OR LICENSED SERVICES from LICENSEE'S LICENSED PRODUCTS or LICENSED SERVICES, (iii) require such third party licensee's SALE of LICENSED PRODUCTS or LICENSED SERVICES in such EDCs at or below cost. For avoidance of doubt, such third party licensee may be permitted to export LICENSED PRODUCTS from the EDC of origin to other EDCs and all other countries mutually agreed to by The UNIVERSITY and LICENSEE.

Notwithstanding the foregoing:

i. *prior to issuance of any such license to UNIVERSITY' PATENT RIGHTS to a third party, the UNIVERSITY will notify LICENSEE of its intention to grant such license so that LICENSEE may have the opportunity to fill the anticipated market need itself and/or to engage in discussions for a sublicense with such third party in accordance with the procedures set forth in Section 4.8; and*

ii. *in the event any LICENSED PRODUCT SOLD in any EDC by any such third party according to the provisions of Section 3.3(b) is exported, re-SOLD or otherwise introduced in any LICENSEE MARKET, LICENSEE will provide the UNIVERSITY with written notification thereof, and if such exportation, re-SALE or introduction does not cease within ninety (90) days after the date of such notice, then an amount equal to the retail price of LICENSED PRODUCTS so exported, re-SOLD or introduced to such LICENSEE MARKET shall be deducted from any royalties due to THE UNIVERSITY hereunder*

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