What is the Affordable Access Plan provision?

In 2020, the Medicines Patent Pool (MPP) was invited to collaborate with the UCLA Technology Development Group (UCLA TDG) to develop a workable clause that would meaningfully improve the university's exclusive licensing template for early-stage medical technologies with regard to affordable access in low- and middle-income countries (LMICs), with the important proviso that the clause should be amenable to a variety of stakeholders.

With that in mind, MPP and UCLA developed an affordable access plan provision that:

- Requires licensees to
  - submit a plan of how they will achieve affordable access for the licensed product(s) in low- and middle-income countries, with strategies and timelines.
  - identify countries in which the licensee has no intention of commercializing.
- Only requires the submission of the plan when it is reasonably certain that the licensed product will be commercialized – i.e., within a specified amount of time of having received regulatory approval, which allows the licensee to focus energy and resources on the critical research and development activities needed to advance a technology and only develop the plan if/when the product is ready for market launch.
- Allows the licensor to call upon a "designated entity" with relevant public health expertise to assist in conversations with the licensee regarding the access plan.

During the course of the discussions, MPP and UCLA vetted this language with various stakeholders, including venture capital firms, IP law firms, civil society groups and others, and UCLA has used this provision in its exclusive biopharma licences since then without issue.

What other entities have begun using this provision?

In addition to UCLA TDG, University of California Berkeley Intellectual Property & Industry Research Alliances (IPIRA), Columbia Technology Ventures, the Innovative Genomics Institute (IGI), and others have begun incorporating a version of this provision into their exclusive licences.

What other entities have similar access obligations in upstream licences or funding agreements?

Bill and Melinda Gates Foundation – Global Access[1]
CARB-X – Stewardship and Access Plan[2] (funded by BARDA, Wellcome Trust, Gates, etc.)
Wellcome Trust[3]
CEPI Equitable Access

Why should such a provision be included at such an early stage of development?

In many disease fields and across many types of health technologies, companies will only focus commercialization strategies on a small subset of high-income countries (HICs) where returns are typically the greatest, and often do not consider access issues in LMICs until several years after receiving regulatory approval, if at all. At times, this may result in key health technologies, originally discovered by universities or public research organizations, not being available or affordable to people needing them in many LMICs. This provision focuses attention on the access issue at an earlier stage while affording licensees a significant degree of flexibility in choosing the appropriate strategy.

What are the advantages to universities/funders/others that may want to utilize this provision?

Many universities, public research organizations, and funders have a public interest mandate or have otherwise indicated in mission statements that they maintain a commitment to equitable access but have struggled to find concrete ways to implement these commitments. The provision potentially advances global health equity in a pro-active manner that may complement other contractual provisions in use, and does so with a flexible, collaborative approach that is conducive to innovation while aligning with access-oriented missions and/or mandates.

What advantages does this provision offer to industry partners?

[1] "Global Access … requires our grantees and partners to commit to making the products and information generated by foundation funding widely available at an affordable price, in sufficient volume, at a level of quality, and in a time frame that benefits the people we're trying to help. What role does Intellectual Property play in the foundation's approach to furthering Global Access? Intellectual Property provides a great opportunity to think creatively and strategically about how we can reach our ultimate beneficiaries. The careful and deliberate management of IP (patents, copyrights, trademarks, trade secrets, and rights in data) and the associated rights created or accessed through foundation-funded projects, is a critical component to achieving Global Access. Global Access commitments also apply to collaborations with for-profit entities. Whether it is a groundbreaking diagnostic tool or a new toilet that does not require a sewer connection or electricity, they are allowed to sell what they develop with foundation funding at a profit in the developed world, as long as the products are made available to the people who need them most." https://globalaccess.gatesfoundation.org/

[2] Section 5.01 of the CARB-X research subaward agreement contains an obligation for the awardee to submit a "stewardship and access plan" with strategies and timelines of how the awardee intends to promote equitable access to antibiotics also adhering to principles of stewardship intended to avoid mismanagement and misuse that worsens the problem of antimicrobial resistance. https://carb-x.org/wp-content/uploads/2021/05/CARB-X_Research-Subaward-Agreement-for-profit_17-May-2021_Redacted.pdf

3 Wellcome Trust uses a range of tools to promote equitable and timely access to interventions supported by Wellcome Trust funds, including via contractual mechanisms that require "that awardees have an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low." https://wellcome.org/what-we-do/our-work/access-healthcare-interventions/wellcomes-approach-equitable-access-healthcare-interventions

The provision does not specify the modality of how access should be addressed, inherently recognizing that different contexts may require different solutions. There may be some technologies for which licensing to manufacturers based in LMICs may be very appropriate, but in other cases there may be other suitable approaches. The nonprescriptive nature affords industry partners control over the activities anticipated to achieve access and allows them to identify options that make sense for their company, and which may in fact yield opportunity for market expansion rather than financial loss. This could be through licensing but may also be through other types of partnerships with organizations that exist to improve affordable access in LMICs.

What global health organizations may be willing to assist in evaluating access plans submitted under this provision?

MPP is very willing to assist universities and its partners in evaluating and discussing submitted access plans when they relate to technologies/areas in which MPP has expertise.

There are a variety of global health non-governmental organizations operating with express mandates to advance access in LMICs through partnership and/or other models of working such as FIND (diagnostics), the Global Antibiotic Research & Development Partnership (antibiotics), PATH (medical devices, in-country technical assistance), the Clinton Health Access Initiative (market shaping), and TB Alliance (tuberculosis) just to name a few. Many routinely collaborate with industry to facilitate equitable access in LMICs.

MPP would be willing to facilitate introductions to these or others that may find this approach of interest.

Does civil society support use of this provision?

Universities Allied for Essential Medicines played an instrumental role in facilitating the negotiation of this language with UCLA and continues to be vocal in support of universities and other institutions that want to adopt similar provisions.

Please feel free to contact us with questions.
upstream@medicinespatentpool.org

Find out more about the Medicines Patent Pool: www.medicinespatentpool.org

UC Berkeley template

4.9 **Affordable Access Plan**. Within three (3) months of receiving FDA (or its foreign equivalent's) 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" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in the U.S., as defined by the Department of Health and Human Services, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that the REGENTS can make available to third parties:

(a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory");

(b) 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; and

(c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S.

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 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 Paragraph 4.9, such discussions will at all times be made subject to the confidentiality obligations set forth in Article 25 (Confidentiality).

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8. PROGRESS AND ROYALTY REPORTS

8.1 **Progress Reports**. For the period beginning [***Date***]**,** LICENSEE will submit to REGENTS a semi-annual progress report covering LICENSEE's activities related to the development and testing of all LICENSED PRODUCTS, LICENSED SERVICES and LICENSED METHODS and the obtaining of necessary governmental approvals, if any, for marketing in the United States. These progress reports will be made for all development activities until the first SALE occurs in the United States. Each progress report will be a sufficiently detailed summary of activities of LICENSEE and any SUBLICENSEES so that REGENTS may evaluate and determine LICENSEE's progress in development of LICENSED PRODUCTS, LICENSED SERVICES, and LICENSED METHODS, and in meeting its diligence obligations under Article 7 (Diligence), and will include (but not be limited to) the following: summary of work completed and in progress; current schedule of anticipated events and milestones, including diligence milestones under Paragraph 7.2; anticipated market introduction dates for the LICENSED TERRITORIES; status of implementation of the Affordable Access Plan and

SUBLICENSEE's activities during the reporting period. LICENSEE also will report to REGENTS in its immediately subsequent progress and royalty reports, the date of first SALE.

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Affordable Access Plan Provision: Language incorporated by UCLA TDG into its exclusive license agreements to biopharma innovations:

- 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. A specified set of low- and middle-income countries ("LMICs") in which the Licensee does not intend to commercialize the Licensed Products (the "NonCommercialized Territory"); and

B. 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.

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**.

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