

Development of technologies borne from Harvard patent rights may lead to licensed products that could result in significant public health benefits in developing countries. Harvard has made a commitment, through its participation in the organization Universities Allied for Essential Medicines, to promote affordable access to such products in developing countries. To meet that commitment, we may require provisions similar to those given below in exclusive licenses of such potentially impactful technology.

## **Global Access Provisions**

### **Definitions:**

**“Developed Country”** means any country other than a Developing Country.

**“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 Immunisation), as such list may be updated from time to time by the GAVI Alliance.

**“Humanitarian Purposes”** means practice of Patent Rights in the prevention or treatment of disease in humans by or on behalf of any Qualified Humanitarian Organization (including, for clarity, practice of Patent Rights by contractors, manufacturers or distributors acting for or on behalf of such Qualified Humanitarian Organizations on a fee-for-service, fee-for-product or charitable basis) (a) to manufacture Licensed Products anywhere in the world for the sole and express purposes of distribution and use of such Licensed Products in one or more Developing Countries, and (b) to sell or otherwise distribute Licensed Products for use solely in one or more Developing Countries; provided, however, that sales and distribution of Licensed Products shall not be deemed made for Humanitarian Purposes unless products are distributed at locally-affordable prices.

**“Qualified Humanitarian Organization”** means any governmental agency, non-governmental agency or other not-for-profit organization that has as one of its bona fide missions to address the public health needs of underserved populations on a not-for-profit basis. For clarity, Qualified Humanitarian Organizations do not include non-governmental agencies and non-for-profit organizations that are formed or established for the benefit of any for-profit entity.

### **Provisions:**

A. **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; provided that:

- (1) Any such license shall expressly exclude the right to export any Licensed Product from any Developing Country into any Developed Country or to use the Licensed Product in any Developed Country;
- (2) Any such license shall be on terms and conditions otherwise in compliance with and not inconsistent with the terms of this Agreement;
- (3) Any such license shall be granted only pursuant to a written agreement; and
- (4) Such licensee shall not have the right to sublicense or to assign such license to any person or entity; provided, however, that (1) upon the express prior written consent of Harvard, such licensee may sublicense or assign such license only to another Qualified Humanitarian Organization; and (2) that such licensee shall be entitled to engage independent Third Parties to practice the Patent Rights on behalf of such licensee solely as set forth in the definition of Humanitarian Purposes without Harvard's consent."

**B. Developing Countries.** [Note: additional language may be added as a proviso to the license grant language or as an addition to the retained rights clause, to allow third parties to manufacture Licensed Products and distribute such Licensed Products in Developing Countries on an affordable basis.]

"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."

**C. Royalties:** [Note: additional language may be added to the royalties provision, in the following manner, to take account of Harvard's global initiative to make products derived from Harvard technologies that can improve public health accessible and affordable in Developing Countries.]

"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 <**number smaller than percentage otherwise due**> 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.”

D. **Patent Control.** [Note: 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).”