

<http://ipira.berkeley.edu>

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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 third party for SALE solely in an EDC at or below cost.

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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.

See additional definitions in Tiered Pricing and Humanitarian Reservation of Rights clauses on pages 4-7.

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 BERKELEY'S 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 by University 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 "LICENSEE MARKETS") 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.