

Promoting Global Access To Health Technologies: A Licensing Toolkit For Public Sector Institutions

Part 1

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Abstract

The growing shift among public sector institutions and pharmaceutical companies towards equitable licensing of their health technologies is commonly termed “Global Access Licensing”¹ or “Socially Responsible Licensing.” This two-part article uses the term “Global Access Licensing” (GAL) to describe a set of licensing provisions and terms that can be utilized by public sector institutions, including funding agencies, universities, and research institutes, and included in license agreements with industry partners to ensure access and affordability of resulting health technologies in the developing world.^{2,3}

A GAL approach is sensitive to the fact that licenses are complex and each will be unique. It offers a flexible framework that does not prescribe specific language for every contract; rather, it provides a range of principles and contractual language that can guide IP commercialization practices during licensing negotiations with industry partners.⁴

This two-part research synthesis draws upon interview discussions with technology transfer office directors of leading North American and British universities with GAL policies and provisions, including Harvard, UC Berkeley, Yale, Oxford, and UCL,⁵ as well as the relevant literature in the field of global access licensing of publicly funded health technologies, in order to present readily imple-

1. Universities Allied for Essential Medicines, GAL Framework: <https://case.edu/research/sites/case.edu/research/files/2018-04/UAEMframework.pdf>.

2. Ashley J. Stevens, “Valuation and Licensing in Global Health,” Chapter 2.5, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

3. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

4. Kapczynski A., Chaifetz S., Katz Z., Benkler Y., “Addressing Global Health Inequities: An Open Licensing Approach for University Innovations,” *Berk Tech Law J.* 2005;20:1031–1089

5. Nguyen T., Veras J., and Shahzad M., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America: Identifying Key Provisions To Promote Global Access To Health Technologies,” *les Nouvelles*, Volume LIII No. 3, 2018.

mentable licensing provisions and clauses in the form of a GAL toolkit for public sector institutions.

GAL provisions that will be outlined in this toolkit include:

Part 1:

- Jurisdictional limitations and field-of-use licenses
- Non-exclusive licensing of research tools and platform technologies
- Affordable pricing provisions (e.g., at-cost, cost-plus pricing)
- Reservation of rights for humanitarian purposes
- Sublicensing in underserved markets
- Non-assertion of patent rights in developing countries

Part 2:

- Reduced royalty payments to ensure affordable cost
- Global access milestones and affordable access plans
- Forgoing patents in developing countries
- Follow-on patents and proactive considerations for global access
- Promoting generic competition in developing countries

Each GAL provision outlined in this toolkit will be supported with:

1. Contractual approach and sample clauses implemented in license agreements by universities;
2. Universities’ experiences with the GAL provision (acquired from interview discussions with technology transfer office directors at various universities);
3. Case studies demonstrating how the GAL provision facilitated access to the university health technology in the context of a university-industry partnership;
4. Implementation considerations offered by licensing officers and technology transfer experts.

Promoting Equitable Access to Health Technologies: A GAL Toolkit—Part 1

The GAL provisions in this toolkit are largely based on a market segmentation (or dual market) approach which addresses “the licensing

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challenge for drugs which treat diseases that afflict both the developed and the developing world...[i.e.] how to achieve competition in developing countries while preserving their patent monopoly in developed countries,” as highlighted by Dr. Ashley Stevens, former director of Boston University’s Office of Technology Development.⁶

This approach can be applied in license agreements to “effectively segment the commercial and humanitarian uses of a technology.”⁷ Thus, through market segmentation, an exclusive license can grant a private sector licensee the sole right to use and sell a technology in profitable, high-income markets, while at the same time ensuring the licensee (or other manufacturers) can use and sell the technology at lower cost or reduced royalties to serve market segments that do not interest the private sector.⁸

The benefits of the market segmentation approach are further outlined by Dr. Sara Boettiger, Head of Global Public Affairs at Bayer, and former Deputy Director of the Gates Foundation:

- “Are there benefits to be gained from segmenting the market? One benefit of choosing to patent...is that patenting provides an opportunity to segment the market of technology users or licensees.
- An IP manager may require **different licensing terms, for instance, depending on whether the technology will be used commercially or for humanitarian purposes.**
- Alternatively, **the license might contain terms to segment the market geographically or by fields of use.** An exclusive license may be implemented, for example, to limit the technology’s use to one major crop, reserving all other uses of the technology for widely accessible and nonexclusive licensing. **Using such an approach, income generation and access may be complementary goals for the IP provider.**
- **Or the rights to a technology in, for instance, developed country markets may be exchanged for contractual obligations to deliver**

6. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

7. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

8. Brewster A., *et al*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

the product to developing countries for a reasonable price.”⁹

Following the outline of a standard technology license, Part 1 of this GAL toolkit will cover:

- **Term sheet**
- **Recitals**
- **Article 1: Definitions**
 - “Humanitarian Purposes”
 - “Developing Countries”
 - “Global Access Policy”
 - “Charitable Objective”
 - “At-cost Markets”
 - “Cost-based Pricing”
- **Article 2: Grant of License**
 - 2.1. Exclusivity-related Provisions for Global Access**
 - a. Reserving non-exclusive rights in developing countries
 - b. Non-exclusive and field-exclusive licensing of research tools and platform technologies
 - c. Exclusive licenses tied with at-cost or cost-based pricing provisions for developing countries
 - 2.2. Territory-related Provisions for Global Access**
 - a. Jurisdictional limitations to exclude developing countries (*i.e.*, licensed territory restrictions)
 - 2.3. Field-of-use-related Provisions for Global Access**
 - a. Field-of-use restrictions
 - 2.4. Reserved Rights**
 - a. Reservation of rights for humanitarian purposes
 - b. Reserved research exemptions
 - c. Sublicensing to address unmet public health needs
 - d. March-in rights
 - 2.5. Non-assertion of Rights Agreement**

A final note is that each institution with a GAL policy has demonstrated success with implementing these various approaches depending on which GAL provisions are found to be (a) most acceptable to their com-

9. Boettiger S., “Defensive Publishing and the Public Domain,” Chapter 10.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

mercial licensees and (b) most effective in promoting affordable access to their technologies in developing countries.^{10,11}

Term sheet

I. Contractual Approach and Sample Clauses

Dr. Stevens offers an approach for introducing GAL using the Term Sheet:

“It is imperative that the concept of Social Responsibility be introduced into the negotiations from the outset. We therefore recommend that the concept be referenced (though, for simplicity, the precise mechanism not be spelled out) in the institution’s standard Term Sheet.

- *Implementation—include in Term Sheet:*
 - **‘Global Access Policy’** means the commercialization of the Technology, Improvements, and any Products in a manner that enables availability and accessibility at reasonable cost to the people in the Developing World.
 - **‘Charitable Objective’** shall mean the availability of the Licensed Products in developing countries at affordable prices.
 - **Include in ‘Exclusivity’:** Non-commercial rights, Government Rights, and Humanitarian Rights reserved.”¹²

The Association of University Technology Managers (AUTM) notes that “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.” Further, AUTM has developed a *Global Health Licensing Toolkit* containing clauses from license agreements successfully executed by U.S. universities.¹³ AUTM provides the following clause in its Global Health Toolkit which universities can include in a standard Term Sheet:

“Include in ‘Term Sheet’, under 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.”

II. Universities’ Experience with GAL Strategy

Several universities have established this practice as a standard part of their license agreements with industry partners. Examples are offered below:

• **Harvard University, Office of Technology Development:**

- *“We discuss at the very beginning what types of global access provisions will be relevant and included in the discussion. If we have a term sheet, we will include them [global access provisions] on a higher level on that term sheet.”¹⁴*

- More specific language will usually take shape as the university and industry partner integrate the context in which the finished technology will be commercialized:
 - *The Director of Yale University’s Office of Cooperative Research, Dr. John Puziss, described their strategy as “starting off with a laundry list of [GAL] terms” that they wish to include in the license. As the negotiation evolves, the initial list “gets narrowed down to a smaller subset.”¹⁵*
- The **UBC Industry Liaison Office** utilizes the AUTM *Global Health Licensing Clause Toolkit* as a source of sample clauses:¹⁶

10. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

11. Nguyen T., et al. “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” (July 23, 2018), *les Nouvelles*, Volume LIII No. 3, September 2018.

12. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

13. AUTM Global Health Toolkit: <https://autm.net/surveys-and-tools/tools/global-health-toolkit>.

14. Interview with Harvard TTO, 2017 - Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

15. Interview with Yale TTO, 2017 - Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

16. AUTM Global Health Toolkit: <https://autm.net/surveys-and-tools/tools/global-health-toolkit>.

- “We would draw upon both our experience, but also some of the clauses that are available from the AUTM clause library, particular clauses that make sense in this case [and context].”¹⁷

Recitals

I. Contractual Approach and Sample Clauses

To develop appropriate Recital clauses that emphasize the university’s commitment to ensuring global access, Dr. Stevens suggests the following approach:

“No matter which licensing approach is being used, as a general proposition it is probably helpful to include in the “WHEREAS” clauses a general statement of purpose, such as:

- *“WHEREAS, It is the policy of the University that its activities in licensing University intellectual property take into consideration Global Social Responsibility Objectives to fulfill unmet needs in Developing Countries, (such as those of neglected patient populations or geographic areas), and Licensee acknowledges and agrees to carry out its activities under this Agreement in a manner designed to fulfill such needs, as set forth below”; or*
- *“WHEREAS, University and Licensee understand and accept that it may serve the public good for there to be competitive sources of Licensed Product in certain markets, with appropriate safeguards to Licensee’s economic interests in other markets as more fully specified herein, and that the result of this will be the availability of drugs at affordable prices to poor segments of the world’s populations.”*

Many universities with GAL policies also utilize similar clauses within the Recitals section of their standard license agreements:

• UC Berkeley:

- *“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.”*
- *“The Parties agree that provisions for humanitarian use license rights, as further described in*

17. Interview with UBC TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

*Section 2 herein, are intended to address economically disadvantaged populations (‘EDPs’ as defined in Article 1), and to induce investment and create markets for such populations where: i) there is strong potential for social impact in EDPs.”*¹⁸

• University College London:

- *“It is the policy of UCL Business PLC, the wholly-owned commercialization company for UCL (UCLB) and UCL that its activities in licensing intellectual property take into consideration ethical and SRL [Socially Responsible Licensing] principles, including ensuring that licensed Products are made available to fulfill unmet needs in Developing Countries, and the licensee acknowledges and agrees to carry out its activities under this Agreement in a manner which complies with UCLB’s ethical and socially responsible licensing principles policy and which is designed to fulfill such needs, all in accordance with the provisions of this Agreement.”*¹⁹

• UBC Industry Liaison Office:

- *“It is UBC’s objective to mobilize its technology for the public benefit, and in a manner consistent with its Global Access Principles, and status as a non-profit, tax-exempt educational institution.”*²⁰

• AUTM offers the following as examples of Recital clauses that were extracted from license agreements successfully executed by U.S. universities:

- *“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”;*
- *“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.”*
- *“It is the desire of both UNIVERSITY and LICENSEE to make LICENSED PRODUCTS available in the developing world, and it is the*

18. UC Berkeley Socially Responsible Licensing Program: https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Guidance_%26_Clauses_v100817.pdf.

19. Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

20. Available: <https://www.sec.gov/Archives/edgar/data/0001703057/000119312520299507/d29983dex106.htm>.

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.”²¹

Article 1: Definitions

I. Contractual Approach and Sample Clauses

A key aspect of developing appropriate definitions to facilitate access in developing countries is the need to specify the humanitarian purposes and the intended beneficiaries.²² The following strategy is offered by Dr. Alan Bennett, former Associate Vice Chancellor Research at UC Davis, and Dr. Stevens:

Humanitarian Purposes

- “There are several approaches used to define humanitarian purposes: by income level, by uses (subsistence or commercial), and by geography—**humanitarian uses can be defined geographically by specifying all uses of the technology within developing countries.**”²³
- **Sample clause (UC Berkeley):**
 - ‘**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 Economically Disadvantaged Country (EDC), and (b) the use of the LICENSED PRODUCTS or LICENSED SERVICES by any nonprofit organization or other third party for SALE [commercial purposes] solely in an EDC at or below cost.”²⁴

Developing Countries

- “**If humanitarian uses are defined geographically then an explicit definition of developing countries is needed. For example, de-**

veloping countries can be defined as those listed by the World Bank or other international agencies.

- While this definition can effectively segment the commercial and humanitarian uses of a technology, the current lists of developing countries may not capture the entire set of desired geographies. **Such a definition should have flexibility to allow the expansion of the geographical list.**
- In addition, if such a geographical definition of humanitarian uses is used, then the issue of use and sales outside of this defined territory should be explicitly addressed.”²⁵

Dr. Stevens further outlines the approach for defining developing countries:

- “What is a Developing Country? There are lists of countries produced by international agencies that can be used to define where competition is to be encouraged, and the license can be written to allow later, updated versions of these lists to govern. Suitable license agreement languages include:
 - **Those countries listed by the World Bank as Low-Income and Lower-Middle-Income Countries, as such list may change from time to time. This is probably the most inclusive list.**
 - Those countries listed on the United Nations Conference on Trade and Development list of ‘Least Developed Countries,’ as such list may change from time to time or any subsequent list that may be agreed to by the University and Licensee.”²⁶
- **Sample clause (Harvard University):**
 - “**Developing Country**’ means any country identified as Low-Income or Lower-Middle Income in the World Bank ‘Country and Lending Groups’ classification, or any country listed as eligible to receive support from the GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunization), as such list may be updated from time to time by the GAVI Alliance.”²⁷

Commercial Purposes

- “Because the reservation of rights for humanitari-

21. AUTM Global Health Toolkit: <https://autm.net/surveys-and-tools/tools/global-health-toolkit>.

22. Brewster A., et al., “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

23. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

24. UC Berkeley Socially Responsible Licensing Program: https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Guidance_%26_Clauses_v100817.pdf.

25. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

26. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

27. Harvard University, Global Access Language: https://otd.harvard.edu/uploads/Files/Sample_Global_Access_Language.pdf.

*an uses is designed to be used in the context of a commercial license and, specifically, to segment the markets for a technology between commercial and humanitarian uses, it may be important to define the scope of commercial uses as well.”*²⁸

Additional GAL Definitions and Sample Clauses

- **“Global Access Policy”** means the commercialization of the Technology, Improvements and any Products in a manner that enables availability and accessibility at reasonable cost to the people in the Developing World.²⁹
- **“Charitable Objective”** shall mean the availability of the Licensed Products in developing countries at affordable prices.³⁰
- Definitions specifying pricing structure have been developed by **University College London**:
 - **At-cost markets**—“Those markets in Developing Countries where individual poverty and insufficient public funding prevent access to healthcare at developed country prices.”
 - **Cost-based price**—“Means, in respect to each licensed product, a price not exceeding that which fairly reflects the direct cost of manufacture of the licensed product plus a typical margin for a generic pharmaceutical product for the respective market.”
 - **Developing country manufacturer**: “Means a manufacturer of pharmaceutical products that is able to efficiently manufacture (either within or outside the Developing Country in which the At-Cost market exists), distribute and supply the licensed product in an At-Cost market at a Cost-Based Price.”³¹
- AUTM provides an additional definition for “cost + 15% pricing”:
 - **“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 percent) of such amount.³²
- Please refer to the *AUTM Global Health Licensing*

Clause Toolkit for additional examples of GAL definitions.³³

Article 2: Grant of License

The Grant of License offers various opportunities for institutions to include GAL provisions in a technology license agreement.³⁴ Several GAL strategies in the Grant of License are emphasized in an article written by Lita Nelsen, former director of MIT’s Technology Licensing Office, where she highlights various pertinent issues that technology transfer offices should consider when deciding whether patenting a new invention is in the public interest:

“Is patenting the right route to maximize social access to the technology? When deciding whether patenting a new invention is in the public interest, the following issues, among many others, should be considered:

- *Is this technology self-evidently useful without substantial further investment in development? **Will it be widely used even if it is not patented but put in the public domain?***
- *If the answer to the previous questions is yes, can the patent-holding institution nonetheless devise a **nonexclusive licensing strategy that allows revenue to be generated without impeding the use of the technology?***
- *If the technology requires substantial high risk investment, and therefore patenting and exclusive licensing is warranted, **should patents be foregone in developing countries to encourage generic competition?** (This approach is reasonable, under some circumstances, for health and agricultural patents.)*
- *Can the patent holder require **sublicensing of other mechanisms to promote low-cost manufacture and distribution in the public sector of developing countries?***
- *If the drug or vaccine is expected to be **used only in developing countries, with little or no market in developed countries, will market aggregation through patenting and limited licenses create a sufficiently profitable market that will encourage development and clinical testing?***
- *Should the patent holder carve out **free use of a patented research tool for nonprofit research institutions?**”*³⁵

33. AUTM, please see above footnote.

34. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

35. Nelsen L., “Evaluating Inventions from Research Institutions,” Chapter 9.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

28. Bennett, 2007 (see above footnote).

29. Stevens, *et al.*, 2008 (see above footnote).

30. Stevens, *et al.*, 2008 (see above footnote).

31. Stevens, *et al.*, 2008 (see above footnote).

32. AUTM Global Health Toolkit: <https://autm.net/surveys-and-tools/tools/global-health-toolkit>.

These GAL strategies are outlined in further detail below through university examples and sample clauses for implementation in license agreements.

2.1 Exclusivity-related Provisions for Global Access

a. Reserving Non-exclusive Rights in Developing Countries

I. Contractual Approach and Sample Clauses

Dr. Stevens notes the following approach for granting only non-exclusive rights in developing countries:³⁶

“This approach reserves a non-exclusive right in the invention for use to develop products for developing countries, allowing the University to issue additional licenses in those countries.”

- **Implementation: Include in ‘Definitions’ section:**
 - **‘Humanitarian Purposes’** means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials, and crops for human or animal consumption, in a Developing Country.
 - **‘Commercial Purposes’** means to make, have made, propagate, have propagated, use, have used, import, or export a product, good, or service for the purpose of selling or offering to sell such product, good, or service.
- **Include in ‘Grant’ section:**
 - **Reservation of rights.** Notwithstanding any other provision of rights granted under this agreement, University hereby reserves an irrevocable, non-exclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials, or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation

materials, or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.”

Case Study 1: UC Berkeley and a Novel Anti-malarial Therapy:

- **Available at:** <https://ipira.berkeley.edu/sites/default/files/shared/docs/Artemisinin%20Case%20Study.pdf>.

b. Non-exclusive and Field-exclusive Licensing of Research Tools and Platform Technologies

Lita Nelsen notes that *“where the invention is a tool for discovery that is useful to many without significant development, then nonexclusive licensing is probably most appropriate for developed country use. Patents in developing countries will essentially be unnecessary. (Many universities will also require that the patents not be asserted against nonprofit research institutions in any country, thus allowing free access by such institutions.)”*³⁷

The University of California also offers the following suggestions in its licensing guidelines:

- *“The TM [technology manager] should consider licensing either non-exclusively, or exclusively within specific fields-of-use when an invention is broad in scope and can be used in multiple industries as well as for a platform technology that could form the basis of new industries.*
- *For example, if a technology will create the greatest public benefit if it becomes an industry standard, the TM should consider making it readily accessible to all interested parties unless significant investment or other factors require exclusivity to incentivize the realization of the commercial potential.”*³⁸

I. Universities’ Experience with GAL Strategy

Universities with experience in implementing GAL policies also stress the importance of context-specific exclusivity for certain research tools, such as diagnostics, in order to allow members of the scientific community to use these patented technologies for non-commercial or research purposes only, thereby maintaining commercial incentives for exclusive licensees.³⁹

37. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

38. UCOP Licensing Guidelines, 2012: https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf.

39. Peter Lee, “Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law,” *58 Emory Law Journal*, 889 (2009).

36. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

This approach is outlined in detail by Stanford University:

- “*Licensing of diagnostic tests based on broadly applicable genomics or proteomics methods should strive to preserve sufficient flexibility to permit testing for multiple indications (i.e., not an exclusive licensee’s single disease of interest) perhaps through multiple field-restricted or nonexclusive licenses.*”
- *A university might license a research reagent, kit, or device exclusively to a company to optimize and sell licensed products and services for research, diagnostic, or other end uses. The drafting of such an exclusive grant should make clear that the license is exclusive for the sale, but not use, of such products and services;*
- *In doing so, the university ensures that it is free to license non-exclusively to others the right to use the patented technology.”*⁴⁰

Case Study 2: The Hospital for Sick Children and the Cystic Fibrosis Carrier Test

- **Available at:** <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/discovery-of-the-cystic-fibrosis-chromosome>.⁴¹

c. Exclusive Licenses Tied With At-cost or Cost-based Pricing Provisions for Developing Countries

The importance of including access considerations in exclusive licenses is stressed by Lita Nelsen:

- “*Where the patent covers the core invention of a potential new drug or a vaccine that requires many years and tens, if not hundreds, of millions of dollars of investment, an exclusive license may be the best strategy. In such a case, patenting in selected developing countries may be an important element in a strategy to ensure global access.*”
- *Exclusive licensing places a large responsibility on the university to negotiate license clauses that ensure both development of the product and rapid distribution to developing countries at affordable prices.”*⁴²

40. Stanford University, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” 2007. Available: <https://web.stanford.edu/group/OTL/documents/whitepaper-10.pdf>.

41. <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/discovery-of-the-cystic-fibrosis-chromosome>.

42. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

One strategy noted by Lita Nelsen is where “**agreements could require preferential pricing for the public sector of developing countries**” in order for the university to achieve “**control over pricing in developing countries. This is usually set at a small percentage over cost (so-called cost-plus pricing).**”

I. Contractual Approach and Sample Clauses

Dr. Stevens outlines a specific GAL approach with sample clauses, which balances exclusivity and affordability considerations:⁴³

“**Contractually requiring availability and affordability in developing countries by specifying pricing structure:** This approach requires developing country development and specifies the pricing structure to be followed.

- **Implementation:** *Require the licensee to develop the product in developing countries and to sell it using cost+ pricing.*
- **Include in Definitions:**
 - **‘At-Cost’ markets** *means those markets in Developing Countries where individual poverty and insufficient public funding prevent access to healthcare at developed country prices.*
 - **‘Cost-Based Price’** *means, in respect of each Licensed Product, a price not exceeding that which fairly reflects the direct cost of manufacture of the Licensed Product plus a typical margin for a generic pharmaceutical product for the respective market.*
 - **‘Developing Country Manufacturer’** *means a manufacturer of pharmaceutical products that is able to efficiently manufacture (either within or outside the Developing Country in which the At-Cost market exists), distribute and supply Licensed Product in an At-Cost market at a Cost-Based Price.*
 - **‘Reasonable Developing Country License Terms’** *means terms that meet the requirements of Clause XXX and shall include terms based on the following principles:*
 - The Licensee shall promptly transfer all required technology to the Developing Country Manufacturer to enable it to manufacture and supply the Licensed Product(s).*
 - The Developing Country License Terms shall not include any payments to be made to the Licensee in respect of the grant of the li-*

43. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

cense in the At-Cost market other than a fee that shall not exceed the direct cost of transfer of technology to the Developing Country Manufacturer.

- iii. If the Developing Country Manufacturer is granted any exclusive rights, the continued grant of those rights shall be conditional upon the Developing Country Manufacturer supplying At-Cost markets at a Cost-Based Price and meeting market demand in that market.
 - iv. The Licensee may impose reasonable conditions, including as to use of trademarks, trade dress, format and pack size, to differentiate the Licensed Product when sold in the At-Cost market from Licensed Products sold in other markets and to prohibit their export into other markets and territories, provided that such conditions or their implementation do not act as an unreasonable barrier to the prompt and efficient supply of Licensed Product in the At-Cost market.
- **Include a Section ‘Supply to Developing Countries’**
 - A. **Supply by Licensee**—The Licensee shall use Diligent and Reasonable Efforts to supply Licensed Products to customers in At-Cost markets at a Cost-Based Price and meet market demand.
 - B. **Sublicensing in Developing Country markets**—In respect of each Licensed Product and At-Cost market, if the Licensee is unable to supply the Licensed Product at a Cost-Based Price to that At-Cost market and meet market demand, it shall use diligent and reasonable efforts to license one or more Developing Country Manufacturers on Reasonable Developing Country License Terms to manufacture, distribute and sell the Licensed Product at a Cost-Based Price to that At-Cost Market.
 - C. **Pass on terms to sublicensees.**—The Licensee shall ensure that the provisions of this Clause XXX form part of any sublicense agreement(s) with any sublicensee (direct or indirect) of the Licensee.”

II. Universities’ Experience with GAL Strategy

Several universities have established this GAL provision as a standard part of their license agreements with industry partners. Examples are offered below:

- **Harvard, Office of Technology Development:**
 - “When the license is exclusively negotiated on a worldwide basis as an unavoidable requirement for the technology development, **the university can seek to negotiate developing world access ‘at cost’ to relevant technologies.**”⁴⁴

- **UC Berkeley:**
 - “[Where] we have patent rights in LMICs or countries defined in any other way such as Economically Disadvantaged Countries or listed in an Appendix, the **licensees are required either to sell the product for free or at cost.**”⁴⁵
- **Yale University:**
 - Dr. Puziss stated that their aim is to get **“licensees to agree that they will offer their licensed products at-cost in LMICs.”**
 - The university also seeks to apply more specific obligations, such as with one licensee, stipulating: **“whereby if they set a price of X in major market countries, they commit to selling these products for no more than 25 percent of X in LMICs.”**⁴⁶
- **UBC, University Industry Liaison Office** commits to **“negotiate access considerations for developing countries by using ‘at cost’ provisions** for relevant technologies which are licensed on a worldwide exclusive basis.”⁴⁷

Case Study 3: UBC and At-cost Distribution of Amphotericin B

- **Available at:** <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/global-access-licensing-deal-for-a-drug-reformulat>.⁴⁸

2.2 Territory-related Provisions for Global Access

a. Jurisdictional Limitations to Exclude Developing Countries (i.e., Licensed Territory Restrictions)

With respect to addressing territorial limitations in license agreements as an approach to facilitate global access, Joachim Oehler, CEO of Concept Foundation, notes the following:

44. Interview with Harvard TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

45. Interview with UC Berkeley TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

46. Interview with Yale TTO, 2017 - Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

47. Principles for Global Access to UBC Technologies. UBC University Industry Liaison Office. 2007. Available: <https://uilo.ubc.ca/technology-transfer/ubc-global-access-principles>.

48. <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/global-access-licensing-deal-for-a-drug-reformulat>.

- “The territorial grant must cover not only large countries and their sizeable private markets—as main incentive that the public sector would be reached as well—but also small countries and their public sector markets that the private sector partner would not normally cover. Only the licensor can guard these public sector interests.
- It is good practice, therefore, not to grant sales rights in large countries to a single licensee without **including an obligation to serve the public sector and markets in the smallest countries.**
- **If a single licensee cannot cover all of a region’s markets, the entire region should be appropriately segmented to ensure that two or more licensees each get a profitable share and that the public sector in the smallest countries will be served.**”⁴⁹

This provision is further outlined by Dr. Richard Mahoney, Director of Vaccine Access, International Vaccine Institute:

- **Under “Best practices for licensing to meet public sector goals”:**
 - **“Territory—The clause could grant an exclusive right to a major portion of developed countries, for example, North America. The licensor could grant another exclusive limited license to countries in Europe. Finally, the licensor could grant nonexclusive licenses to both licensees for an agreed list of developing countries. Then the two primary licensees would have to compete for sales to developing countries.”**⁵⁰

Roose-Snyder, *et al.*, of Georgetown Law Center note that “a university can give an exclusive license to one entity for high-income markets, and a license to other entities for low- to middle-income markets. It could take advantage of market segmentation as a strategy and could also facilitate generic competition.”⁵¹

49. Oehler J., “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” Chapter 2.7, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

50. Mahoney R., “Negotiating an Agreement: Skills, Tactics, and Best Practices,” Chapter 12.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

51. Roose-Snyder B., *et al.*, “The global health licensing program: a new model for humanitarian licensing at the university level.” *American Journal of Law & Medicine*, 2009; 35(2-3):281-309.

I. Contractual Approach and Sample Clauses

Dr. Stevens notes the following GAL strategy:⁵²

- “This approach excludes developing countries from the license, allowing the University to license the technology non-exclusively in Developing Countries. The National Institutes of Health is using this approach.
- **Implementation—Include in Definitions:**
 - Territory shall exclude Developing Countries.”

II. Universities’ Experience with GAL Strategy

Several universities have also adopted this practice as a part of their GAL policies:

- **Stanford University:**
 - “There are many alternatives to strict exclusive licensing... **territorial limitations, where patent rights exist in multiple jurisdictions (e.g., the U.S. or North America; Europe; Asia; major-market countries; or developing countries).**”⁵³
- **UBC Industry Liaison Office:**
 - “Consider field-of-use and **jurisdictional limitations in exclusive licenses to exclude developing world countries.**”⁵⁴
- **McGill University and University of Calgary** have also committed to utilizing “**territory-specific licenses**” and “**jurisdictional limitations in exclusive licenses to improve access for those in LMICs**” as part of their Global Access strategies.⁵⁵

Case Study 4: UC Berkeley and Pesticide-free Crops

- **Available at:** <https://ipira.berkeley.edu/sites/default/files/shared/docs/Panel%20Brochure.pdf>.⁵⁶

2.3 Field-of-use-related Provisions for Global Access

a. Field-of-use Restrictions

The approach and benefits of utilizing field-of-use restrictions is highlighted by Dr. Boettiger:

- “[T]he license might contain terms to **segment**

52. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

53. Stanford University, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” 2007. Available: <https://web.stanford.edu/group/OTL/documents/whitepaper-10.pdf>.

54. Principles for Global Access to UBC Technologies. UBC University Industry Liaison Office. 2007. Available: <https://uilo.ubc.ca/technology-transfer/ubc-global-access-principles>.

55. <https://www.mcgill.ca/research/mcgill-global-access-principles>.

56. <https://ipira.berkeley.edu/sites/default/files/shared/docs/Panel%20Brochure.pdf>.

the market geographically or by fields of use. An exclusive license may be implemented, for example, to limit the technology's use to one major crop, reserving all other uses of the technology for widely accessible and non-exclusive licensing.

- *Using such an approach, income generation and access may be complementary goals for the IP provider.*⁵⁷

This strategy is further outlined by the University of California under its Licensing Guidelines:

- *“Alternatively, an exclusive ‘field-of-use’ license is a way to create market incentives for one company while enabling the University to identify additional licensees to commercialize the invention in additional markets. In some cases, a limited-term exclusive license that converts to a non-exclusive license can be an effective strategy to meet the public benefit objective.*
- *TMs [technology managers] should use care when licensing multiple technologies, invention portfolios, or a single technology with multiple variant applications to a single commercial organization to ensure that the licensing strategy meets the University’s desire to maximize public benefit.*⁵⁸

I. Universities’ Experience with GAL Strategy

- **UC Berkeley:**
 - *“License restrictions that grant rights only in a defined field of use can also preserve access. For example, a license granting the right to use a gene sequence for a diagnostic test in one format, such as on a high-density nucleotide array (a gene chip) leaves open the possibility of re-licensing that same gene to another company for development into a different diagnostic test.” - Dr. Carol Mimura, director of UC Berkeley’s Office of Intellectual Property.*⁵⁹
- **Stanford University:**
 - *“There are many alternatives to strict exclusive licensing... ‘Field-restricted’ licenses grant*

rights that cover only specific products that a licensee is able, and will undertake a firm commitment, to develop.

- *This approach safeguards the licensee’s investment in a technology, while still leaving it open for development by other parties who do not compete with them (i.e., those who do not operate in the field of the exclusive license grant).*⁶⁰

- **Harvard University:**

- *“In the case of an exclusive license granted in all or many fields, the licensee may initially be focused on a limited number of products or uses for the licensed technology.”*⁶¹

- **UBC University Industry Liaison Office:**

- *“Consider field-of-use and jurisdictional limitations in exclusive licenses to exclude developing world countries.”*⁶²

- **University of Edinburgh:**

- *“Application of field-of-use limitations in technology transfer agreements.”*⁶³

- **McGill University and University of Calgary** have also committed to utilizing “Field-specific licenses” and “promoting field-of-use limitations... in exclusive licenses to improve access for those in LMICs” as part of their Global Access strategies.⁶⁴

Case Study 5: Vanderbilt University and Aeras Global TB Vaccine Foundation⁶⁵

- **Available at:** https://themys.sid.uncu.edu.ar/~r-palma/Toma_Decision/Intellectual%20Property%20Management%20Handbook/gsd/collect/iphandbook/index/assoc/iphb0021/iphb0021.pdf

Case Study 6: University of Toronto and ChipCare⁶⁶

- **Available at:** <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/chipcare>.

57. Boettiger S., “Defensive Publishing and the Public Domain,” Chapter 10.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

58. UCOP Licensing Guidelines, 2012: https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf.

59. Mimura C., “Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program,” *Journal of the Association of University Technology Managers*, 2016. Volume XVIII Number 2.

60. Stanford University, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” 2007. Available: <https://web.stanford.edu/group/OTL/documents/whitepaper-10.pdf>.

61. <https://otd.harvard.edu/industry-investors/sample-agreements/licensing/>.

62. Principles for Global Access to UBC Technologies. UBC University Industry Liaison Office. 2007. Available: <https://uilo.ubc.ca/technology-transfer/ubc-global-access-principles>.

63. https://www.ed.ac.uk/files/atoms/files/essential_medicines_sep2020.pdf.

64. <https://www.mcgill.ca/research/mcgill-global-access-principles>.

65. Ashley J. Stevens, “Valuation and Licensing in Global Health,” Chapter 2.5, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

66. <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/chipcare>.

2.4 Reserved Rights

Thus far, the GAL provisions highlighted above address limits on exclusivity, as well as restrictions on field-of-use and territory, as IP strategies to facilitate global access. However, when broad exclusive licenses are required to incentivize investment from licensees, universities have reported that a reservation of rights agreement may be a more appropriate GAL strategy to include in license agreements.⁶⁷ This approach is noted by Dr. Bennett:

- “[F]or some technologies and in some technology sectors—including biotechnology—broad exclusive licenses are often required to induce follow-on investment in research and development. In these cases it can be important for the licensor to explicitly reserve rights...to ensure that institutional objectives to support humanitarian applications of its technology are not inadvertently sidetracked by an overly broad commercial license.”
- A reservation of rights can “help ensure that the terms of the license will not block other specific goals that the licensor may have. Such goals are typically noncommercial and therefore do not directly impair the licensee’s ability to commercialize the technology, but they may be important to ensure that the licensor can continue to meet other institutional objectives such as education, research, and public service.”⁶⁸

Dr. Bennett further notes the growing significance of reservation of rights clauses for humanitarian uses among non-profit foundations and philanthropic sponsors:

- “Awareness is increasing of the utility and importance of such clauses, particularly as philanthropic research sponsors begin to require grantees to ensure that results and discoveries will be made available for humanitarian purposes.”
- “Based on this type of sponsor requirement, grantees who execute a commercial license to any technology developed under the research agreement would thus be required to include a clause that acknowledged this existing obligation and reserved rights for humanitarian purposes.”

a. Reservation of Rights for Humanitarian Purposes

Roose-Snyder, *et al.*, offer the following advice on

67. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

68. Bennett, 2007 (please see above footnote).

utilizing the Reservation of Rights to address humanitarian applications of a licensed technology:

- “The [reservation of rights] mechanism could be used for humanitarian licensing as well. For instance, the university could segment markets and then grant the licensee the right to develop, market, and distribute a technology only in high-income countries. **Then the university could reserve the rights to license to another entity the right to develop, market, and distribute a technology in a low-income country.**
- Reservation of rights agreements are useful in that they define explicitly what a licensee can do and where, so that a university that tries to improve access to medicines later on down the line will not find itself blocked from doing so by vague provisions in the license.
- However, to ensure that these agreements actually have ‘teeth’ and are not merely an expansion of already present, and rarely enforced, due diligence clauses, a reservation of rights agreement **must be very specific about what rights are being licensed and what rights are being retained. Universities should also be clear that reserved rights can be licensed to a variety of organizations to serve underserved markets.**”⁶⁹

I. Contractual Approach and Sample Clauses

Dr. Bennett provides a detailed outline of the structure of a Reservation of Rights for humanitarian uses, along with standard clauses for implementation in a license agreement, as noted below:⁷⁰

“For public research institutions, a reservation of humanitarian rights in commercial technology licenses is one **mechanism to help it meet its mission to serve the public benefit through both commercial and humanitarian channels.**

The structure of a clause to reserve rights for humanitarian use ideally both expresses the philosophical intent of the licensee and **clearly defines the boundaries of humanitarian use, particularly in relation to commercial use.**”

• 1. Definitions:

- The definitions are the most critical component of a reservation of humanitarian use rights. The key definitions are:

69. Roose-Snyder B., *et al.*, “The global health licensing program: a new model for humanitarian licensing at the university level.” *American Journal of Law & Medicine*, 2009; 35(2-3):281-309.

70. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

- **Humanitarian Purposes**—There are several approaches used to define humanitarian purposes: by income level, by uses (subsistence or commercial), and by geography - humanitarian uses can be defined geographically by specifying all uses of the technology within developing countries.
- **Developing Countries**—If humanitarian uses is defined geographically then an explicit definition of developing countries is needed. For example, developing countries can be defined as those listed by the World Bank or other international agencies. While this definition can effectively segment the commercial and humanitarian uses of a technology, the current lists of developing countries may not capture the entire set of desired geographies. Such a definition should have flexibility to allow the expansion of the geographical list. In addition, if such a geographical definition of humanitarian uses is used, then the issue of use and sales outside of this defined territory should be explicitly addressed.
- **Commercial Purposes:** Because the reservation of rights for humanitarian uses is designed to be used in the context of a commercial license and, specifically, to segment the markets for a technology between commercial and humanitarian uses, it may be important to define the scope of commercial uses as well.

• 2. Reservation of rights:

- The reservation of rights is the operative paragraph of the clause, and its structure will rely upon and follow the above definitions. The reservation of rights needs to **clearly articulate what rights are being reserved and should leave no doubt that the reserved rights may be granted to other appropriate companies or organizations that can fulfill the humanitarian objectives.** This may be a topic of discussion in license negotiations, largely because it is likely to be an unfamiliar term to a commercial licensee.

II. Universities' Experience with GAL Strategy

Other universities also utilize a humanitarian reservation of rights as a standard GAL clause within license agreements. Notable examples include:

• Harvard University:

- **Retained Rights** (Note: additional retained rights language may be added to allow Harvard to grant licenses in the Patent Rights to non-profits for purposes of alleviating unmet health needs of local populations in Developing Countries.)
- **Harvard retains the right to grant non-exclusive licenses to practice the Patent Rights and to use the Harvard Technology**

*Transfer Materials, in each case solely to **Qualified Humanitarian Organizations and solely for Humanitarian Purposes.***⁷¹

- Please see Harvard's "Global Access Provisions" web page for complete versions of these clauses.

• UC Berkeley:

- "Nothing in this Agreement will be deemed to limit the right of UNIVERSITY to: **license the UNIVERSITY PATENT RIGHTS to any third parties solely for HUMANITARIAN PURPOSES.**"⁷²
- Please see UC Berkeley's *Socially Responsible Licensing Program* webpage on sample clauses for complete version of these clauses

Case Study 7: Emory University and the Proko-Pack Mosquito Aspirator

- **Available at:** <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/proko-pack>.⁷³

Case Study 8: UC Berkeley and Silicon Biodevices

- **Available at:** https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Highlights_100910.pdf.⁷⁴

b. Reserved Research Exemptions

Increasingly, universities are reserving research exceptions for themselves, academic institutions, and other nonprofit organizations as a condition of licensing patented technologies to outside parties.⁷⁵ Typically, these provisions reserve the right of the university and others in the non-profit sector to use the licensed rights for education and research purposes.⁷⁶

I. Contractual Approach and Sample Clauses

This provision is outlined in further detail by Dr. Bennett:⁷⁷

71. https://otd.harvard.edu/uploads/Files/Sample_Global_Access_Language.pdf.

72. https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Guidance_%26_Clauses_v100817.pdf.

73. <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/proko-pack>.

74. https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Highlights_100910.pdf.

75. Peter Lee, "Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law," *58 Emory Law Journal*, 889 (2009).

76. Mimura, *et al.*, "Socially Responsible Licensing, Euclidean Innovation, and the Valley of Death," *Stanford Journal of Law, Science and Policy*, 2011.

77. Alan B. Bennett, "Reservation of Rights for Humanitarian Uses," Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

- “Universities frequently incorporate a clause that reserves rights to carry on research using licensed patents and/or technology; **many universities in their exclusive license agreements now reserve rights for the use of inventions within their own institution or, even more broadly, within all academic or nonprofit research institutions.**
- *This type of reservation-of-rights clause is perhaps the most common type used in university license agreements, although even this straightforward and reasonable term still is not used by many universities in their exclusive license agreements. The University of California and Stanford University routinely incorporate clauses into their exclusive license agreements:*
 - **The University of California:** *‘Nothing in this Agreement will be deemed to limit the right of The Regents (the University)...to make and use the Invention...and associated technology and allow other educational and nonprofit institutions to do so for educational and research purposes.’*
 - **Stanford University:** *‘Stanford retains the right, on behalf of itself and all other nonprofit academic research institutions, to practice the Licensed Patent and Technology for any purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution.’”*

II. Universities’ Experience with GAL Strategy

Dr. Mimura highlights how reserved research exemptions are included within exclusive IP licenses as part of the Socially Responsible licensing Program (SRLP) at UC Berkeley:

- **“Good stewards of IP rights take care to protect public-sector access to research tools for research purposes, and a non-negotiable reservation-of-rights clause is appropriate in this [SRLP] programme, as it is when licensing any publicly-developed IP right.**
- **All IP licenses, inside and outside the SRLP, reserve the right of the university and others in the non-profit sector to use the licensed rights for education and research purposes (and also a right to transfer tangible materials that are required to practice a given invention to non-profit institutions for the same purpose).**
- *When exclusive IP licenses are granted to an entity, we always reserve specific shop rights for the University and for others in the private sector, to practice the invention for our own purposes.”*⁷⁸

An exclusive license from Harvard University states:

- *“2.1.1. Harvard retains the right, for itself and for other not-for-profit research organizations, to practice the Patent Rights and to use the Harvard Technology Transfer Materials within the scope of the license granted above, solely for research, educational and scholarly purposes.”*⁷⁹

c. Sublicensing to Address Unmet Public Health Needs

Another GAL provision to ensure diligent development of university technologies is the requirement for exclusive licensees to grant sublicenses to third parties to address unmet market needs and/or to diligently commercialize new applications of the licensed rights.⁸⁰ Such a requirement can also be implemented through a reserved right of the licensor to grant direct licenses within the scope of the exclusive grant to third parties based on unmet need.⁸¹

Case Study 9: UC Berkeley’s Mandatory Sublicensing Approach

As part of their Socially Responsible Licensing Program (SRLP), UC Berkeley utilizes mandatory sublicensing clauses when licensees insist on exclusivity, as a mechanism to facilitate global access in developing countries. Dr. Mimura outlines this approach in detail:⁸²

- *“In nearly all of Berkeley’s exclusive license and option agreements (and most in the SRLP) a ‘mandatory sublicensing’ or ‘comprehensive commercialization’ requirement allows us to **ensure that if new and possibly unanticipated uses of a licensed technology are discovered, a given exclusive license does not prevent future investment to fill an unmet need.***
- *The underlying motivation is that when the university grants a broad exclusive license we must have a **mechanism to ensure that the comprehensive market demand is met. As future, per-***

78. Mimura C., “Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program,” *Journal of the Association of University Technology Managers*, 2016. Volume XVIII Number 2.

79. https://otd.harvard.edu/uploads/Files/Sample_Basic_Patent_Rights_Exclusive_License_Agreement.pdf.

80. Mimura, et al., “Socially Responsible Licensing, Euclidean Innovation, and the Valley of Death,” *Stanford Journal of Law, Science and Policy*, 2011.

81. Stanford University, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” 2007. Available: <https://web.stanford.edu/group/OTL/documents/whitepaper-10.pdf>.

82. Mimura, C., “Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact,” (July 15, 2009). *Oxford University Press*, 2010.

haps unanticipated, new uses arise we have an obligation to address new market niches for the public good. This is especially important when our inventions are developed using U.S. federal funds and when an enabling technology has many potential applications.

- *The clause essentially states that if we become aware of a new use that our licensee is not addressing, or if a third party approaches us for the (licensed) rights in order to develop ‘a new use for the licensed IP right or other unmet need,’ then we ask our licensee to inform us within 90 days if it will: (a) develop the new application on its own, or (b) grant a sublicense to the third party. If the licensee chooses to develop the new application then it must diligently undertake the new development and report such progress to us.*
- *The clause has also been used to drive a licensed product to the lowest possible price, by replacing the trigger of ‘a new use or unmet need’ with ‘for free or at cost.’ Under the latter trigger, a third party that can offer prices lower than those of the existing licensee may be granted a sublicense—unless the licensee is willing to lower its prices to the same level.”*

Dr. Mimura further provides examples of mandatory sublicensing clauses that have been incorporated into patent license agreements at UC Berkeley since 1998. These suggested clauses can be found in *UC Berkeley’s Socially Responsible Licensing Program* sample clauses webpage, under “mandatory sublicensing clause” (pages 2-3).^{83,84}

Dr. Stevens comments on UC Berkeley’s success with this GAL strategy and highlights the acceptability of these terms by industry partners:

- *“Mandatory Sublicensing with a Reservation of a March-In Right: This approach is being used by the University of California, Berkeley...Berkeley adopted the following as a balance between their need to grant exclusivity to allow licensees to justify investing in developing early-stage technologies and the need to ensure that technologies that were exclusively licensed are fully developed.*
- *Berkeley has included the provision in most*

83. UC Berkeley Socially Responsible Licensing Program: https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Guidance_%26_Clauses_v100817.pdf.

84. Mimura C., “Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program,” *Journal of the Association of University Technology Managers*, 2016. Volume XVIII Number 2.

of its exclusive licenses and option agreements starting in 1997, and has executed over 25 licenses containing it, including four with large companies (one negotiated directly, one due to a large company acquisition of a start-up and assignment of the license to the acquirer, while another was due to a sublicense by a licensee to a large entity).

- *Berkeley’s experience has been that companies find the provision acceptable, rather than being punitive, because it is tantamount to free market research, since they get first shot at fulfilling the newly identified opportunity.*
- *That said, the details frequently change during the course of negotiations. The provision has been invoked at least twice. The resolution in each case was that, rather than the licensee issuing a sublicense, they elected to renegotiate the license to a narrower field of use. In one of the two cases, Berkeley issued a new license to the second company, so clearly, the mechanism is both acceptable to licensees and effective.”*⁸⁵

I. Contractual Approach and Sample Clauses

Dr. Stevens also outlines a variation of this approach that is being used by MIT and the University of Vermont:

- *“MIT has also used this [mandatory sublicensing] approach, particularly in exclusive licenses to start-ups, for a number of years. MIT reports that licensees have found the measure acceptable because they get the first opportunity to develop the newly identified opportunity. Like Berkeley, MIT has had to implement the process on more than one occasion and the outcome has typically been a narrowing of the field of use.*
- *MIT and the University of Vermont apply the approach to socially responsible licensing, defining a ‘Charitable Objective’ as being the availability of the product in developing countries at low cost and requires the licensee to issue sublicenses to additional parties that request licenses for developing countries, with the University reserving the right to issue a license itself directly if the licensee does not respond to the request promptly.*
- **Implementation:**

85. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

–Include in ‘Definitions’:

- **‘Charitable Objective’** shall mean the availability of the Licensed Products in developing countries at affordable prices.

– Include in ‘Grant’ section:

- If Licensee elects not to develop and commercialize the proposed Licensed Products for the Charitable Objective, University may seek one or more third parties to develop and commercialize the proposed Licensed Products for the Charitable Objective. If 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 it to University.
- 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 University 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 University, 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 University 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.”⁸⁶

AUTM also provides several variations of mandatory sublicensing clauses that have been extracted from license agreements successfully executed by U.S. universities. Sample clauses can be found in AUTM’s *Global Health Licensing Clause Toolkit* which serves as a resource for universities seeking to develop licensing language for their GAL policies.⁸⁷

Additional considerations for universities seeking to

adopt this GAL practice are provided by several institutions and technology transfer experts:

- Stanford University states that the mandatory sublicensing “**requirement could also be implemented through a reserved right of the licensor to grant direct licenses within the scope of the exclusive grant to third parties based on unmet need.** In such situations, it is important to ensure that the **parties have a common understanding of what constitutes a new application or unmet need** for the purpose of implementing such a provision.”⁸⁸
- Dr. Amanda Brewster, UC Berkeley School of Public Health, highlights the need “to think through how the humanitarian-purpose licensee (usually sublicensee) will actually use the technology and to reserve an appropriate set of rights and exemptions.
 - The humanitarian licensee might need the **right to carry out research or manufacture within the commercial licensee’s territory, so long as the research is done only for developing nation needs or the manufacture for export to developing nations.**
 - The **humanitarian licensee may also need rights for commercial use in low- and middle-income regions.** Although the reservation may be defined as humanitarian use, licensors may wish to consider additional, more specific reservations.
 - The commercial licensee may then wish to be protected against re-export into its primary commercial market.”⁸⁹
- Roose-Snyder, et al., note:
 - “It is imperative that the **university draft the sublicense terms and include them in the original license to ensure that the corporate partner does not use its ability to sublicense for non-humanitarian purposes or to undermine such purposes.**
 - **An advantage of this use of sublicenses or non-exclusive licensing is that it may be a viable option for universities licensing technology related to vaccines and biologics.** Many of the ‘generic competition’ strategies listed

88. Stanford University, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” 2007. Available: <https://web.stanford.edu/group/OTL/documents/whitepaper-10.pdf>.

89. Brewster A., et al., “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

86. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

87. AUTM Global Health Toolkit: <https://autm.net/surveys-and-tools/tools/global-health-toolkit>.

thus far may not be viable options for licensing biologics or vaccines because these are difficult—if not impossible with current science—for a generic producer to reverse-engineer and manufacture.”⁹⁰

d. March-In Rights

Universities can reserve march-in rights if the humanitarian purposes or milestones within the license agreement are not being met. This could be pursued through enforcement mechanisms such as granting additional licenses to address unmet needs, requiring the primary licensee to sublicense to third parties (such as generics manufacturers) in order to ensure access, or revoking a license.^{91,92}

I. Contractual Approach and Sample Clauses

Dr. Stevens describes this approach and offers language for implementation in a license agreement.⁹³

“Specifying desired outcomes of availability and affordability in developing countries and including an enforcement mechanism (such as a March-in right) to achieve competition if the specified outcomes do not occur.”

“This approach sets the institution’s expectations for global socially responsible access and reserves the right of the institution to grant additional licenses (‘March In’) if they are not met. The University of British Columbia and the Massachusetts General Hospital are experimenting with this approach.

- **Implementation:**

- Reserving a march-in right to grant additional licenses to be exercised if the product is not made available in developing countries in a timely manner or if prices in developing countries are too high.

- **Include in Definitions:**

- **‘Global Access Policy’** means the commercialization of the Technology, Improvements and any Products in a manner that enables availability and accessibility at reasonable cost to the people in the Developing World.

90. Roose-Snyder B., et al., “The global health licensing program: a new model for humanitarian licensing at the university level.” *American Journal of Law & Medicine*, 2009; 35(2-3):281-309.

91. Mimura C., “Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program,” *Journal of the Association of University Technology Managers*, 2016. Volume XVIII Number 2.

92. Brewster A., et al., “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

93. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

- **‘Humanitarian Purposes’** means (a) the use of Licensed Products covered under Compound Patent Rights (‘Compound Products’) for research and development purposes by any organization or other third party, anywhere in the world, that has the express purpose of developing the Compound Products for use in an Economically Disadvantaged Country, and (b) the use of the Compound Products by any organization or other third party for Commercial Purposes in an Economically Disadvantaged Country.

- **‘Commercial Purposes’** means to make, have made, use, have used, import, or export a product, good, method, or service for the purpose of selling or offering to sell such product, good, method, or service.

- **Include in Grant:**

- The Licensee agrees to commercialize the Technology and any Products in a manner consistent with the Global Access Policy. Without limiting the generality of the foregoing, the Licensee agrees to require all sublicensees and other parties involved in any aspect of the commercialization of the Technology 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 and any Products) to comply with the Global Access Policy.
- The Licensee acknowledges and agrees that: 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 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 or any Products available to the Developing World in a manner consistent with the Global Access Policy.”

II. Universities’ Experience with GAL Strategy

As part of UC Berkeley’s mandatory sublicensing approach, the university also utilizes the option of reserving a march-in right, as noted by Dr. Mimura:

- **“If an exclusive licensee does not or cannot provide a drug in an area with an unmet need, a more aggressive reserved right of the university would be the right to re-license the IP rights to a drug generics manufacturer**

*for the purpose of providing access to such country or region. If the SRLP licensee does not provide the drug for a certain market niche, then there should be a mechanism whereby another provider can serve that market.”*⁹⁴

2.5 Non-Assertion of Rights Agreement

Dr. Stevens notes that a non-assertion of rights, or a non-assert approach, **“requires the primary licensee to agree not to assert the licensed patents against third party manufacturers and sellers in developing countries. It therefore allows for generic competition in developing countries.”**⁹⁵

As part of a comprehensive university GAL policy, non-assertion agreements can be utilized as a tool to facilitate humanitarian licensing, as highlighted by Dr. Anatole Krattiger, Professor at Cornell University:

- **“Specifically targeted non-asserts can also be effective instruments...to permit the use of patented inventions anywhere in the world, provided such use is for the express purposes of addressing specific humanitarian needs in developing countries. This could have broad-ranging and significant positive impact, as this approach reduces transaction costs, encourages innovation to help the poor, and accomplishes this without any loss of commercial opportunities.**
- **In the case of humanitarian licensing, certain restrictions may be included such as the limiting of use to not-for-profit humanitarian purposes for the exclusive benefit of people in developing countries or even to for-profit entities solely for humanitarian purposes in developing countries.”**⁹⁶

Case Study 10: MIT’s Public Non-assert Statement for Tuschl I siRNA Patent Applications

For a complete version of MIT’s public non-assert statement, please see Chapter 7.6 in the following link: [“The Use of Nonassertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability,](#)

94. Mimura C., “Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program,” *Journal of the Association of University Technology Managers*, 2016. Volume XVIII Number 2.

95. Ashley J. Stevens, “Valuation and Licensing in Global Health,” Chapter 2.5, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

96. Krattiger A., “The Use of Nonassertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access,” Chapter 7.6, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

and Foster Global Access.” Chapter 7.6, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

I. Contractual Approach and Sample Clauses

Dr. Stevens provides the following structure for including this GAL provision in a license agreement, through the example of **‘Boston University’s Non-assert Approach’**:⁹⁷

“A set of provisions has also been developed at Boston University. They are meant for use as a starting point to discuss products that have markets in both the developed and the developing world.

The provisions utilize a non-assert approach to manufacture for sale in developing countries. The approach protects against parallel imports by requiring a distinctive trade dress for products for which the non-assert is invoked, and it allows for commercial markets within developing countries by limiting the non-assert to sales to public agencies, broadly defined.

• Implementation:

1. Include in the ‘WHEREAS’ clauses:

- **WHEREAS**, University and Licensee acknowledge that it may serve the public good to make certain drugs available at affordable prices to Non-Market Countries in certain circumstances, with appropriate safeguards to Licensee’s economic interests in other markets.

2. Include in the ‘Definitions’:

- **Market Countries** shall mean: (a) All current and future member countries of the Organization for Economic Cooperation and Development (OECD), presently consisting of Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States; and (b) All current and future members of the European Union; and (c) Russian Federation, Republic of China (Chinese Taipei), Korea, Malaysia and Singapore.

- **Amend the definition of Net Sales to exclude sales of products made pursuant to the Non-Suit provision of Section [XX; not given here] from the calculation of Net Sales.**

97. Ashley J. Stevens, “Valuation and Licensing in Global Health,” Chapter 2.5, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

- **Non-Market Countries** shall mean all countries other than Market Countries.
- **Public Sector** shall include: (a) The sovereign government of a country; (b) Agencies of the United Nations, the World Health Organization, and the World Bank; (c) Organizations which are members of the International Committee of the Red Cross and Red Crescent; (d) International charitable agencies (also known as Non-Governmental Organizations or NGOs), including but not limited to Oxfam, Médecins Sans Frontières, and so forth; (e) Organizations substantially supported by philanthropic organizations including but not limited to the Bill and Melinda Gates Foundation, the Rockefeller Foundation, and so forth, specifically including global product development and distribution public-private partnerships.
- **Trade Dress** shall mean the physical appearance of Product as sold in any Market Country by Licensee, including but not limited to such characteristics as shape, color, flavor, tradename, trademark, service mark, etc.

3. Include in the ‘Grant’ clauses:

- **Non-suit:** University and Licensee on behalf of themselves and any successors-in-interest to the Intellectual Property covenant that they will not, before or after the date of this Agreement, assert any claim of infringement (including direct infringement, contributory infringement, and inducing infringement) of the Intellectual Property against any person or entity that sells or offers to sell the Licensed Product to Public Sector entities for use in Non-Market countries, or any entity that manufactures or otherwise makes the Licensed Product for sale to Public Sector entities for use in Non-Market countries, or any person or entity that uses the Licensed Product in a Non-Market country, to the extent such claims relate to or arise out of such manufacture, sale or offer to sell.
- Notwithstanding any other provision herein, this non-suit provision shall not apply to Products that bear any element of the Trade Dress used by Licensee in any of the Market Countries, or to Products that have not gained regulatory approval from either the U.S. Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMA) or been pre-qualified by the World Health Organization pre-qualification scheme.”

Additionally, there are several key benefits for universities in using a non-assertion of rights agreement as a licensing strategy. These are described in detail by Dr. Krattiger in his article *‘The Use of Non-assertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access’*.⁹⁸

- “A non-assert can take one of three forms: 1) an agreement between two parties (bilateral), 2) an agreement among several parties (multilateral), and 3) a public statement (proclamation). **In the form of public statements, non-asserts provide a number of advantages** over traditional open-standards committees or institutions:
 - Non-asserts can be **issued unilaterally without the need for any complex negotiations with third parties** (such as open-standards committees).
 - Non-asserts in the form of public statements **carry no enforcement cost. In essence, they are self-executing.** Once proclaimed, no legal staff time is required to negotiate licenses. Everyone gets the same deal and the deal is free.
 - **Reduction of high-transaction costs** associated with negotiating bilateral or multilateral licensing agreements. The negotiation of any license agreement is a time-consuming endeavor. In cases where the license is for humanitarian purposes in particular, the licensor generally gains no material benefits and often places the negotiation of such agreements at the bottom of the priority list.
 - Non-asserts, even bilateral ones, are **relatively easy to negotiate as they primarily require agreement on two fairly simple aspects:**
 - **listing of the patents (or other forms of intellectual property protection)**
 - **specific permitted use, or limitations to the permitted use, or both.”**

II. Universities’ Experience with GAL Strategy

- Dr. Puziss noted that “[with respect to the term] ‘licensee won’t file its own patents that would claim licensed products in those developing world territories’...**that’s a tall order to get into a licensing agreement—but one fallback that we’re often successful with is that they agree not to pursue infringers of those patents in the developing world provided that the in-**

98. Krattiger A., 2007 (please see above footnote).

*fringing activity is not intended to export the product back to a major market country.”*⁹⁹

- Lita Nelsen notes that “*many universities will also require that the patents not be asserted against nonprofit research institutions in any country, thus allowing free access by such institutions.*”¹⁰⁰

It is hoped that the range of GAL strategies, sample clauses, and university case studies offered in this toolkit will provide public sector institutions with a robust and readily implementable set of contractual provisions that they can utilize in license agreements with industry partners. To conclude, Dr. Stevens highlights the significance of license agreements as opportunities to promote global social responsibility:

- “*This learning allows licensing officers to focus on the business negotiation of agreeing a license; social responsibility protections become just another business term and element of the overall negotiation. We hope that this article has shown that it is straightforward contractually to do so, so that the issue will devolve to a business negotiation.*
- *Academic licensing officers have consistently shown ingenuity, resiliency and creativity in their business negotiations, and we are confident that academic institutions will increasingly not only incorporate one of these licensing approaches into their standard license agreements, but will make it a formal policy of their institution to use licensing to promote global social responsibility.*”¹⁰¹

The next section of this two-part article will cover the following GAL strategies that public sector institutions can utilize in license agreements with industry partners:

- **Reduced royalty payments to ensure affordable cost**
- **Global access milestones and affordable access plans**
- **Forgoing patents in developing countries**
- **Follow-on patents and proactive considerations for global access**
- **Promoting generic competition in developing countries.** ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=4179649>.

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99. Interview with Yale TTO, 2017 - Nguyen T., Shahzad M., Veras J., “Recent Experiences In Policy Implementation Of Socially Responsible Licensing In Select Universities Across Europe And North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

100. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

101. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

Promoting Global Access To Health Technologies: A Licensing Toolkit For Public Sector Institutions

Part 2

By Mohammad Shahzad

Abstract

The growing shift among public-sector institutions and pharmaceutical companies towards equitable licensing of their health technologies is commonly termed Global Access Licensing¹ or Socially Responsible Licensing. This two-part article uses the term Global Access Licensing (GAL) to describe a set of licensing provisions and terms that can be utilized by public sector institutions, including funding agencies, universities, and research institutes, and included in license agreements with industry partners to ensure access and affordability of resulting health technologies in the developing world.^{2,3}

A GAL approach is sensitive to the fact that licenses are complex and each will be unique. It offers a flexible framework that does not prescribe specific language for every contract; rather, it provides a range of principles and contractual language that can guide IP commercialization practices during licensing negotiations with industry partners.⁴

This two-part research synthesis draws upon interview discussions with technology transfer office directors of leading North American and British universities with GAL policies and provisions, including Harvard, UC Berkeley, Yale, Oxford and UCL,⁵ as well as the

relevant literature in the field of global access licensing of publicly funded health technologies, in order to present readily implementable licensing provisions and clauses in the form of a GAL toolkit for public sector institutions.

GAL provisions that are outlined in this toolkit include:

Part 1:

- Jurisdictional limitations and field-of-use licenses
- Non-exclusive licensing of research tools and platform technologies
- Affordable pricing provisions (e.g., at-cost, cost-plus pricing)
- Reservation of rights for humanitarian purposes
- Sub-licensing in underserved markets
- Non-assertion of patent rights in developing countries

Part 2:

- Reduced royalty payments to ensure affordable cost
- Global access milestones and affordable access plans
- Forgoing patents in developing countries
- Follow-on patents and proactive considerations for global access
- Promoting generic competition in developing countries

Each GAL provision outlined in this toolkit will be supported with:

1. Contractual approach and sample clauses implemented in license agreements by universities;
2. Universities' experiences with the GAL provision (acquired from interview discussions with technology transfer office directors at various universities);
3. Case studies demonstrating how the GAL provision facilitated access to the university health technology in the context of a university-industry partnership;

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1. Universities Allied for Essential Medicines, GAL Framework: <https://case.edu/research/sites/case.edu.research/files/2018-04/UAEMframework.pdf>.

2. Ashley J. Stevens, "Valuation and Licensing in Global Health," Chapter 2.5, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

3. Lita Nelsen, "Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions," Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

4. Kapczynski A., Chaifetz S., Katz Z., Benkler Y., "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations," *Berk Tech Law J.* 2005;20:1031–1089

5. Nguyen T., Veras J., and Shahzad M., "Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America: Identifying Key Provisions to Promote Global Access to Health Technologies," *les Nouvelles*, Volume LIII No. 3, 2018.

4. Implementation considerations offered by licensing officers and technology transfer experts.

Promoting Equitable Access to Health Technologies: A GAL Toolkit—Part 2

The GAL provisions in this toolkit are largely based on a market segmentation (or dual market) approach which addresses *“the licensing challenge for drugs which treat diseases that afflict both the developed and the developing world... [i.e.] how to achieve competition in developing countries while preserving their patent monopoly in developed countries,”* as highlighted by Dr. Ashley Stevens, former director of Boston University’s Office of Technology Development.⁶

This approach can be applied in license agreements to *“effectively segment the commercial and humanitarian uses of a technology.”*⁷ Thus, through market segmentation, an exclusive license can grant a private sector licensee the sole right to use and sell a technology in profitable, high-income markets, while at the same time ensuring the licensee (or other manufacturers) can use and sell the technology at lower cost or reduced royalties to serve market segments that do not interest the private sector.⁸

The benefits of the market segmentation approach are further outlined by Dr. Sara Boettiger, Head of Global Public Affairs at Bayer, and former Deputy Director of the Gates Foundation:

- *“Are there benefits to be gained from segmenting the market? One benefit of choosing to patent... is that patenting provides an opportunity to segment the market of technology users or licensees.*
- *An IP manager may require **different licensing terms, for instance, depending on whether the technology will be used commercially or for humanitarian purposes.***
- *Alternatively, **the license might contain terms to segment the market geographically or by fields of use.** An exclusive license may be implemented, for example, to limit the technology’s use to one major crop, reserving all other uses of the technology for widely accessible and nonexclusive*

6. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

7. Alan B. Bennett, “Reservation of Rights for Humanitarian Uses,” Chapter 2.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

8. Brewster *et al.*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

licensing. Using such an approach, income generation and access may be complementary goals for the IP provider.

- *Or the rights to a technology in, for instance, developed country markets may be exchanged for contractual obligations to deliver the product to developing countries for a reasonable price.”*⁹

Following the outline of a standard technology license, Part 2 of this GAL toolkit will cover:

• Article 3: Consideration

3.1 Royalty

- a. Royalty Payment Structures to Encourage Affordable Pricing in Developing Countries

3.2 Milestones

- a. Structuring Diligence Obligations to Include Global Access Milestones
- b. Ensuring Diligent Development and Global Access through Sublicenses
- c. Reporting and Affordable Access Plans for Developing Countries
- d. Failure to Meet Global Access Milestones and Opportunity to Cure

• Article 4: Intellectual Property

4.1 Patents and Patent Applications

- a. Refraining from Filing Patents in Developing Countries Except When Doing So will Promote Global Access
- b. Refraining from Patenting Research Tools that only have Research (Non-Commercial) Purposes

4.2 Improvements

- a. Follow-on Patents and Proactive Considerations for Global Access

• Additional GAL Strategies Adopted by Universities in License Agreements

- a. Strategies to Facilitate Generic Competition in Developing Countries
- b. Affordable Pricing Strategies for Developing Countries
- c. Mandatory Development Clauses
- d. Mandatory Donation Clauses
- e. Transferring Health Technologies to Public-Private Partnerships (PPPs)

A final note is that each institution with a GAL policy has demonstrated success with implementing these various approaches depending on which GAL provisions

9. Boettiger S., “Defensive Publishing and the Public Domain,” Chapter 10.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

are found to be (a) most acceptable to their commercial licensees and (b) most effective in promoting affordable access to their technologies in developing countries.^{10,11}

ARTICLE 3: Consideration

3.1 Royalty

a. Royalty Payment Structures to Encourage Affordable Pricing in Developing Countries

Another strategy that utilizes the market segmentation approach and is commonly adopted by various universities is to offer financial incentives to licensees, such as reduced or eliminated royalty rates, in exchange for products being sold at affordable cost in developing country markets.¹²

This strategy is noted by Dr. Amanda Brewster, UC Berkeley School of Public Health:

- *“A market segmentation, or dual market, approach is often used to target intended beneficiaries... with this approach, an exclusive license might give a private sector entity the sole right to use a technology in profitable markets, while allowing others to **use the technology at no cost or reduced royalties to serve market segments that do not interest the private sector.**”*
- *“**Humanitarian conditions in licensing agreements... may include marketing a product in developing nations at a reduced royalty or price.**”¹³*

The rationale for adopting this approach is offered by Dr. Stevens:

- *“**The right valuation formula is to ask for the licensee(s) in developing countries to take over responsibility for future patent costs and to ask for...no running royalties. Any financial return to the university will be derived from opportunities in developed countries.***
- *Indeed, if a university’s objective truly is to get drugs that have been discovered at rich universities in developed countries...to the worlds’*

10. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

11. Nguyen *et al.*, “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” (July 23, 2018), *les Nouvelles*, Volume LIII No. 3, September 2018.

12. Mimura C., “Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact,” (July 15, 2009), Oxford University Press, 2010.

13. Brewster *et al.*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

neediest people as cheaply as possible, then true leadership requires that those same universities not start off the process by putting their hands out and saying, “We have to charge a royalty.”¹⁴

I. Universities’ Experience with GAL strategy

Interview discussions with directors of technology transfer offices at several universities have revealed the acceptability of this GAL provision as a standard part of license agreements:

- **Harvard University’s** Office of Technology Development applies a “\$0 royalty on locally-affordable sales or sales aimed at humanitarian distribution to underserved populations.”¹⁵
- **Yale University** noted that “when the TTO negotiates with a company to distribute a drug for free in sub-Saharan Africa... there will be no sales, consequently there would be no royalties involved. The practice of renouncing royalties appears as a non-controversial practice within the TTO.”¹⁶
- **Emory University** “proactively address[es] reduced or eliminated royalty for global access.” The university’s Office of Technology Transfer further revealed that it has never received royalty payments from a developing country.¹⁷

The most noteworthy example of a university’s success with employing this GAL strategy is demonstrated through UC Berkeley’s Socially Responsible Licensing Program (SRLP). Dr. Carol Mimura, director of UC Berkeley’s Office of Intellectual Property, highlights this strategy:

- *“To stimulate and support investment by licensees and philanthropic foundations with humanitarian goals, certain contracts forgo royalty payments to Berkeley on sales in defined regions.*
- *The license waives royalties on sales in “least developed countries” but royalties will be paid on sales in other regions. Licensees that are willing*

14. Ashley J. Stevens, “Valuation and Licensing in Global Health,” Chapter 2.5, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

15. Interview with Harvard TTO, 2017-Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

16. Interview with Yale TTO, 2017-Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

17. https://ott.emory.edu/documents/policies/emory_global_access_principles.pdf.

to provide licensed products for free or at minimal cost in the poorest countries may expect to be able to sell products in countries with large middle classes at a profit under tiered pricing structures.”¹⁸

Case Study 11: Royalty-Free Licensing Contracts under UC Berkeley’s Socially Responsible Licensing Program (SRLP)

- **Available at:** <https://www.autm.net/AUTM-Main/media/Advocacy/Documents/MimuraAUTMJournalFall06.pdf>.¹⁹

Case Study 12: Rice University and the Pumani Bubble CPAP

- **Available at:** <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/bubble-cpap-pumani>.²⁰

II. Contractual Approach and Sample Clauses

Several other universities also utilize adjusted royalty payment structures as a strategy to facilitate global access. Examples along with sample clauses are provided below:

- **Harvard University’s** Global Access Provisions include the following:

- Under **“Royalties”**: *“With respect to Net Sales attributable to Licensed Products sold in any Developing Country(ies), solely for use in such Developing Country(ies) and not for further sale or use in any Developed Country(ies), Licensee and Harvard will negotiate in good faith on a country by country basis a **royalty percentage for such Developing Country(ies), which percentage will generally be in the range of zero percent (0%) to percent (#%), keeping in mind anticipated and actual profits in such countries, as well as the degree to which Licensed Products are available on a locally-affordable basis on a Developing Country by Developing Country basis.**”*²¹

- **University of California’s** Licensing Guidelines note:

- Under **“Global Health”**: *“Financial terms for products that address diseases that disproportionately affect developing countries should, where possible, facilitate product availability in the country of need. **At a minimum, the financial terms should recognize the low profitability of such products. The University could also consider foregoing royalties on products distributed in such countries.**”*²²

The Association of University Technology Managers (AUTM) also provides several examples of “no royalties due” and “reduced royalties due” clauses that have been extracted from license agreements successfully executed by U.S. universities. These can be found in AUTM’s Global Health Licensing Clause Toolkit. One such example from AUTM’s Toolkit is noted below:

- *“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.”*²³

3.2 Milestones

a. Structuring Diligence Obligations to Include ‘Global Access’ Milestones

An important GAL strategy that balances the commercial interests of industry partners with a university’s mission of facilitating affordable access to their health technologies involves the use of diligence requirements that are included up-front in an exclusive license.²⁴ These provisions require the licensee to meet specific humanitarian or Global Access milestones, or else the university can take certain actions, such as license the technology to a third party to meet the humanitarian goals.

18. Mimura C., “Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact,” (July 15, 2009), *Oxford University Press*, 2010.

19. Mimura C., “Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program.” *Journal of the Association of University Technology Managers*, 2016, Volume XVIII Number 2.

20. <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/bubble-cpap-pumani>.

21. https://otd.harvard.edu/uploads/Files/Sample_Global_Access_Language.pdf.

22. UCOP Licensing Guidelines, 2012: https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf.

23. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClause-Toolkit3-17-12.pdf>.

24. Oehler J., “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” Chapter 2.7, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIP-RA, 2007.

This approach is noted by Lita Nelsen, former director of MIT's Technology Licensing Office, in her article "Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions":

• Strategies universities can use to “ensure both development of the product and rapid distribution to developing countries at affordable prices” include:

“a. **Development of milestones**—The university may also require certain success milestones (for example, first clinical trials by a certain date, product on the market by a certain later date).

“b. **Requirement of delivery of product for developing countries**—The university may require the company to **begin testing and distributing the product for developing countries simultaneously, or nearly simultaneously, with its introduction to developed countries.** This is particularly important for vaccines, for which the trickle-down theory has sometimes deprived developing countries of suitable product for decades.”²⁵

Examples of global access milestones that universities could require a licensee to meet are offered by Roose-Snyder *et al.* of Georgetown Law Center and Dr. Brewster:

- “A requirement that on or before the date of the first phase of a clinical trial for a new drug, **the licensee will have identified a generic manufacturer in a middle-income country to produce the licensed technology at a reasonable price for developing countries.**”²⁶
- “1) **delivery to a certain percentage of the developing world by a certain date, 2) meeting a certain sales volume in low-and middle-income markets, or 3) penetration of public markets to a specified extent.**”²⁷

Roose-Snyder *et al.* also share key benefits of using global access milestones:

- “**This strategy establishes the goals of a license at the outset, and demonstrates that**

humanitarian purposes are an important goal of the license.

- **Plus, it allows a university to negotiate an exclusive license—which is more attractive to industry—but gives the university a way out if the licensee does not market/distribute the product in a way that is in keeping with the humanitarian goals of the license or the university.**”²⁸

Case Study 13: Yale University and a Humanitarian License for a Novel Glaucoma Drainage Device

1. **“Licensee shall make the use of licensed products in low-income and lower-middle-income countries a part of its Corporate Mission Statement.**
2. **Licensee agrees to use commercially reasonable efforts to pursue clinical testing of the licensed products in low-income and lower-middle-income countries.**
3. **Licensee agrees that, upon achieving \$5,000,000 in cumulative profits (determined in accordance with [Generally Accepted Accounting Principles] GAAP) from sales of licensed products, Licensee will commit an amount equal to 1 percent of net sales, up to a maximum of \$500,000 per year, in the form of licensed products, grants and/or services, to governments in underdeveloped regions, or not-for profit charitable organizations.”**²⁹

- **Source:** Gates Foundation, “A Glaucoma Treatment Option with Global Promise,” *Case Studies for Global Health*

I. Contractual Approach and Sample Clauses

A sample **Mandatory Development clause with global access milestones attached** is provided in the AUTM Global Health Licensing Clause toolkit:

- “Licensee agrees that in GAVI [Global Alliance for Vaccines and Immunization] 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

25. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

26. Brewster *et al.*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

27. Roose-Snyder *et al.*, “The Global Health Licensing Program: A New Model For Humanitarian Licensing At The University Level,” *American Journal of Law and Medicine*, 2009; 35(2-3):281-309.

28. Roose-Snyder *et al.*, 2009 (please see above footnote).

29. <https://docs.gatesfoundation.org/Documents/case-studies-for-global-health.pdf>.

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.”

- **GLOBAL ACCESS MILESTONES:** *“Licensee shall make a first commercial sale in a GAVI Country by <X date>” OR “within Six (6) Months of achieving One Hundred Million Dollars (\$100,000,000) of profit.”*³⁰

Harvard University utilizes the following clause as part of their “Global Access Provisions” to address affordability of their health technologies in developing countries:

- Under Developing countries:

*“At any time beginning ___ () years after marketing approval of any Licensed Product in a first country, Harvard shall have the right to grant Third Parties licenses under the Patent Rights to develop, manufacture, have manufactured, import, have imported, offer for sale, sell, have sold or otherwise distribute or have distributed such Licensed Product or equivalent thereof (e.g., a generic product), in each case solely for sale or other distribution of Licensed Products or equivalents on a locally-affordable basis in any Developing Country(ies) in which such Licensed Product is not then available on a locally-affordable basis, and not for sale in any Developed Country.”*³¹

More specifically, in order for universities to maximize the public health benefits of their health technology licensing, global access milestones included in license agreements can address four key aspects:³²

1. Territory
2. Exclusivity
3. Pricing to the public sector
4. Regulatory period and time-to-market

Dr. Jochaim Oehler, CEO of Concept Foundation, notes that the “principal way to address these [four] issues is to **set contractual milestones that prevent**

the marginalization of the poor in smaller countries, regulate public sector access, and set the geographic coverage for all countries in a territory (even in countries and regions that are not interesting enough to generate sizeable returns on investments and would therefore normally not be served).”

A comprehensive approach to developing global access milestones that address each of these four aspects is provided in detail by Dr. Oehler in his article “**Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries**”:³³

- *“When well defined, milestones can be used to ensure the availability of the most modern healthcare products to the developing world...When it comes to public sector benefits, simply making a product available at market prices or quickly placing it on the market does not indicate progress. Success is instead defined by how many poor people the product will reach, how easily it will be available to them, and who and how many will be able to afford the product. The goal is to reduce morbidity and mortality. For the public sector, this is the ultimate aim of product development.”*
- Global access milestones cover: “1) definition of the geographic coverage for marketing the product (that is territory); 2) the claim for product exclusivity by the private sector licensee; 3) the definition of the preferred public sector price or other public sector benefit, and 4) regulatory period and time-to-market.”

1. Territory:

- *“The territorial grant must cover not only large countries and their sizable private markets—as main incentive that the public sector would be reached as well—but also small countries and their public sector markets that the private sector partner would not normally cover. Only the licensor can guard these public sector interests.*
- *It is good practice, therefore, not to grant sales rights in large countries to a single licensee without including an obligation to serve the public sector and markets in the smallest countries. If a single licensee cannot cover all of a region’s markets, the entire region*

30. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClause-Toolkit3-17-12.pdf>.

31. https://otd.harvard.edu/uploads/Files/Sample_Global_Access_Language.pdf.

32. Mahoney R., “Negotiating an Agreement: Skills, Tactics, and Best Practices,” Chapter 12.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

33. Oehler J., “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” Chapter 2.7, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

should be appropriately segmented to ensure that two or more licensees each get a profitable share and that the public sector in the smallest countries will be served.

- As outlined above, this goal needs to be adequately supported by specific milestones... [and] a wide range of options for these milestones/conditions are available and could be specified in the license agreement, such as:

1. Specify expected launch dates for the product—For example, the license agreement could stipulate that the product be made available in the public sector not later than two years after the signing of the agreement. Should a product require initial sales in the private market for any reason, an adequate requirement for public sector introduction could be “not later than X years after private-sector launch.”

2. Sales volume—Licensee will gain the rights to sell into other countries after an annual sales volume of five million units is realized in the X market, as measured by cumulative sales reports from distribution agents.

3. Set sales volumes in the private and public sectors in relation to each other. A powerful milestone definition, for example, specifies that public sector sales reach 40% (or any other agreed upon ratio) of the sales volume for the private market within three years after product launch.”

- “These country priorities and milestone definitions should be set when signing the license agreement, with the option to revise the priorities and milestones after a certain period.”³⁴

2. Exclusivity:

- “It is good practice to **evaluate the [licensee’s] request for exclusivity with respect to the public sector benefits that a potential licensee could deliver...**It is especially important for the public sector partner to understand what kind of resources—in terms of quality and quantity—the **private sector company will make available and mobilize for the public sector segment of the exclusive territory.**”
- “Since the request for exclusivity is made to protect the commercial potential of a market place, **the public-sector partner has the right in a quid pro quo to ensure the protection of public-sector needs.**”
- “It is important to link such requests [for exclusivity] with specific milestones, such as:

1. **Volume of sales reached in certain markets** after a certain time period from launch or from the signing of the agreement;
2. **Level of coverage of different regions** in a large market or across different countries of a region;
3. **Latest product launch date** into a market that will secure product/technology exclusivity for the company, in general, for a selected territory.”³⁵

3. Pricing to the Public Sector

- “**Prices must ensure the widest possible availability.** Prices, however, are calculated differently in the pharmaceutical industry than in the public sector.

- Pharmaceutical companies commonly use a retrograde calculation scheme. **They base product prices on the perceived purchasing power of the target segment in a market.** Manufacturing costs are not a major factor for the price calculation. Overhead and marketing costs are usually higher than production costs and need to be well offset by product pricing. To a large extent, adequate product positioning into affluent markets determines achievable margins and operating profitability.

- In contrast, **the public sector mostly uses the cost-plus model for price determination.** Manufacturing and organizational infrastructure contribute significantly to costs. Sales and marketing costs are kept at the lowest possible levels so as not to increase the product’s price. A reasonable, but small, rate of operating profit is added on top of these costs to determine the product price. **With the purchasing power of the public sector under severe limitations, a price determination along the lines of a cost-plus model is the method of choice.**

- An effective license agreement needs to employ...a cost-calculation model. Its aim should be to understand all attributed product costs that contribute to final cost. By applying the model and marking up the ex-factory product price with a mutually accepted profit margin for sales into the public sector, a reasonable platform for determining the lowest possible public sector price can be achieved.

- **It is good practice to mandate the annual submission of manufacturing cost reports and product cost-calculation details.**”

- “Should a manufacturer be **unable to match expected price levels for the public sector**

34. Oehler J., 2007 (please see footnote #33).

35. Oehler J., 2007 (please see footnote #33).

when the company begins manufacturing, a definite timeline with adequate milestones should be set to reach those levels.³⁶

Dr. Brewster further outlines this approach of ensuring affordable pricing through contractual milestones:

- *“Licenses to companies [can] include an appropriate balance of 1) incentives to the licensee and 2) market access for the poor. Licensees might be required to meet certain milestones, such as government procurement targets in defined countries, and at prices that are deemed appropriate for that market. Here, an appropriate price may be defined as the cost of production plus a small profit, usually in the 5%–10% range prior to being allowed to commercialize the product in more lucrative markets.*
- *To ensure that an appropriate price is reached and maintained, the licensor may include contractual language that mandates the submission of manufacturing cost reports and product cost calculation details on a regular basis.”*
- *“Despite the inherent difficulties in defining what is reasonable, price is a readily measurable condition that is easier to monitor than more broadly defined requirements concerning access.”^{37,38}*

Dr. Stevens provides the following contractual approach to implement this strategy in a license agreement:

“Contractually requiring availability and affordability in developing countries by specifying pricing structure.”

“This approach requires developing country development and specifies the pricing structure to be followed. The model adheres closely to the Bill and Melinda Gates Foundation’s Global Access Strategy guidelines.

- **Implementation: Require the licensee to develop the product in developing countries and to sell it using cost+ pricing.**

Include in Definitions:

- **“At-Cost” markets** means those markets in Developing Countries where individual poverty and insufficient public funding

prevent access to healthcare at developed country prices.

- **“Cost-Based Price”** means, in respect of each Licensed Product, a price not exceeding that which fairly reflects the direct cost of manufacture of the Licensed Product plus a typical margin for a generic pharmaceutical product for the respective market.

Include a Section “Supply to Developing Countries”:

- **Supply by Licensee**—*The Licensee shall use Diligent and Reasonable Efforts to supply Licensed Products to customers in At-Cost markets at a Cost-Based Price and meet market demand.”³⁹*

4. Regulatory Period and Time-to-Market

Dr. Oehler further notes:

- *“It is good practice to stipulate in the license agreement when the licensee must bring the product forward to registration. It is also best to specify within what time period after signing the license agreement the licensee has to forward a complete registration filing to the relevant authorities.*
- *For a multi-country territory, specifying the sequence of registration filings in the various countries and the maximum time allowed between individual filings is vital.*
- *It is also advantageous to specify how much time may pass between registration approval and the product launch in the public sector. This prevents the unusual, but realistic, scenario in which a licensee sits on its rights and doesn’t utilize them for the benefit of the public sector.”⁴⁰*

Dr. Oehler also shares the following considerations, which are relevant for universities seeking to develop global access milestones for license agreements:

1. *“When it comes to the detailed specifications of individual milestones, it does not really matter if one is choosing an absolute or a relative goal, or which definition is finally settled upon. What matters is to get the commitment of the private-sector company to recognize public-sector targets.*

36. Oehler J., 2007 (please see footnote #33).

37. Brewster *et al.*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

38. Kapczynski A., Chaifetz S., Katz Z., Benkler Y., “Addressing Global Health Inequities: An Open Licensing Approach for University Innovations,” *Berkeley Technology Law Journal*, 2005; 20:1031–1089.

39. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

40. Oehler J., “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” Chapter 2.7, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

2. **Milestones should not, however, be cast in stone.** Based on detailed analyses of market conditions, **milestones need to remain adjustable throughout the life of the contract...** One can provide for a regular update of the details of these conditions, when a changed environment requires them, for example, by calls for revisions.
3. Finally, it is crucial to recognize that public–private partnerships are not a magic solution *per se* for tasks that have not been well specified. In this sense, **public–private partnerships are a poor substitute for specific, well-defined targets.** In fact, **successful public–private partnerships are built upon specific, well-defined targets.**⁴¹

b. Ensuring Diligent Development and Global Access Through Sublicenses

In addition to including global access milestones within diligence requirements, another GAL strategy used by universities is to ensure diligent development and global access through sublicenses.

I. Contractual Approach and Sample Clauses

Dr. Stevens provides the following contractual approach to implement this strategy in a license agreement:

“Contractually requiring availability and affordability in developing countries by specifying pricing structure.”

- Implementation: Include a Section “Supply to Developing Countries”
 - a. **“Supply by Licensee**—*The Licensee shall use Diligent and Reasonable Efforts to supply Licensed Products to customers in At-Cost markets at a Cost-Based Price and meet market demand.*
 - b. **Sub-licensing in Developing Country Markets**—*In respect of each Licensed Product and At-Cost market, if the Licensee is unable to supply the Licensed Product at a Cost-Based Price to that At-Cost market and meet market demand, it shall use diligent and reasonable efforts to license one or more Developing Country Manufacturers on Reasonable Developing Country License Terms to manufacture, distribute and sell the Licensed Product at a Cost-Based Price to that At-Cost Market.*
 - c. **Pass on Terms to Sub-licensees**—*The Licensee shall ensure that the provisions of this Clause XXX form part of any sub-license agree-*

*ment(s) with any sub-licensee (direct or indirect) of the Licensee.”*⁴²

AUTM provides the following sample clauses in their Global Health Licensing Toolkit:

- **“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.”

- **“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.”*⁴³

41. Oehler J., 2007 (please see footnote #40).

42. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

43. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf>.

Case Study 14: University College London’s Socially Responsible Licensing Policy⁴⁴

c. Reporting and Affordable Access Plans for Developing Countries

In the same way that standard technology license agreements require commercial licensees to provide reports and development updates on R&D results, commercialization activities, and marketing efforts, institutions can also address public health objectives by requiring product development plans for developing countries.⁴⁵ This will ensure the licensee continues to demonstrate progress towards the Global Access milestones included in the license agreement.

Case Study 15: UCLA’s ‘Affordable Access Plan’ Provision

In March 2022, UCLA announced their commitment towards “Underserved Populations When Licensing Medical Research Discoveries.” As part of this commitment, the university administration and the UCLA Technology Development Group (TDG) “**implemented a practice of including in its patent license agreements to UCLA’s biopharmaceutical innovations a provision requiring its licensee to provide and implement an ‘Affordable Access Plan’ (AAP) in order to support “affordable access to the UCLA patented drug in low- and middle-income countries (LMICs).”**⁴⁶

*“UCLA TDG and MPP [Medicines Patent Pool] had several collaborative conversations regarding the challenges university technology transfer offices have had in **identifying contract language of substance which would influence its licensees’ behavior but not deter pharmaceutical partners from taking a license. Ultimately, it was concluded that the AAP provision was ideal as it provided UCLA an opportunity to participate in and facilitate dialogue among UCLA, its licensee, and key stakeholders such as MPP, so that LMICs are considered sufficiently early in the commercialization stage to have a positive impact on affordable access.**”*

“The AAP provision has also been vetted with, and received encouraging feedback from, numerous UCLA constituents, industry representatives, and attorneys

44. Interview with UCL TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

45. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

46. <https://tdg.ucla.edu/ucla-considers-underserved-populations-when-licensing-medical-research-discoveries>.

*who regularly represent UCLA licensees. To date, UCLA TDG has been successful in incorporating such a provision in its biopharmaceutical license agreements and has received minimal pushback from its licensees.”*⁴⁷

The university’s Affordable Access Plan provision is provided in Appendix A of the following document: Affordable Access Plan Provision: Language incorporated by UCLA TDG into its exclusive license agreements to biopharma innovations, and the contractual approach for implementing this provision is outlined below:

- **Insert the following in the whereas clauses:**

***WHEREAS**, as part of its public mission to bring products to the marketplace, The Regents uses good faith efforts to enable underserved communities, which have limited access to adequate quantities of medical innovations arising from UCLA’s laboratories, to have affordable access to these innovative products;*

- **Insert the following as a Diligence/Development Milestone:**

***Affordable Access Plan.** Within __ (X) months of receiving FDA or EMA approval of a Licensed Product, Licensee will provide The Regents with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), Licensee agrees to discuss such reasoning with The Regents in good faith within one (1) month thereafter (“**Initial Discussion**”) and, if following such Initial Discussion The Regents concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to The Regents within three (3) months of such Initial Discussion. The “**Affordable Access Plan**” shall include the following—to the extent such Plan includes confidential information, Licensee will also provide a non-confidential version or statement of such Plan that The Regents can make available to third parties:*

- A specified set of low-and middle-income countries (**LMICs**) in which the Licensee does not intend to commercialize the Licensed Products (the “**Non- Commercialized Territory**”); and
- Licensee’s and/or its Sublicensees’ plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and **Non-Commercialized Territories**, such as through licensing or partnerships including with non-profit organizations.

47. <https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf>.

Within thirty (30) days of The Regents' request (but no more often than once annually), Licensee agrees to confer with The Regents to review Licensee's progress, and to consider in good faith any reasonable modifications suggested by The Regents, with respect to its Affordable Access Plan ("Progress Discussions"). For clarity, while The Regents may invite a designated entity to join either the Initial and/or Progress Discussions under this Section 5.3, such discussions will at all times be made subject to the confidentiality obligations set forth in Section 19 (Confidentiality).

- **Incorporate subpart (f) bolded below into the Progress Reports requirements section:**

Progress Reports...** Each report will contain at least the following information: ...**(f) status of implementation of the Affordable Access Plan.⁴⁸

I. Universities' Experience with GAL Strategy

Several universities have revealed the importance of monitoring a licensee's product development plan for commercialization and delivery of products in developing country markets:

- When asked how **UC Berkeley** monitors a licensee's implementation of global access milestones, Dr. Mimura stated: *"In the same way that we monitor any other license—reports and frequent communication between the case manager and the company. They [licensee] already have a lot of obligations to us under a license."*⁴⁹
- **University College London** highlighted that the licensee is obligated to keep the university *"regularly updated regarding the licensee's efforts to fulfill the SRL [Socially Responsible Licensing] obligations in the license."*⁵⁰
- The director of **Yale University's** Office of Technology Licensing, Dr. John Puziss, noted that *"once clinical trials begin, they [licensee] must maintain some demonstrable clinical activity. The important thing is that these activities can all be easily documented and*

monitored." According to Yale's experience, all global access terms are part of the university's due diligence licensing provisions. Thus, a failure to uphold any of these provisions can be considered a breach of the contract.⁵¹

II. Contractual Approach and Sample Clauses

Dr. Stevens provides the following example of a contractual approach to implement this strategy in a license agreement:

"Contractually requiring availability in developing countries."

"This approach requires the licensee to develop the product for developing countries. Failure to do so would be a material breach of the license, which would at a minimum reopen discussion of license terms and in the extreme could lead to termination.

- **Implementation: Requiring the licensee to include developmental milestones.**

—Include in Milestones:

- ***Within six (6) months of New Drug Application/Biologic License Application 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*

48. <https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf>.

49. Interview with UC Berkeley TTO, 2017—Nguyen T., Shahzad M., Veras J., "Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America," *les Nouvelles*, Volume LIII No. 3, September 2018.

50. Interview with UCL TTO, 2017—Nguyen T., Shahzad M., Veras J., "Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America," *les Nouvelles*, Volume LIII No. 3, September 2018.

51. Interview with Yale TTO, 2017—Nguyen T., Shahzad M., Veras J., "Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America," *les Nouvelles*, Volume LIII No. 3, September 2018.

the company to work a plan for product development in developing countries 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.”⁵²

AUTM provides a more comprehensive sample clause in their Global Health Licensing Toolkit:

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.”⁵³

A final note on diligence requirements and reporting is with respect to ensuring fair pricing in developing countries:

- Dr. Oehler notes that “it is good practice to **mandate the annual submission of manufacturing cost reports and product cost-calculation details...** Should a manufacturer be unable to match expected price levels for the public sector when the company begins manufacturing, **a definite timeline with adequate milestones should be set to reach those levels.**”⁵⁴
- Dr. Brewster of UC Berkeley offers similar advice: “**To ensure that an appropriate price is reached and maintained**, the licensor may include contractual language that mandates the **submission of manufacturing cost reports and product cost calculation details on a regular basis.**”⁵⁵
- Harvard University includes the following clause in their exclusive license agreements:
 - “5.1.1. Reports - Licensee shall deliver to Harvard a report containing the following information (in each instance, with a Licensed

53. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClause-Toolkit3-17-12.pdf>.

54. Oehler J., “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” Chapter 2.7, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

55. Brewster et al., “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

52. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

Product-by-Licensed Product and country-by-country breakdown):

- 5.1.1.3. *with respect to each Licensed Product sold or otherwise distributed in any Developing Country on a tiered-pricing schedule, the sale prices of such Licensed Product during the applicable Calendar Quarter and number of units of Licensed Product sold at each price.*⁵⁶

d. Failure to Meet Global Access Milestones and Opportunity to Cure

Several universities with GAL policies utilize different mechanisms if certain global access milestones are not met by the licensee.⁵⁷ Examples of provisions and reservations in the license agreement that would be activated upon failure to meet specified milestones include loss of exclusivity (conversion to non-exclusive rights), sublicensing, exercise of march-in rights, and, under extreme circumstances, termination of the agreement.⁵⁸

I. Universities' Experience with GAL Strategy

- **University College London (UCL)** revealed that *“if at any time UCL acting reasonably considers that the Licensee is not meeting its obligations...UCL may by written notice require the Licensee to seek one or more third parties to develop, commercialize and supply the Licensed Products to customers in At-Cost Markets.”*⁵⁹
- Dr. Mimura of **UC Berkeley's** Office of Intellectual Property notes that *“if the licensee refuses to grant a sublicense to the third party, then Berkeley may submit a report specifying the license terms proposed by the third party and a written justification for the licensee to grant the proposed sublicense. If Berkeley determines that the terms of the proposed sublicense by the third party are reasonable, then the university has the right to grant the third party a license to utilize*

*the licensed products for use in the licensed field-of-use.”*⁶⁰

- **Harvard University** includes some reversion of the license if the licensee fails to meet certain milestones, for example regarding access in certain geographical areas. The exclusive license can be converted into a non-exclusive license, and the licensee will be informed that a third party will be brought in to meet the need. But Harvard would usually first give licensees *“an opportunity to make it work under their own terms.”*⁶¹

Dr. Oehler of Concept Foundation also offers the following advice:

- **“Specifying penalties and fines for the licensee if these milestones are not reached is just as important as setting the specific milestones. The penalties could be:**
- **Temporary increase of royalties on private sector sales until the milestone condition has been reached;**
- **Loss of exclusivity for the product or technology and conversion to a nonexclusive license, in general, or for a specific region;**
- **Loss of exclusivity and territory to a competitor;**
- **Payment of a fine, in a predefined amount, for failure to introduce a product into a country under exclusivity for the licensee.”**⁶²

II. Contractual Approach and Sample Clauses

AUTM provides a sample clause in their Global Health Licensing Toolkit that can be added at the end of a “diligence requirements for developing countries” clause:

- **“Diligence Requirements for 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

56. https://otd.harvard.edu/uploads/Files/Sample_Basic_Patent_Rights_Exclusive_License_Agreement.pdf.

57. Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

58. Brewster *et al.*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

59. Interview with UCL TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

60. UC Berkeley Socially Responsible Licensing Program: https://ipira.berkeley.edu/sites/default/files/shared/docs/SRLP_Guidance_%26_Clauses_v100817.pdf.

61. Interview with Harvard TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

62. Oehler J., “Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries,” Chapter 2.7, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

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.”⁶³

ARTICLE 4: Intellectual Property

4.1 Patents and Patent Applications

When considering whether patenting a new invention is in the public interest and will maximize global access, Lita Nelsen, the former director of MIT's Technology Licensing Office, provides the following approach:

“Is patenting the right route to maximize social access to the technology? When deciding whether patenting a new invention is in the public interest, the following issues, among many others, should be considered:

1. Is this technology self-evidently useful without substantial further investment in development? **Will it be widely used even if it is not patented but put in the public domain?**

2. If the answer to the previous questions is yes, **can the patent-holding institution nonetheless devise a nonexclusive licensing strategy** that allows revenue to be generated without impeding the use of the technology?

3. If the technology requires substantial high-risk investment, and therefore patenting and exclusive licensing is warranted, **should patents be foregone in developing countries to encourage generic competition?** (This approach is reasonable, under some circumstances, for health and agricultural patents.)

4. Can the patent holder require **sublicensing of other mechanisms to promote low-cost manufacture and distribution in the public sector of developing countries?**

5. If the drug or vaccine is expected to be used only in developing countries, with little or no market in developed countries, will market aggregation through patenting and limited licenses create a sufficiently profitable market that will encourage development and clinical testing?

63. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf>.

6. Should the patent holder carve out free use of a patented research tool for nonprofit research institutions?”⁶⁴

a. Refraining from Filing Patents in Developing Countries Except When Doing So Will Promote Global Access

A key consideration for a university seeking to facilitate global access to its health technologies is to determine which countries the patent will be filed in and to ensure that their patents do not hinder access in developing countries.⁶⁵

The essential need for universities to carefully consider this provision is highlighted by Dr. Stevens, the former director of Boston University's Office of Technology Development, who gives the example of the Yale-Bristol Myers Squibb licensing controversy (which is outlined in part A of this document):

- “The issue that the Yale/Bristol-Myers Squibb case highlighted is that **academic license agreements generally allow the licensee to determine in which foreign countries to file for patent protection.** What caused the problem with Zeret [anti-retroviral] was that **Bristol-Myers Squibb elected to file for patent protection in South Africa and then asserted that patent.**
- Seven years after the Zeret case first highlighted this problem, **most academic license agreements still give the licensee complete discretion as to where to file patents.** Indeed, most academic institutions will only file for foreign patent protection if there is a licensee in place to reimburse the costs of the filings and welcome a licensee filing foreign patent applications because these filings increase the size of the sales base on which royalties will be paid.
- It is therefore imperative that **institutions start to include a safeguard in their license agreements so that licensee agreements signed today do not cause problems in the future when the products that result from them are ready for the marketplace.**”⁶⁶

University of California's Licensing Guidelines highlight the following dual market approach to seeking patent protection:

- **“For diseases that disproportionately affect developing countries, one approach**

64. Nelsen L., “Evaluating Inventions from Research Institutions,” Chapter 9.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

65. Nelsen, 2007 (please see above footnote).

66. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

*might be to seek protection only in developed countries to allow a company to obtain a return on its investment by excluding competition while allowing others in developing countries, including generics manufacturers, to provide the same product without having to enter into a license agreement with the University.”*⁶⁷

I. Universities’ Experience with GAL Strategy

Lita Nelsen provides a comprehensive outline of this GAL strategy and also shares licensing strategies adopted at MIT that maximize access of the university’s health technologies in developing countries:⁶⁸

“Research institutions have the most control over optimizing the use of their inventions at the time of licensing. It is before the invention is licensed that the university can best ensure that the invention will be used to advance—or at least not hinder—solutions to developing country health needs.

- **1. Considering Where to File Patents:**

—When a research institution patents and licenses out a technology, usually the institution can—if it insists—continue to own the patent after licensing. (This is the practice in most U.S. universities.) The institution can then control, by contract with the licensee, which countries the patent will be filed in.

- **2. Prohibition of Filing Strategy:**

—Where a drug or vaccine in question has a large developed-country market, one possible strategy is to prohibit the patent from being filed in developing countries. Most of the licensee’s profits would presumably come from markets in developed countries—with or without developing country patents.

—The loss of potential revenue from developing countries (which in any case could not afford to purchase large quantities of the medicines at developed country prices) would be negligible, and the licensee most likely would not be substantially disadvantaged by this approach. The absence of patents in the developing world, howev-

er, could allow “generic” competitors to produce the drugs in those countries at low prices.

—This strategy will be effective only if:

a.) The developed country market for the medicine is large. If the developed country market is only a specialty “travelers’ market” and the primary demand for the medicine is in developing countries (malaria vaccines are a good example), this strategy may not be acceptable to the licensee company.

b.) The drug or vaccine is relatively easy to manufacture and does not rely on special know-how possessed only by the licensee company (including valuable regulator dossiers). This is more likely with simple chemical drugs than with biological drugs (including vaccines), whose techniques for production and purification may be beyond the capabilities of most developing country manufacturers. Also, if the drug is easy to manufacture, then safeguards must be in place to avoid parallel imports.

c.) The research institution owns the core patent for the drug or vaccine, while other “secondary” patents, owned by the licensee, are not critical to developing and manufacturing the medicine. If secondary patents are critical and the licensee chooses to file them in developing countries, then attempts by the university to provide its own technology free of charge may be moot.

- **3. When Patent Filing in Developing Countries Can Promote Access:**

a.) When the demand for a drug or vaccine is primarily (or exclusively) in developing countries and there are no alternative products, the primary problem is to develop a sufficiently profitable market to provide an incentive for the private sector to invest in R&D.

b.) Patents may provide an incentive to the private sector to invest by aggregating the developing world market into a single, larger market.”

Case Study 16: MIT’s Patenting Policies for Promoting Access in Developing Countries

Lita Nelsen shares the following institutional examples from MIT in her article “*The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship*”:

- “M.I.T. usually files patents only in North America, Europe, and Japan (though occasionally we

67. UCOP Licensing Guidelines, 2012: https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf.

68. Nelsen L., “Evaluating Inventions from Research Institutions,” Chapter 9.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

file in China, Singapore, Republic of China, and Korea for the electronics field). **Thus, the biomedicine-related patents we file are not often likely to affect the development and distribution of medicines and vaccines in developing countries.**

- We are, however, mindful of the issues surrounding the development and distribution of new health-related products for developing countries, and we consider both our patenting procedures and our licensing terms when working with relevant technologies.

—1. **For example, it may sometimes be advisable for patents to be filed in some developing countries so that local companies in those countries can protect their investments in further developing our technology.**

—2. **In other cases, we may choose not to file patents in those countries and may prohibit our licensees from doing so—or we may refrain from granting exclusive licenses in developing countries unless we feel exclusivity will enhance development and access.**

—3. **Other agreements could require preferential pricing for the public sector of developing countries.”**⁶⁹

II. Contractual Approach and Sample Clauses

Dr. Stevens provides the following contractual approach to implement this strategy in a license agreement:

“Creating competitive sources in developing countries - Not allowing a licensee to patent in developing countries: This approach requires the Licensee not to patent in developing countries, therefore permitting generic manufacturers and not-for-profit organizations freedom to operate in those developing countries.

• **Implementation:**

—**Include in Patent Rights:**

- *The University and Licensee on behalf of themselves and any successors-in-interest to the Intellectual Property covenant that they have not previously, are not currently and will not after the date of this agreement, obtain Patent Rights in Developing Countries.”*⁷⁰

69. Nelsen L., “The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship,” Chapter 3.13, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

70. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

A sample **Non-patent—clause** is also provided in the AUTM Global Health Licensing Clause toolkit:

- *“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.”*⁷¹

In a joint statement published by **Harvard, Yale, and Boston University** (among several other institutions including AUTM), these universities highlight certain situations in which it would be beneficial to seek patent protection in developing countries:

- *“We will seek patent protection for such [health-related] technologies in developing countries only in a manner that is consistent with our objective of facilitating global access. For example, it may be necessary to account for special circumstances (e.g., in India, China or Brazil) that may warrant patenting in such countries on a case-by-case basis, including but not limited to:*

—1. **The existence in a developing country of pharmaceutical manufacturing capacity suitable to support product distribution both within and outside the developing world; or**

—2. **The opportunity to gain greater leverage in seeking concessions, such as access to others’ intellectual property, that would help to ensure that the health-related technology can be made available affordably; or**

—3. **To enable our licensee(s) to implement tiered pricing in those developing countries where a significant private market exists.”**⁷²

In addition to MIT, several other universities with GAL policies have developed licensing terms to safeguard their prerogative to not file patents in developing countries:⁷³

- **Harvard University’s** “Global Access Provisions” note the following strategy:

71. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf>.

72. https://otd.harvard.edu/uploads/Files/Global_Access_Statement_of_Principles.pdf.

73. Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

—Under **“Patent control”**: additional language may be added to the patent prosecution provision, to allow Harvard to retain full control of patent prosecution and enforcement in Developing Countries, as follows:

—*“In particular, and without intending to limit any of Harvard’s rights pursuant to this Agreement, **Harvard expressly reserves the right to decline Licensee’s request to file, prosecute, maintain or defend any of the Patent Rights in any Developing Country(ies) unless (i) Licensee demonstrates to Harvard’s reasonable satisfaction that the filing, prosecution, maintenance or defense of such Patent Rights in such Developing Country(ies) would materially increase the locally-affordable availability of Licensed Products or equivalents thereof (e.g., generic products) in those and/or other Developing Country(ies) and (ii) the provisions of Section [__ - Enforcement] notwithstanding, Licensee agrees that Harvard shall hold final decision-making authority, on a case-by-case basis, as to whether Licensee will be permitted to enforce such Patent Rights in such Developing Country(ies).**”*⁷⁴

- Dr. Mimura revealed that UC Berkeley uses various IP strategies within their Socially Responsible Licensing Program (SRLP), including:

—*“forbearance of patenting outside potentially lucrative markets (Japan, Canada, Europe, Australia and the United States).”*⁷⁵

—She further notes that *“one strategy proposed in our [SRLP] Guidance and Clauses document is **where we have patent rights in LMICs or countries defined in any other way such as EDCs or listed in an Appendix, the licensees are required either to sell the product for free or at cost. There is also another strategy which is to simply be careful about where we patent.**”*⁷⁶

- **Dr. Puziss of Yale University** noted that the simplest term to adopt is selecting which coun-

tries the university chooses to file patents in. Yale is **“very clear in the license agreement that they do not file patent applications in LMICs [low- and middle-income countries] as defined by the World Bank.”**⁷⁷

- **The University of Oxford** states that *“its policy when licensing its technology for commercial exploitation purposes is, as far as is practicable: **to prosecute patent applications in less developed countries only as necessary** (for example, to provide development and marketing leverage for new products, or to exert leverage over global licensees).”*⁷⁸

b. Refraining from Patenting Research Tools that only have Research or Non-Commercial Purposes

Lita Nelsen shares the following licensing strategy for research tools:

- *“Where the invention is a tool for discovery that is useful to many without significant development, then **nonexclusive licensing is probably most appropriate for developed country use. Patents in developing countries will essentially be unnecessary.**”*
- *“Many universities will also **require that the patents not be asserted against nonprofit research institutions in any country, thus allowing free access by such institutions.**”*⁷⁹

Peter Lee, Professor of Law at UC Davis, notes an important consideration for universities with respect to patenting of research tools:

- *“Assuming that public support has already satisfied the incentive to invent a research tool, patent protection can only be justified to provide ex post incentives to develop. **However, some existing research tools function solely as discovery aids for which no additional development (or incentives to encourage development) is necessary.**”*

74. https://otd.harvard.edu/uploads/Files/Sample_Global_Access_Language.pdf.

75. Mimura C., “Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact,” (July 15, 2009), *Oxford University Press*, 2010.

76. Interview with UC Berkeley TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

77. Interview with Yale TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

78. Interview with Oxford TTO, 2017—Nguyen T., Shahzad M., Veras J., “Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America,” *les Nouvelles*, Volume LIII No. 3, September 2018.

79. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

- *Illustrative in this regard, the NIH invoked its Bayh-Dole rights to discourage participants in the Human Genome Project from patenting raw genomic DNA. CIRM [California Institute for Regenerative Medicine] expressly discourages grantees from patenting biomedical resources that only have a research function.*
- *Some universities voluntarily refrain from patenting DNA sequences that serve only as markers and are not candidates for additional commercial development. Public institutions should conscientiously apply incentives based analyses to determine whether certain research tools warrant any patent protection at all.*⁸⁰

4.2 Improvements

a. Follow-on Patents and Proactive Considerations for Global Access

While the strategy of refraining from patenting in developing countries has been a widely adopted and successful practice among several universities with GAL policies, the use of private sector follow-on patents (or secondary patents) is a source of particular concern for access to essential health technologies in developing countries.^{81, 82}

With respect to follow-on patents and university licensing, Dr. Lisa Ouellette, Professor of Law at Stanford Law School, notes the following key consideration for universities:

- *“Many universities and public-sector institutions have important drug patents, but efforts to license these patents to promote the public interest can be derailed by private-sector follow-on patents.”*
- *“Sixty percent of public-sector drugs do have private-sector patents. Therefore, policies focused on increasing access to university medicines by simply not patenting in low- and middle-income countries may be insufficient to ensure generic access to these drugs...because even if the public-sector patents are not a barrier, private-sector follow-on patents could be.”*
- *Instead, public-sector institutions will need proactive licensing terms to ensure that fol-*

80. Peter Lee, “Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law,” 58 *Emory Law Journal* 889 (2009).

81. Lisa Ouellette, “How Many Patents Does It Take To Make a Drug? Follow-On Pharmaceutical Patents and University Licensing,” 17 *Michigan Telecomm. Tech. L. Rev.* 299 (2010).

82. Bhaven N. Sampat and Kenneth C. Shadlen, “Secondary Pharmaceutical Patenting: A Global Perspective,” *Research Policy*, vol 46(3), pages 693-707.

low-on patents do not block access to the end products that are needed by patients...such as reserved or ‘march-in’ rights, mandatory sub-licenses or non-assert provisions.”

The effect of follow-on patents on access to university innovations is also noted by Lita Nelsen:

- *“The prohibition of filing [in developing countries] strategy is only useful when... the research institution owns the core patent for the drug or vaccine, while other “secondary” patents, owned by the licensee, are not critical to developing and manufacturing the medicine.*
- *If secondary patents are critical and the licensee chooses to file them in developing countries, then attempts by the university to provide its own technology free of charge may be moot.”*⁸³

I. Contractual Approach and Sample Clauses

To address the issue of follow-on patents, Dr. Stevens provides a middle ground approach that would be more acceptable to licensees and that universities can implement in license agreements:

“Which IP Should be Covered by Social Responsibility Provisions?”

- *“A number of the [global access] licensing frameworks proposed...achieve their objectives through the terms of access to the university’s patents. If the licensee develops their own IP that is an additive to but independent of the university’s IP (i.e., the licensee’s patents are not continuations-in-part of the university’s patents), these mechanisms may not be effective.”*
- *“Using the university’s patents to ‘reach through’ and impose terms on the licensee’s independently developed patents will likely be strongly resisted by the licensee...it is a universal experience of academic licensing negotiations that licensees strongly resist grant-backs of the developments they make to the licensed intellectual property.”*
- *“One possible approach to this problem would be to explicitly limit the reach through to the licensee’s patents for purposes of implementing the social responsibility protections.”*
- *Implementation: “One contractual approach to implement this might be to include in the*

83. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

definition of Patent Rights the following:

—Solely for purposes of implementing the Social Responsibility Purpose, (and, for avoidance of doubt, not for purposes of determining royalties payable to University) Patent Rights shall include all patents owned or controlled by Licensee that are co-listed with Patent Rights solely or jointly owned by University in the Orange Book maintained by the U.S. Food and Drug Administration.”⁸⁴

Dr. Brewster offers another variation of this approach that universities can utilize:

- Under “Humanitarian conditions in licensing agreements”: A licensor could also insert language **requiring the licensee to make products developed from improvements to the technology available in low- and middle-income countries at a reduced cost.**”

II. Universities’ Experience with GAL Strategy

Case study 17: UBC’s Global Access Principles

The University of British Columbia (UBC) has successfully executed a license agreement with a clause that addresses the role of the licensee, as well as any sublicensees, in commercializing any improvements on the patented technology “in a manner consistent with [UBC’s] Global Access Principles [and]...for the benefit of the Developing World.” This clause is provided in the Global Health Licensing Toolkit published by AUTM:⁸⁵

- “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 foregoing, 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.
- The Licensee acknowledges and agrees that:
 - 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.”⁸⁶

Additional GAL Strategies

In addition to the range of GAL provisions and terms outlined previously in this section, universities and public research institutions have also selectively utilized a variety of other strategies on a case-by-case basis to facilitate global access to their health innovations.

a. Strategies to Facilitate Generic Competition in Developing Countries

Several of the GAL strategies noted thus far in this section utilize a market segmentation approach to facilitate generic competition in developing countries and ensure affordable prices. Examples of such strategies used by universities include:

- Non-assert declarations
- Refraining from filing patents in developing countries
- Excluding developing countries from exclusive licenses
- Reserved rights to grant non-exclusive licenses in developing countries

84. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).

85. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf>.

86. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf>.

It is critical for universities to utilize these approaches whenever possible as market competition generated by generic provision is recognized as the most effective means of driving down prices and increasing access in developing countries.^{87,88,89} Dr. Suerie Moon of Harvard School of Public Health emphasizes this point and highlights key advantages of market competition for ensuring affordability of health products:

- *“In comparison [to other pricing strategies], when markets are sufficiently large and multiple sources of production exist, **robust competition has consistently proven across different therapeutic areas to result in lower prices.**”*
- *Making competitively produced medicines available in all developing countries would **minimize the complications of internal market segmentation, since the lowest prices would be available across all sectors.***
- *In general, **competition should be the default option for improving the affordability of medicines in developing countries.**”⁹⁰*

b. Affordable Pricing Strategies for Developing Countries

However, there are particular situations in which generic competition is not always possible and, instead, universities have adopted various other affordable pricing strategies as effective substitutes. Specific cases where alternative pricing strategies such as at-cost, cost-based, or tiered pricing may be useful include:

1. **When the drug, process, technology, diagnostic, or other component of the licensed product is too complex to be feasible for replication and generic production.** For example, university licensing of vaccines and bio-

logics may require at-cost or cost-based pricing provisions.^{91,92}

2. **When the demand for the product in resource-limited countries is too small to induce a generic company to enter into production.** Causes of a small demand could include a very small affected patient population as in rare genetic diseases, or an isolated or constrained geographic distribution.^{93,94}
3. **When the university owns only some of the intellectual property needed to produce the health technology.** For example, while the university may own the patent to the key protein used in a vaccine, if another entity has patented the production process or other elements required to produce the vaccine, the strategies to facilitate generic competition, such as a non-assert declaration, alone will not be effective. In this case, a sublicensing agreement tied with at-cost provisions for developing countries may be more appropriate.^{95,96}

Lita Nelsen highlights the importance of using exclusive licenses to ensure fair pricing in developing countries:

- *“**Exclusive licensing places a large responsibility on the university to negotiate license clauses that ensure both development of the product and rapid distribution to developing countries at affordable prices.**”*
- *Licensing strategies include...**control over pricing in developing countries. This is usually set at a small percentage over cost (so-called cost-plus pricing).***
- *Other agreements could require **preferential***

87. Moon S., Jambert E., Childs M. *et al.*, “A Win-Win Solution? A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries,” *Global Health* 7, 39 (2011).

88. “Report to Congress by the U.S. Global AIDS Coordinator on the Use of Generic Drugs in the President’s Emergency Plan for AIDS Relief,” PEPFAR (May 2008), <http://www.pepfar.gov/documents/organization/105842.pdf>.

89. Kapczynski A., Chaifetz S., Katz Z., Benkler Y., “Addressing Global Health Inequities: An Open Licensing Approach for University Innovations,” *Berkeley Technology Law Journal*, 2005; 20:1031–1089.

90. Moon S., Jambert E., Childs M. *et al.*, “A Win-Win Solution? A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries,” *Global Health* 7, 39 (2011).

91. UAEM Global Access Licensing Framework, 2009: <https://case.edu/research/sites/case.edu/research/files/2018-04/UAEMframework.pdf>.

92. Roose-Snyder B. *et al.*, “The Global Health Licensing Program: A New Model For Humanitarian Licensing At The University Level,” *Am J Law Med.* 2009 ;35(2-3):281-309.

93. UAEM Global Access Licensing Framework, 2009: <https://case.edu/research/sites/case.edu/research/files/2018-04/UAEMframework.pdf>.

94. Moon S., Jambert E., Childs M. *et al.*, “A Win-Win Solution? A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries,” *Global Health* 7, 39 (2011).

95. Mimura *et al.*, “Socially Responsible Licensing, Euclidean Innovation, and the Valley of Death,” *Stanford Journal of Law, Science and Policy*, 2011.

96. Roose-Snyder B. *et al.*, “The Global Health Licensing Program: A New Model For Humanitarian Licensing At The University Level,” *Am J Law Med.* 2009 ;35(2-3):281-309.

pricing for the public sector of developing countries.”⁹⁷

I. Universities’ Experience with GAL Strategy

Various affordable pricing strategies are being utilized by universities to facilitate global access.⁹⁸ Experts in the technology transfer field offer specific examples along with key considerations for implementation:

Dr. Mimura of UC Berkeley’s Office of Intellectual Property highlights the following strategy:

- **“Tiered pricing—Licensees that are willing to provide licensed products for free or at minimal cost in the poorest countries may expect to be able to sell products in countries with large middle classes at a profit under tiered pricing structures. Tiered pricing is consistent with the goals of the program as long as the neediest target populations receive the lowest prices or the negotiated prices.**
- *An existing example of contract language to address tiered pricing involves a definition of economically disadvantaged population “strata” within a given country according to income level (that is distinct from the definition of economically disadvantaged countries); coupled to a conversion option right (that would allow the licensee to convert from one pricing obligation to another, if a given group graduates from one income level to another).*
- *This construct allows both parties to acknowledge the need to preserve market incentives for the licensee, while mutually agreeing on a target market that will be entitled to the lowest prices.”⁹⁹*

Roose-Snyder *et al.* of Georgetown Law Center note:

- **“At-cost pricing—Almost all strategies using a pricing approach involve at-cost pricing – the idea that a drug or biologic should be priced in low- and middle-income countries at cost of production or cost of production plus a moderate markup.**

97. Lita Nelsen, “Ensuring Developing-Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions,” Chapter 1.4, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

98. Brewster A. *et al.*, “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

99. Mimura C., “Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact,” (July 15, 2009), *Oxford University Press*, 2010.

- *A university would include terms in its license to an industry partner that requires the licensee to make the resultant product available in low- and middle-income countries at-cost, or at a specified markup.*
- *Since it is difficult at the outset to have an idea of an adequate price, as it is not yet possible to determine cost of production, the university would also include clauses that require the licensee to submit regular reports on manufacturing costs and product cost calculation details, so that the university could devise a fair at-cost price.”¹⁰⁰*

Dr. Richard Mahoney, Director of Vaccine Access, International Vaccine Institute, notes that “the licensor can consider several options of setting a condition of the price to the public sector in developing countries:

- **“The price could be set at cost of production plus a reasonable markup, for example, 15% of cost of production. This is feasible when the licensor has a reasonable expectation of being able to monitor the cost of production.**
- **The price could be set at “no higher than the lowest price offered to any private sector buyer.” This may be preferred in cases where it is expected there will be large bulk purchases by private sector buyers who are good at negotiating the very best price.”¹⁰¹**

Dr. Gerald Keusch, Provost and Dean for Global Health at Boston University Medical Center, highlights an important benefit for universities and licensees in using a market segmentation approach for affordable pricing:

- *“Developing country markets can also be segmented: the technology could be provided at low or no cost to the poorest countries through a subsidy mechanism (market pull), at a sustained rather than reduced price in middle-income developing countries, and at a higher price as the market develops.*
- *Such an arrangement would be consistent with economic theory, in which price discrimination can increase market efficiency and equity. It actually resembles the pricing methods that*

100. Roose-Snyder B. *et al.*, “The Global Health Licensing Program: A New Model For Humanitarian Licensing At The University Level,” *Am J Law Med.* 2009;35(2-3):281-309.

101. Mahoney R., “Negotiating an Agreement: Skills, Tactics, and Best Practices,” Chapter 12.1, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

pharmaceutical companies currently use in developed country markets and could make some technologies suddenly more financially attractive.¹⁰²

In an economic review of differential pricing strategies for pharmaceuticals, Dr. Prashant Yadav of Harvard Medical School, suggests other key benefits for commercial licensees in the pharmaceutical sector:

- **“Differential pricing allows pharmaceutical companies to signal that their pricing policies are socially responsible and consistent with their obligations to society and not just geared towards maximizing profits. In addition, differential pricing on select drugs opens opportunities to serve low and middle-income markets and creates economies of scope for pharmaceutical companies.**
- **The analysis also suggests that social welfare is enhanced when differential pricing opens new markets for pharmaceutical companies in countries where the affordability for the drug is significantly lower than the prevailing price in existing markets.**¹⁰³

c. Mandatory Development Clauses

AUTM provides the following “mandatory development” clauses as part of their Global Health Licensing Toolkit, which contains clauses from license agreements successfully executed by U.S. universities:

1. Mandatory Development:

—“*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.*”

2. Mandatory Development with Reasonable Cost Distribution:

—“*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>.”**

d. Mandatory Donation Clauses

AUTM also provides the following “mandatory donation” clause as part of their Global Health Licensing Toolkit:

- *“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.”¹⁰⁴*

e. Transferring Health Technologies to Public-Private Partnerships (PPPs)

Dr. Brewster outlines the following strategy universities can utilize as part of their GAL policies:

- **“When it is clear that a technology could benefit neglected markets (for example, a low-cost HIV diagnostic or an agricultural trait important for subsistence agriculture), university technology managers may be able to transfer the technology to a nonprofit corporation for product development either on an exclusive or nonexclusive basis.**
- **The transfer of technology could take forms ranging from direct licensing or donation of a patented invention to contributions of know-how or scientific expertise. Another possible model is an arrangement in which a commercial licensee focused on markets in affluent countries makes the technology available to a PPP on concessionary terms for marketing or development for poor countries.**

102. Keusch G., “Global Health: Lessons from Bayh-Dole,” Chapter 3.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

103. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67672/diff-pcing-pharma.pdf.

104. AUTM Global Health Toolkit: <https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClause-Toolkit3-17-12.pdf>.

- *In order to minimize transaction costs for the PPP, it is highly preferable for the university to engage with the nonprofit developer before completing negotiations with the commercial licensee.*
- *University technology managers can also facilitate nonprofit product-development efforts by offering PPPs ownership of patents that the university no longer wishes to maintain. Even when a technology does not appear to have a clear application for developing regions, it may prove useful for some aspect of the PPP's work to develop products for these regions.”*¹⁰⁵
- *Academic licensing officers have consistently shown ingenuity, resiliency and creativity in their business negotiations, and we are confident that academic institutions will increasingly not only incorporate one of these licensing approaches into their standard license agreements, but will make it a formal policy of their institution to use licensing to promote global social responsibility.”*¹⁰⁶ ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=4337749>.

It is hoped that the range of GAL strategies, sample clauses and university case studies offered in this toolkit will provide public-sector institutions with a robust and readily implementable set of contractual provisions that they can utilize in license agreements with industry partners. To conclude, Dr. Stevens, former director of Boston University's Office of Technology Development, highlights the significance of license agreements as opportunities to promote global social responsibility:

- *“This learning allows licensing officers to focus on the business negotiation of agreeing a license; social responsibility protections become just another business term and element of the overall negotiation. We hope that this article has shown that it is straightforward contractually to do so, in order that the issue will devolve to a business negotiation.*

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105. Brewster A., et al., “Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,” Chapter 2.2, *IP Handbook of Best Practices, Intellectual Property Management in Health and Agricultural Innovation*, PIPRA, 2007.

106. A. J. Stevens, A. E. Effort, “Using Academic License Agreements To Promote Global Social Responsibility,” *les Nouvelles* 43, 85–101 (2008).