AUTM Global Health Toolkit – Examples of Executed Licenses Clauses

As of Saturday, March 17, 2012

The list below is a non-exhaustive set of examples of verbatim clauses related to global health issues, as extracted from license agreements successfully executed by U.S. universities. This document is meant to be part of the broader AUTM Global Health Toolkit (http://www.autm.net/Global_Health.htm), which includes AUTM position documents as well as relevant papers & articles on global health issues.

These sample clauses were solicited from the AUTM membership in the Spring of 2009, and represent input from multiple institutions. A few notes on the examples below:

- All examples are from license agreements. A separate list of clauses from sponsored research agreements will be compiled as part of a separate project.
- Although each of these clauses has been used in one or more executed license agreements, each was done under specific circumstances, i.e. taking into account the specific technology, the circumstances and other negotiated terms. Any one of these clauses may need to be further modified to fit other particular circumstances.
- The names of the participating institutions and companies have been removed, so as to protect the confidentiality provisions of the agreements themselves.
- Where multiple universities submitted substantially similar clauses, only one example was provided for the purposes of brevity.
- Where noted, "various" means that the university has used the specific clause in many executed agreements, and therefore the Agreement Type could not be specified.
- The clauses have been broken into thematic categories, for ease of reference. They are:
 - 1. Definitions ("Developing Countries", "Humanitarian Purposes", etc)
 - 2. Non-patent
 - 3. Non-suit
 - 4. Mandatory sublicensing
 - 5. Reasonable cost
 - 6. Mandatory development
 - 7. Statement of principles
 - 8. No royalties due
 - 9. Mandatory donation

Clause Type Agmt Type Clause itself

AUTM's intent is for the list to be a living document, to be amended and supplemented over time. Accordingly, if your University has other approaches or different wording to add, we encourage you to send your specific examples to Orin Herskowitz, Executive Director of Columbia Technology Ventures, at orin.herskowitz@columbia.edu.

# Clause Type	Agmt Type	Clause itself
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1a	Definitions	Various	"Humanitarian Purposes" means (a) the use of Licensed Products covered under Patent Rights for research and development purposes by any organization or other third party, anywhere in the world that has the express purpose of developing the Products for use in an Economically Disadvantaged Country, and (b) the use of the Products by any organization or other third party for Commercial Purposes in an Economically Disadvantaged Country. "Economically Disadvantaged Country" ("EDC") means all countries listed on the United Nations Conference on Trade and Development list of "Least Developed Countries" in effect as of the date of first commercial Sale of Products of which are set forth on Appendix I hereto.
1b	Definitions	Therapeutic	"DEVELOPING COUNTRIES" shall mean, within the TERRITORY, the countries designated by The World Bank (www.worldbank.org) as Low-Income Economies, as such list may change from time to time, or any subsequent list that may be mutually agreed to by University and COMPANY.
1c	Definitions	Various	"GAVI Country" shall mean any country listed as eligible to receive support from the GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunisation), as such list may be updated from to time by the GAVI Alliance. "Humanitarian Purposes" shall mean practice of Patent Rights in the prevention or treatment of disease in humans by or on behalf of any Qualified Humanitarian Organization (including, for clarity, practice of Patent Rights by contractors, manufactures or distributors acting for or on behalf of such Qualified Humanitarian Organizations on a fee-for-service, fee-for-product or charitable basis) (a) to manufacture Licensed Products anywhere in the world for the sole and express purposes of distribution and use of such Licensed Products in one or more GAVI Countries, and (b) to sell or otherwise distribute Licensed Products for use solely in one or more GAVI Countries; provided, however, that sales and distribution of Licensed Products shall not be deemed made for Humanitarian Purposes unless products are distributed at locally-affordable prices. "Non-GAVI Country" shall mean any country that is not a GAVI Country. "Qualified Humanitarian Organization" shall mean any governmental agency, non-governmental agency or other not-for-profit organization that has as one of its bona fide missions to address the public health needs of underserved populations on a not-for-profit basis. For clarity, Qualified Humanitarian Organizations do not include non-governmental agencies and non-for-profit organizations that are formed or established for the benefit of any for-profit entity.
1d	Definitions	Diagnostic license to start- up	Countries eligible to receive support from GAVI ("GAVI Countries", a list of the 72 countries eligible at the Effective Date to receive aid from GAVI are in Exhibit 2.3.1)

1e	Definitions	Infectious disease	University retains the right to grant non-exclusive licenses under Patent Rights, solely to Qualified Humanitarian Organizations for use solely for Humanitarian Purposes; provided that any such license shall expressly exclude the right to export any Licensed Product from any GAVI Country into any Non-GAVI Country or to use the Licensed Product in any Non-GAVI Country.
			"GAVI Country" shall mean any country listed as eligible to receive support from the GAVI Alliance, as such list may be updated from to time by the GAVI Alliance.
			"Humanitarian Purposes" shall mean practice of Patent Rights in the prevention or treatment of disease in humans by or on behalf of any Qualified Humanitarian Organization (including, for clarity, practice of Patent Rights by contractors, manufactures or distributors acting for or on behalf of such Qualified Humanitarian Organizations on a fee-for-service, fee-for-product or charitable basis) (a) to manufacture Licensed Products anywhere in the world for the sole and express purposes of distribution and use of such Licensed Products in one or more GAVI Countries, and (b) to sell or otherwise distribute Licensed Products for use solely in one or more GAVI Countries; provided, however, that sales and distribution of Licensed Products shall not be deemed made for Humanitarian Purposes unless products are distributed at locally-affordable prices. "Qualified Humanitarian Organization" shall mean any governmental agency, non-governmental agency or other not-for-profit organization that has as one of its bona fide missions to address the public health needs of underserved populations on a not-for-profit basis. For clarity, Qualified Humanitarian Organizations do not
			include non-governmental agencies or not-for-profit organizations that are formed or established for the benefit of any for-profit entity.
1f	Definitions	Osteoarthritic joints license to a start-up	 Public Sector shall include: (a) agencies of the United Nations and the World Health Organization; (b) organizations which comprise the International Committee of the Red Cross and Red Crescent; (c) the following international charitable and funding agencies (also known as Non-Governmental Agencies): Oxfam, Medecins Sans Frontieres, the Bill and Melinda Gates Foundation, and the Rockefeller Foundation; and (d) any other accredited charitable or philanthropic organization that the Parties may agree to in writing.
1g	Definitions	Metabolic disorder and drug discovery license to a start-up	Countries other than: All current (as of the Effective Date) and future Organization for Economic Cooperation and Development (OECD) countries, presently consisting of Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Republic of Korea, Japan, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the UK, and the United States; and All current and future members of the European Union not otherwise members of the OECD; and People's Republic of China, India, Malaysia, Russian Federation, Singapore, South Korea and Taiwan. All members of the Organization of Petroleum Exporting Countries not previously identified above; and (e) Any other country of the world that, as a result of its progress and economic development after the Effective Date, Licensee reasonably determines that the market potential for the applicable Licensed Product is substantial and, therefore, should be included as one of the Market Countries.

Agmt Type

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
1h	Definitions	Exclusive licenses	"Humanitarian Purposes" shall mean the exercise of the rights to UNIVERSITY Intellectual Property granted under Section 2 of the License Agreement with respect to Products, by Company, and/or to the extent such rights are exercised by Company's "Affiliates", as defined in Section 1(a) of the License Agreement, Company's "Sublicensees", as defined in Section 1(l) of the License Agreement (collectively "Company and/or its Subicensees"), and/or by "Qualified Humanitarian Organizations", as defined below, for the express and sole purpose of manufacture, distribution, use, lease, transfer, and/or sale of Products in order to assure availability and affordable access to such Products in a Developing Country(ies) at reasonable prices;
1i	Definitions	Exclusive license to medical device start-up (related to clause 4k below)	"Cost + 15%" shall mean the cost of goods sold, including the direct unit costs of manufacturing and preparing the Product and/or Process for sale, exclusive of selling, general and administrative expense, research and development expense, and distribution costs, plus fifteen percent (15%) of such amount. [NOTE: used together with clause 4K below) "Qualified Organization" shall mean: (a) a non-governmental organization; (b) a government-based program that is not a nationalized health care system; (c) a not-for-profit medical service provider; or (d) any organization to which a tax deductible charitable contribution, under applicable IRS code or regulations or applicable foreign counterpart, may be made, and that is not owned or controlled by Company.

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
2a	Non-patent	Various	LICENSEE shall be responsible for all past, present and future costs of filing, prosecution and maintenance of all foreign patent applications, and patents contained in the LICENSED PATENTS in the countries outside the United States in the LICENSED TERRITORY selected by UNIVERSITY and agreed to by LICENSEE. All such applications or patents shall remain the property of UNIVERSITY. LICENSEE acknowledges that UNIVERSITY shall not file any such applications in low or lower-middle income countries, as designated by the World Bank. Furthermore, LICENSEE agrees not to file any patent rights that are owned by LICENSEE and that claim LICENSED PRODUCTS in any such low or lower-middle income countries.
2b	Non-patent	Large biotech	LICENSEE acknowledges that LICENSOR may elect to not file any such applications in LOWER INCOME COUNTRIES, unless otherwise agreed upon in advance and in writing by both parties.
3a	Non-suit	Metabolic disorder and drug discovery license to a start-up	University and Licensee on behalf of themselves and any successors-in-interest to the Licensed Patents and Licensed Processes covenant that they have not and will not, before or after the date of this Agreement, assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under the Licensed Patents and Licensed Processes for manufacture, use, sale, offer for sale or importation of Licensed Products against any third party engaged in the manufacture, use, sale, offer for sale, or importation of Licensed Products in or for Non-Suit Countries for sale to only Public Sector Entities that resell or redistribute such products to end users only. The above notwithstanding, this non-suit provision shall only apply to products which when offered for sale to end users are in a Trade Dress that is different from Licensee's Trade Dress in every respect.

3b	Non-suit	Osteoarthritic joints license to a start-up	University and Licensee on behalf of themselves and any successors-in-interest to the Licensed Patents acknowledge their mutual general intent not to assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under the Licensed Patents for manufacture, use, sale, offer for sale or importation of Licensed Products against any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Products in Non-Suit Countries if for sale to Public Sector entities. Accordingly, in the event that either University or Licensee becomes aware of activity in a Non-Suit Country that is potentially infringing issued Claims of the Patent Rights, each will notify the other in writing. Neither party may institute in court a claim of infringement of the Patent Rights in a Non-Suit Country against a third party if such third party is engaged in the manufacture, use, sale, offering for sale or importation of Licensed Products under written agreement the purpose of which is reasonably interpreted to be sale to a Public Sector entity but only to the extent any infringement is for such purpose. The above notwithstanding, this non-suit provision shall only apply to products which when offered for sale to end users are in a Trade Dress that is different from Licensee's Trade Dress in every respect. **NOTE: The typical response from Licensees is the concern that the clause takes away the right of the licensee to sue infringers. Also, there is a fear that a third party will manufacture and sell to approved agencies, but will also sell for profit. It takes some explaining that if a third party does sell into the market, they can be sued. It needs to be explained that the clause does not give a third party the right to sell at market if they sell at cost to a public sector entity. Often a concern is that a third party will sell \$1 worth of product to the public sector and then be able to sell into the market. It is explained that this is not the c
3c	Non-suit	Genetic therapy license to a start-up	Licensors and Licensee on behalf of themselves and any successors-in-interest to the Licensed Patents covenant that they will not, after the date the United States Food and Drug Administration (FDA) approves for marketing a therapeutic Licensed Product, assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under the Licensed Patents for manufacture, use, sale, offer for sale or importation of such FDA approved therapeutic Licensed Product against any Public Sector entity engaged in the manufacture, use, sale offer for sale, or importation of such FDA approved therapeutic Licensed Product in Non-Suit Countries. The above notwithstanding, this non-suit provision shall only apply to products which when offered for sale to end users are in a Trade Dress that is different from Licensee's Trade Dress in every respect.

Agmt Type

3d	Non-suit	Various	Non-suit:
			Non-suit. University and Licensee on behalf of themselves and any successors-in-interest to the
			Licensed Patents and Licensed Processes covenant that they will not, before or after the date of
			this Agreement, assert any claim of patent infringement (including direct infringement,
			contributory infringement, and induced infringement) under the Licensed Patents and Licensed
			Processes for manufacture, use, sale, offer for sale or importation of Licensed Products against
			any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Products in or for Non-Suit Countries for sale to Public Sector entities. The above
			notwithstanding, this non-suit provision shall only apply to products which when offered for sale
			to end users are in a Trade Dress that is different from Licensee's Trade Dress in every respect.
			Non-Suit Countries shall mean all countries other than Market Countries.
			Market Countries shall mean:
			(a) All current and future Organization for Economic Cooperation and Development (OECD)
			countries, presently consisting of Australia, Austria, Belgium, Canada, Czech Republic, Denmark,
			Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Republic of Korea, Japan,
			Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Spain, Sweden,
			Switzerland, Turkey, the UK, and the United States; and
			(b) All current and future members of the European Union not otherwise members of the OECD;
			and (a) Papula's Papullia of China India Malaysia Presion Federation Singapore South Konse and
			(c) People's Republic of China, India, Malaysia, Russian Federation, Singapore, South Korea and
			Taiwan.

Agmt Type

Mandatory ublicensing	Therapeutic	GRANT OF RIGHTS – EXCLUSIVITY
uoncensing		(a) If UNIVERSITY or COMPANY or an AFFILIATE receives a bona fide request from a capable third party for a license under the PATENT RIGHTS to develop and commercialize a PRODUCT for [*Disease*] at affordable prices in one or more DEVELOPING COUNTRIES that is not being sold (including without limitation sufficient supply to meet market demand at reasonable costs) or diligently developed for sale by COMPANY or an AFFILIATE or SUBLICENSEE in such DEVELOPING COUNTRY(IES), then the party receiving such inquiry shall promptly notify the other party in writing within fifteen (15) days of such inquiry (an "INQUIRY NOTICE"), setting forth the type of PRODUCT desired, the commercialization area desired, the name and contact information of the third party, and any other pertinent information. Within six (6) months of such INQUIRY NOTICE, COMPANY or an AFFILIATE shall enter into a sublicense agreement containing commercially reasonable terms and conditions with such third party for the requested PRODUCT for [*Disease*] in the requested DEVELOPING COUNTRY(IES). If COMPANY or an AFFILIATE does not grant a sublicense under the PATENT RIGHTS to the third party within six (6) months of such INQUIRY NOTICE, and UNIVERSITY, at its sole discretion, determines that a sublicense to the third party is reasonable under the totality of the circumstances (taking into account development efforts of COMPANY, AFFILIATES and SUBLICENSEES) to make PRODUCTS for [*Disease*] available in DEVELOPING COUNTRIES, then UNIVERSITY shall have the right to grant a non-exclusive license under the PATENT RIGHTS to such third party for such purposes. For clarity, any license granted by UNIVERSITY under this Section 2.2(b) shall be solely for bringing PRODUCTS for [*Disease*] from such DEVELOPING COUNTRY(IES) (and other countries mutually agreed to by UNIVERSITY and COMPANY or AFFILIATE) in a manner that enables availability and accessibility at reasonable cost, and shall specifically exclude the right of the third party licensee to export or sell PRODUCTS

Agmt Type

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
4b	Mandatory sublicensing	Various	The Licensee agrees to commercialize the Technology, Improvements and any Products in a manner consistent with the Global Access Principles. Without limiting the generality of the forgoing, the Licensee agrees to require all sublicensees and other parties involved in any aspect of the commercialization of the Technology, Improvements and any Products to execute agreements that bind such sublicensees or other parties (to the extent that they by agreement or operation of law obtain any rights in or to the Technology, Improvements and any Products) to comply with the Global Access Principles.
			 UNIVERSITY may use the Technology and any Improvements without charge in any manner at all for research, scholarly publication, educational and all other non-commercial uses; and the rights granted to the Licensee under this Agreement shall at all times be subject to a reservation by UNIVERSITY of a transferable, irrevocable, perpetual, non-exclusive, royalty free right to use and sublicense the Technology and any Improvements and to manufacture, have made, distribute, and sell the Products for the benefit of the Developing World. Exercise of this right will be at UNIVERSITY's sole discretion, which UNIVERSITY does not intend to exercise unless UNIVERSITY determines that the Licensee is taking inadequate steps toward making the Technology and any Improvements or any Products available to the Developing World in a manner consistent with the Global Access Principles.
			Any sublicense granted by the Licensee will be granted only to the sublicensee and cannot be assigned or further sub-sublicensed without the prior written consent of UNIVERSITY. All sublicenses must contain covenants by each sublicensee to observe and perform terms and conditions similar to those contained in this Agreement, including the Global Access Principles.
			NOTE: the Global Access Principles are principles that are mutually agreed between the UNIVERSITY and Licensee.
4c	Mandatory sublicensing	Various	Required Sublicensing. If Licensee is unable or unwilling to serve or develop a potential market or market territory for which there is a company willing to be a sublicensee, Licensee will, at UNIVERSITY's request, negotiate in good faith a sublicense with any such sublicensee. UNIVERSITY would like licensees to 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.

<u>#</u>	Clause Type	Agmt Type	Clause itself
4d	Mandatory sublicensing	Various	"(c) University retains the right to grant non-exclusive licenses under Patent Rights, solely to Qualified Humanitarian Organizations for use solely for Humanitarian Purposes; provided that:
			(i) Any such license shall expressly exclude the right to export any Licensed Product from any GAVI Country into any Non-GAVI Country or to use the Licensed Product in any Non-GAVI Country;
			(ii) University shall provide a complete copy of such license agreement, and any amendments thereto, (including any agreement pursuant to which a licensee grants a sublicense or assigns its rights pursuant to Section (v)), subject to redaction of any non-financial confidential information that does not affect, in any way, the obligations of University under this Section (c) or Licensee's ability to monitor University's performance of, or compliance with, its obligations under this Section (c), to Licensee within thirty (30) days after execution. Licensee shall keep any such copies of any such agreements in its confidential files, shall not disclose such agreements or the contents thereof to any third party (except auditors or legal advisors of Licensee for the purpose set forth below), and shall use them solely for the purpose of monitoring University's and such licensee's compliance with their obligations hereunder and enforcing Licensee's rights under this Agreement;
			(iii) Any such license shall be on terms and conditions in compliance with and not inconsistent with the terms of this Agreement;
			(iv) Any such license shall be granted only pursuant to a written agreement;
			(v) Such licensee shall not have the right to sublicense or to assign such license to any person or entity; provided, however, that (1) upon the express prior written consent of University, such licensee may sublicense or assign such licensee only to another Qualified Humanitarian Organization; and (2) that such licensee shall be entitled to engage independent third parties to practice Patent Rights on behalf of such licensee solely as set forth in the definition of Humanitarian Purposes without University's consent; and
			(vi) <number, as="" by="" generally="" income="" licensee="" of="" percent="" retained="" same="" sublicense=""> percent (80%) of any royalties or other consideration received by University in consideration of the grant of any such license shall be paid to Licensee."</number,>
4e	Mandatory sublicensing	Transgenic crops	The license is exclusive but the licensee grants "no-cost sublicenses solely for sale or use of the technology in a Least Developed Country.

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4f	Mandatory sublicensing	Diagnostic license to start-up	2.3.1. If, at any time following the third (3rd) anniversary of the Effective Date of this Agreement, (a) UNIVERSITY wishes to develop, or a third party makes a bona fide proposal to UNIVERSITY for developing, a Public Market Product that will be subsidized and distributed by non-profit and/or governmental organizations in one or more countries eligible to receive support from GAVI ("GAVI Countries", a list of the 72 countries eligible at the Effective Date to receive aid from GAVI are in Exhibit 2.3.1) and (b) Licensee either (i) is not developing such Public Market Product or (ii) is in the process of developing such Public Market Product, but is not planning for it to be subsidized and distributed by non-profit and/or governmental organizations in GAVI Countries or (iii) has commercialized such Public Market Product, but such product is not being subsidized and distributed by non-profit and/or governmental organizations in GAVI Countries, then UNIVERSITY shall notify Licensee of and shall provide Licensee with information regarding its or the third party's proposal. Within sixty (60) days of the receipt of such notification from UNIVERSITY, Licensee shall notify UNIVERSITY whether it is interested in developing such Public Market Product for subsidization and distribution by non-profit and/or governmental organizations in GAVI Countries or, if such product is already being commercialized, whether it will agree to ensure that such product be subsidized and distributed by non-profit and/or governmental organizations in GAVI Countries. 2.3.3. With respect to a Public Market Product that Licensee already has commercialized, if Licensee notifies UNIVERSITY within the sixty (60) day period specified in Section 2.3.1 that it is interested in ensuring that such product be subsidized and distributed by non-profit and/or governmental organizations in GAVI Countries, the retiremental organizations in GAVI Countries, the retiremental organizations in GAVI Countries.
			the parties will agree upon a plan with respect thereto, which plan will include reasonable milestones. In such case, Licensee shall be obligated to use commercially reasonable efforts to ensure that such Public Market Product is subsidized and distributed by non-profit and/or governmental organizations in accordance with such plan and to meet the milestones with respect thereto. NOTE: University started with straight diligence requirements, obligating the company to develop the product themselves for GAVI countries, but ended up with march-in rights if University or a 3rd party requests it. The reason for the switch was to not overburden the company to develop for global health causes, unless such a development was requested of them or it became part of their own business plan.
4g	Mandatory sublicensing	Various	2.15 Notwithstanding other provision of rights granted under this Agreement, should Licensee not be able or willing to provide Products in a reasonable time to an EDC as provided in Paragraph, UNIVERSITY hereby reserves the right to license the Patent Rights to any third parties for solely Humanitarian Purposes. Such licenses for Humanitarian Purposes will expressly exclude the right of the third party licensee to export or sell the Products from an EDC into a market outside of the EDC where Licensee has introduced or will introduce a Product and where Patent Rights exist. In any such license, the third party licensee's commercial use of the Patent Rights to make, use, sell, offer for sale and import Products in EDCs for Humanitarian Purposes will be royalty free and the third party licensee will be required to provide to any requesting EDC the Products at either no cost or at cost. For avoidance of doubt, the third party licensee may be permitted to export Products from the EDC of origin to other EDCs and all other countries mutually agreed to by UNIVERSITY and Licensee.

Clause Type Agmt Type

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
4h	Mandatory sublicensing	Various	In Sublicensing: "If UNIVERSITY (as represented by the actual knowledge of the licensing professional responsible for administration of UNIVERSITY 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 RODUCTS have not been developed or are not currently under development by LICENSEE, then UNIVERSITY, as represented by the Office of Technology Transfer, 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 UNIVERSITY personnel who do not assent to its disclosure to LICENSEE. Within ninety (90) days following LICENSEE's receipt of UNIVERSITY' notification LICENSEE shall give UNIVERSITY 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 UNIVERSITY pursuant to Article xx herein. If LICENSEE elects not to develop and commercialize the proposed LICENSED PRODUCTS for use in the new application, UNIVERSITY may seek (a) third party(ies) to develop and commercialize the proposed LICENSED PRODUCTS for use in the new application, UNIVERSITY may seek (in UNIVERSITY 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 UNIVERSITY within thirty (30) days from the date of such written request. If the request results in a sublicense, then LICENSEE shall report to UNIVERSITY within thirty (30) days from the date of such written request. If the request results in a sublicense, then LICENSEE shall report to UNIVERSITY are proprosed by the third party are re

#	Clause Type	Agmt Type	Clause itself
4i	Mandatory sublicensing (w/ reasonable cost distribution)	Antibiotic potentiation license to a start-up	Mandatory Sublicensing and Retained Sublicensing Rights. At the request of University made at any time after a Licensed Product is being sold and commercialized by Licensee in the Market Countries and subject to and upon the terms and conditions of this Section 2.03, Licensee shall negotiate in good faith to enter into one or more appropriate distribution agreements with one or more Non-Suit Country Distributors on reasonable terms for the purpose of enabling the sale and distribution of such Licensed Product in any Non-Suit Countries requested by University. Such distribution agreements (i) shall provide for the sale of such Licensed Product in such Non-Suit Countries at Cost-Based Prices, (ii) shall contain reasonable provisions intended to ensure that sales of such Licensed Product in such Non-Suit Countries does not adversely affect sales, or revenues from sales, of such Licensed Product in Market Countries, (iii) shall contain reasonable provisions, including as to use of trademarks, trade dress, format and packet size, to ensure the differentiation of any Licensed Product sold and distributed in any Non-Suit Country as contemplated in this Section 2.03 from Licenseed Products sold in Market Country, (iv) shall not provide that any payments be made to Licensee Product sold and distributed in any Non-Suit Country, (iv) shall not provide that any payments be made to Licensee in respect of the grant by Licensee of any sublicense of the rights licenseed to Licensee under this Agreement to allow the sale of any Licensed Products pursuant to such distribution agreements for use in any Non-Suit Country, and (v) shall provide, to the extent that any exclusive rights are granted to any Non-Suit Country Distributor pursuant to such distribution agreements with respect to any Non-Suit Country, that the continued grant of such exclusive rights to such Non-Suit Country Distributor in such Non-Suit Country Shall be conditioned on such Non-Suit Country Distributor supplying one or more Licensed Products in such Non-Suit
4j	Mandatory sublicensing	Various	contemplated in this Section 2.03. In the event that University believes that Licensee's refusal or unwillingness to enter into a distribution agreement with any Non-Suit Country Distributor constitutes a breach or violation of the provisions of this Section 2.03, University may, in addition to any other remedies that University may exercise in connection with such breach or violation and only after compliance with the provisions of Section 10.01 hereof, commence an action in any court of competent jurisdiction in accordance with the provisions of Section 10.04 of this Agreement seeking specific performance to force Licensee to force Licensee to enter into such distribution agreement. If (a) the licensing professional responsible for administration of UNIVERSITY Case No.[] receives notice from either UNIVERSITY or a third party that UNIVERSITY or such third party has discovered and can outline and reduce to practice a methodology that uses one or more of the INVENTIONS for the [HUMANITARIAN PURPOSE] purpose of producing, for free or at cost, LICENSED PRODUCTS solely for the treatment of malaria in EDCs (an "EDC HUMANITARIAN APPLICATION"), and (b) at the time of such notice, LICENSED PRODUCTS have not been developed for an EDC HUMANITARIAN APPLICATION and neither the LICENSEE nor any of its SUBLICENSEES is currently engaged in efforts to use one or more of the INVENTIONS for an an EDC HUMANITARIAN APPLICATION, then the UNIVERSITY, as represented by the Office of Technology Transfer, shall give written notice to the LICENSEE,"

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
4k	Mandatory sublicensing w/ reasonable cost distributions	Exclusive license to medical device start-up (related to Definition 1i)	Diligence Requirements (and in addition to typical commercial diligence requirements): (i) Within 24 months of First Commercial Sale, Company will adopt and enact a plan, reasonably acceptable to Hospital, to make Products and/or Processes available for sale at Cost + 15% plus applicable shipping, taxes, customs duties and other government charges to Qualified Organizations. Making Products and/or Processes available for sale includes, but is not limited to, making continuing reasonable efforts to fulfill requests for orders from Qualified Organizations. (ii) Upon 24 months after First Commercial Sale and thereafter, at Hospital's request, Company agrees to discuss in good faith entering into sublicensing discussions with third parties that Hospital may introduce to Company to make, have made, use, have used, Sell and have Sold, Products and/or Processes in Middle Income and Low Income Countries. This section shall not relieve Company of its obligations under Section (i) above.
4L	Sublicensing	Exclusive pharma license to specialty pharma company	LICENSEE shall have the exclusive right and responsibility for sublicensing the LICENSED PRODUCT. LICENSEE may sublicense the rights granted to it under this Agreement (including the right to grant to a SUBLICENSEE the right to grant further sublicenses) to QUALIFIED SUBLICENSEEs without the prior written consent of LICENSOR; provided, however, (a) X; and provided, further,
			(b) that any sublicense has provisions, reasonably acceptable to SUBLICENSEE, credibly enabling the sale or distribution of a LICENSED PRODUCT, by an internationally recognized non-profit non-governmental organization for the treatment of diseases in DEVELOPING ECONOMIES; and provided further,
			(c) z.
5a	Reasonable cost distribution	Various	LICENSEE agrees that LICENSED PRODUCTS will be offered for sale in low and lower-middle income countries at a price that is equal to LICENSEE'S actual cost to manufacture and distribute such LICENSED PRODUCTS.

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6a	Mandatory development (w/ reasonable cost distribution)	Infectious disease	Licensee agrees that in GAVI Countries in which it is, at any time during the term of this Agreement, selling Licensed Products, it will during such period use commercially reasonable efforts to make such Licensed Products reasonably available to needy populations in such countries at affordable prices. In addition, Licensee shall use commercially reasonable efforts to cause Sublicensees to make similar commitments, provided that if any Sublicensee makes any such similar commitment, the efforts of such Sublicensee shall be considered efforts of Licensee for purposes of determining Licensee's compliance with its obligation to use commercially reasonable efforts as set forth in this Section." Licensee shall make a first commercial sale in a GAVI Country by <date>.</date>
6b	Mandatory	Various	LICENSEE agrees to use commercially reasonable efforts to pursue
	development		clinical testing of the LICENSED PRODUCT in low-income and lower-middle-income countries
6с	Mandatory development	Various	Within six (6) months of NDA/BLA approval in the US or its equivalent in Europe, Licensee shall send a written report to UNIVERSITY detailing the potential Public Sector market to fulfill the public health need for the approved drug or vaccine in Developing Countries, including the impact of any approved competing drug or vaccine. The report shall also include Licensee's proposed amendment to the Commercial Development Plan, Appendix E, and the Benchmarks and Performance, Appendix D to address the needs for Licensed Products in Developing Countries. Licensee will diligently consider if it is possible from a commercial and technical point of view, to satisfy said potential Public Sector market either directly with Licensee's own resources and/or through joint ventures with third parties. Acceptance of this report and amendment is required by UNIVERSITY in writing; such acceptance will not be unreasonably denied.
			NOTE: Per above, at the time when the product is launched in a "major market", the company must submit a

plan that addresses the need for such products in developing countries. By doing so, UNIVERSITY allows the company to work a plan for product development in developing counties into an overall global strategy and still

achieve necessary returns from traditional commercial markets. The actual mode of distribution to the developing world is not dictated by the UNIVERSITY, either at time of execution or in later years. It can vary

according to the circumstances involved -- direct distribution, sublicense or a joint venture.

Clause Type | Agmt Type

_=	Clause Type	right Type	Charles risen
6d	Mandatory development	Therapeutic	Diligence Requirements for DEVELOPING COUNTRIES. UNIVERSITY and COMPANY agree that it is an important objective of both parties that PRODUCTS for [*Disease*] be made available in DEVELOPING COUNTRIES on reasonable terms, both with respect to availability of sufficient quantities of PRODUCTS and the cost thereof. Specifically, COMPANY or AFFILIATE shall fulfill the following obligations:
			(i) Within twelve (12) months after the EFFECTIVE DATE, COMPANY shall furnish UNIVERSITY with a written development and commercialization plan describing the COMPANY's strategy for bringing PRODUCTS for [*Disease*] to market in DEVELOPING COUNTRIES in a manner that is designed to enable availability and accessibility at reasonable cost, and shall discuss with UNIVERSITY the plan and provide an opportunity for UNIVERSITY to comment on the plan. COMPANY shall use diligent efforts to develop and commercialize PRODUCTS for [*Disease*] in DEVELOPING COUNTRIES in accordance with such plan.
			(ii) Within sixty (60) days after the end of each calendar year, COMPANY shall furnish UNIVERSITY with a written report on the progress of its efforts during the immediately preceding calendar year to develop and commercialize PRODUCTS for [*Disease*] in DEVELOPING COUNTRIES.
			(iii) COMPANY shall use reasonable efforts to either (x) obtain the commitment of its SUBLICENSEES to use diligent efforts to develop and commercialize PRODUCTS for [*Disease*] in DEVELOPING COUNTRIES in a manner that is designed to enable availability and accessibility at reasonable cost, or (y) retain rights to develop and commercialize PRODUCTS for [*Disease*] in DEVELOPING COUNTRIES.
			In addition to the remedies set forth in Section 2.2(b) with respect to PRODUCTS, in the event COMPANY (or an AFFILIATE or SUBLICENSEE) has failed to fulfill any of its obligations under this Section 3.1(b), UNIVERSITY may treat such failure as a material breach in accordance with Section 12.3(b), provided that any termination under Section 12.3(b) for breach of obligations under this Section 3.1(b) shall be limited to COMPANY's and its AFFILIATE's licenses and rights under the PATENT RIGHTS for PRODUCTS for [*Disease*] in DEVELOPING COUNTRIES in which such failure has occurred. The termination of COMPANY's and AFFILIATE's licenses and rights in such DEVELOPING COUNTRIES for PRODUCTS for [*Disease*] will not affect the remaining terms of this Agreement.
			"NOTE: start-ups survive by partnering, so ensuring these rights pass through to the sublicensees is important as well"

Clause Type Agmt Type

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
бе	Mandatory development	Exclusive pharma license, specialty pharma	(g) LICENSEE agrees that any sublicense shall have due diligence terms such that: X.It is the desire of both LICENSOR and LICENSEE to make LICENSED PRODUCTS available in DEVELOPING ECONOMIES, to that end, LICENSEE agrees to use REASONABLE COMMERCIAL EFFORTS, and shall use REASONABLE COMMERCIAL EFFORTS to cause SUBLICENSEE to use REASONABLE COMMERCIAL EFFORTS, to make such LICENSED PRODUCTS available in a credible manner consistent with the specific financial capability of the DEVELOPING ECONOMIES.
6f	Mandatory development	Biotech license	It is the desire of both LICENSOR and LICENSEE to make LICENSED PRODUCTS available in LOWER INCOME COUNTRIES, and it is the parties' common desire for the LICENSEE to develop LICENSED PRODUCTS that are clinically and economically suited for use in LOWER INCOME COUNTRIES. To that end, LICENSEE agrees to make available on commercially reasonable terms and where commercially viable LICENSED PRODUCTS, medical products, medical services, advisory services, grants, or services to governments, non-profit medical agencies, governmental agencies or affiliates or not-for-profit charitable organizations in LOWER INCOME COUNTRIES, not-for-profit charitable organizations such as Doctors Without Borders or The Gates Foundation, or other such organizations for the purpose of treating patients located in LOWER INCOME COUNTRIES, within Six (6) Months of achieving One Hundred Million Dollars (\$100,000,000) of profit.

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
6g	Mandatory development w/ reasonable cost distribution	Various	Global Health. The University and Licensee mutually agree on the importance of ensuring that Licensed Products and Licensed Processes are made available to people in all economic strata around the world. On a country-by-country and case-by-case basis in countries in which there is at least one valid Claim and where the Licensee has already made its first commercial sale of a Licensed Product in the Territory, Licensee shall take commercially reasonable measures to sell, offer for sale Licensed Products to Public Sector Entities in Developing Territories, provided that in each case, such Public Sector Entity has put into place adequate measures to ensure that the Licensed Product will only be used in the country in the Developing Territory which such Public Sector Entity is located and will not be used to diagnose, test, analyze, review, or produce data for, or distributed outside to, directly or indirectly, any person or entity outside of the such country in the Developing Territory. The Licensee agrees that such Products will be sold at the fully burdened manufacturing costs (including without limitation, tariffs. fees, taxes, training, sublicense fees, royalties and all other costs related to manufacturing and distribution) plus no more than a 20% profit margin to such Public Sector Entity in the country in the Developing Territory for so long as such country remains in the Developing Territory. Licensee shall not be required to distribute to any Developing Territory if such distribution would violate any law, rule, regulation, treaty or order or to the extent that such Developing Nation restricts or prohibits the termination of any sublicensee or distributor in such Developing Nation. For avoidance of doubt, Licensee is entitled to the full extent of the law to protect its Licensed Rights granted hereunder.

#	Clause Type	Agmt Type	<u>Clause itself</u>
7a	Statement of principles	Various	"Many licenses contain language that commit both parties to "good faith discussions" about global health strategies and especially if either party receives an inquiry from a government or NGO about humanitarian use."
7b	Statement of principles	Various	Licensee agrees to consider, at its sole option, means to address third world access to Products on a compassionate basis. In the event that, during the term of this Agreement, any U.S. law or regulation is passed in the U.S. which obliges UNIVERSITY and/or the Licensee to supply Compounds and/or Products to third world countries on a compassionate use or similar basis as a result of the funding of the Licensed Patents and UNIVERSITY Know-How by US governmental agencies or foundations, the Parties will negotiate in good faith how to comply with such requirement in the most effective way.
7c	Statement of principles	IIA template	In the case of Inventions with significant medical applications, Institution(s) shall carefully consider its patenting and licensing strategy in an effort to enhance the availability of medical treatments within the developing world.
7d	Statement of principles	Therapeutic	WHEREAS, University and COMPANY understand and accept that the availability of LICENSED PRODUCTS for [*Disease*] at affordable prices to poor segments of the world's populations in DEVELOPING COUNTRIES is an important objective of the parties;
7e	Statement of principles	Various	It is the desire of both UNIVERSITY and LICENSEE to make LICENSED PRODUCTS available in the developing world, and it is the parties' common desire for the LICENSEE to develop LICENSED PRODUCTS that are clinically and economically suited for use in those areas. To that end, UNIVERSITY and LICENSEE agree that LICENSEE shall make the use of LICENSED PRODUCTS in low income and lower-middle income countries a part of its Corporate Mission Statement.
7f	Statement of principles	Exclusive License & Term Sheets	Section Global Social Responsibility During the term of this Agreement, UNIVERSITY and Company agree to take into consideration the principle of "Global Social Responsibility" in performing the various activities contemplated under this Agreement. "Global Social Responsibility" means facilitating the availability of (Licensed) Products in "Developing Countries" at locally affordable prices, under reasonable circumstances and terms to improve access to such Products in such countries. "Developing Countries" shall mean those countries listed by the World Bank as "Low-Income Economies", as such list may change from time to time. Solely by way of example, the Parties may mutually agree to revise royalty rates, adjust fair market value, consider non-monetary consideration, and / or develop patent strategies in support of each party's dedication to Global Social Responsibility.

<u>#</u>	Clause Type	Agmt Type	Clause itself
7g	Statement of principles	Various	In order for UNIVERSITY technologies to maximize their societal impact, practical mechanisms and partnering strategies are required that (a) enhance both the economic and societal impact of University innovations; (b) extend these impacts to broader global settings; and (c) ensure fair access to these technologies for the world's poor within an evolving framework of licensing practices, legal concerns, business opportunity and time constraints.
			Broadening the societal impact of and global access to UNIVERSITY technologies requires that these concerns are addressed when new UNIVERSITY technologies are developed, patented and licensed. To this end, while applying the University's intellectual property policy, UNIVERSITY will:
			 Promote global access by entering public/private partnerships to develop new technologies to benefit the developing world
			 Prioritize environmentally friendly research and green alternatives, and take the lead in community sustainability
			 Respect biodiversity, ensuring value return to countries of origin
			 Endeavour to ensure that under privileged populations have 'at cost' access to UNIVERSITY research innovations through negotiated global access terms whenever appropriate
			As the understanding of issues relating to societal licensing evolves, balancing ambitious objectives with legitimate business concerns requires patience, determination, and the willingness to be both pragmatic and flexible. To support our social licensing commitment, UNIVERSITY will, where possible, employ the following strategies:
			 Build on the values of access and dissemination as demonstrated in the open source movement in the IT sector Promote the use of non-exclusive licensing of research tools
			 Consider field-of-use and jurisdictional limitations in exclusive licenses to exclude developing world countries Negotiate developing world access 'at cost' to relevant technologies which are licensed on a world-wide exclusive
			 basis (required for technology development) Continue to seek partnerships with not-for-profit and charitable organizations to provide much needed funding for neglected disease areas
			 Design patent strategies with our development partners that ensure quality product delivery to those most in need, while promoting sustainable, local infrastructure
			In measuring the success of technology transfer activities at UNIVERSITY, societal impact has become a key metric alongside standard throughput, financial and economic measurements. Positive societal impacts include improving human and veterinary health, supporting international biodiversity, protection of the environment, and promoting sustainable green alternatives.

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
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8a	No royalties due	Malaria therapy	In section: Royalties – "shall be royalty-free if the relevant LICENSED PRODUCT is a pharmaceutical product intended for the treatment of malaria (the "MALARIA FIELD")." NOTE: inventors are always required to sign a consent form acknowledging that the royalties are being waived for those purposes, to avoid questions after the fact.
8b	No royalties due	Therapeutic	e. RUNNING ROYALTIES: Royalties shall not be due to UNIVERSITY on NET SALES of (i) PRODUCTS in DEVELOPING COUNTRIES, or (ii) any other LICENSED PRODUCTS to the public sector (i.e., governmental, quasi- governmental or non-profit entities providing LICENSED PRODUCTS at a COST BASED PRICE) in DEVELOPING COUNTRIES. As used in this subsection, the term "COST BASED PRICE" means, in respect of each LICENSED PRODUCT, a price not exceeding that which fairly reflects the direct cost of manufacture of such LICENSED PRODUCT plus a typical margin for a generic pharmaceutical product for the respective market.
8c	No royalties due	Infectious disease	Licensee understands and acknowledges that it is University's goal that Licensed Products be made available to needy populations in GAVI Countries at affordable prices, and that it is in furtherance of this goal, and in hopes of providing Licensee with a further incentive to make Licensed Products so available, that University agrees not to be entitled to royalties under Section XX with respect to sales, leases or other transfers of Licensed Products by Licensee or its Affiliates for use in GAVI Countries and not for further sale or other transfer to, or use in, any Non-GAVI Country.
8d	No royalties due	Various	Notwithstanding any other provision of this Agreement, Licensee's commercial use of the Patent Rights to make, use, sell, offer for sale and import Products in EDCs for Humanitarian Purposes will be royalty free and the Licensee will be required to provide to any requesting EDC the Products at either no cost or at cost once Licensee has achieved commercial Sales of the Products.
8e	No royalties due	Various	"Licensee understands and acknowledges that it is University's goal that Licensed Products be made available to needy populations in GAVI Countries at affordable prices, and that it is in furtherance of this goal, and in hopes of providing Licensee with a further incentive to make Licensed Products so available, that University agrees not to be entitled to royalties under Section XX with respect to sales, leases or other transfers of Licensed Products by Licensee or its Affiliates for use in GAVI Countries and not for further sale or other transfer to, or use in, any Non-GAVI Country."

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
8f	No royalties due	Exclusive license (as a bolt-on appendix to boilerplate license)	(1) In furtherance of UNIVERSITY's goal to make Humanitarian Products available in Developing Countries, and to encourage Company's efforts to meet this goal, UNIVERSITY agrees that the provisions of Section 4(i) of the License Agreement ["Sales Below Fair Market Value"] will not be applicable solely with respect to any manufacture, distribution, use, lease, transfer, and/or sale of Humanitarian Products for Humanitarian Purposes in any Developing Country. (2) UNIVERSITY further agrees that it will not be entitled to royalties or other payments on "Net Sales" as defined in Section 1(g) of the License Agreement ("License Royalties") solely with respect to any manufacture, distribution, use, lease, transfer, and/or sale of Humanitarian Products for Humanitarian Purposes in any Developing Country at reasonable prices, but will be entitled to License Royalties for any further sale, resale, lease, distribution and/or other transfer to, or use in, any part of the licensed Territory that is not a Developing Country.

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
8g	Decreased royalties due	Exclusive license to medical device start-up (related to clauses 1i and 4k above)	(b) After the second anniversary of the First Commercial Sale, Company shall pay Hospital 5% on Net Sales (including, without limitation, imputed fair market value of transfers) by Company, its Affiliates, Sublicensees, and Distributors of Products and/or Processes in High-Income Countries where there are Patent Rights and/or Claims at the time such Net Sales accrue.
			(i) For each year in which Company sells Products and/or Processes at a Cost + 15% basis sufficient to treat x,xxx or more patients, through Qualified Organizations, in Low-Income Countries and/or Middle-Income Countries, royalty owed by Company to Hospital for sales in High-Income Countries where there are Patent Rights and/or Claims at the time such Net Sales accrue shall be 4% of Net Sales.
			(c) Company shall pay Hospital 2% on Net Sales (including, without limitation, imputed fair market value of transfers) by Company, its Affiliates, Sublicensees, and Distributors of Products and/or Processes in Middle-Income and Low-Income Countries where there are Patent Rights and/or Claims at the time such Net Sales accrue.
			(d) Company shall pay Hospital 1% on Net Sales (including, without limitation, imputed fair market value of transfers) by Company, its Affiliates, Sublicensees, and Distributors of Products and/or Processes in High-Income Countries and Middle-Income Countries where there are no Patent Rights and/or Claims at the time such Net Sales accrue. Company acknowledges that Products and/or Processes were or will be developed using, based upon, or derived from Technological Information.

<u>#</u>	Clause Type	Agmt Type	<u>Clause itself</u>
8g	Decreased royalties due (continued from priorpage)	Exclusive license to medical device start-up (related to clauses 1i and 4k above)	CONTINUED FROM PRIOR PAGE: e) Company shall pay Hospital 0.5% on Net Sales (including, without limitation, imputed fair market value of transfers) by Company, its Affiliates,
			Sublicensees, and Distributors of Products and/or Processes in Low-Income Countries where there are no Patent Rights and/or Claims at the time such Net Sales accrue. Company acknowledges that Products and/or Processes were or will be developed using, based upon, or derived from Technological Information.
			(f) Company shall pay Hospital 0% on Net Sales (including, without limitation, imputed fair market value of transfers) by Company, its Affiliates, Sublicensees, and Distributors of Products and/or Processes Sold to Qualified Organizations in Low-Income Countries and/or Middle Income Countries at a Cost + 15% basis.
9	Mandatory donation	Various	LICENSEE agrees that, upon achieving \$ X,000,000 in cumulative profits (determined in accordance with GAAP) from sales of LICENSED PRODUCTS, LICENSEE will commit an amount equal to 1% of NET SALES, in the form of LICENSED PRODUCTS, grants and/or services to governments in underdeveloped regions, not-for-profit charitable organizations such as Doctors Without Borders or The Gates Foundation, or other such organizations for the purpose of treating XXX in patients located in underdeveloped regions.