UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES
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GLOBAL ACCESS LICENSING FRAMEWORK

Every university-developed technology with potential for further development into a drug, vaccine, or medical diagnostic should be licensed with a concrete and transparent strategy to make affordable versions available in resource-limited countries for medical care. Licenses are complex and each will be unique. Universities should therefore implement Global Access Policies that adhere to the following six principles:

Goals

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end product needed by patients (e.g. formulated pills or vaccines).

2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.

Strategies

3. Generic competition is the most efficient method of facilitating affordable access to medicines in resource-limited countries. Legal barriers to generic production of these products for use in resource-limited countries should therefore be removed. In the cases of biologic compounds or other drugs where generic provision is forecast to be technically or economically infeasible, “at-cost” or other provisioning requirements should be used as a supplement to generic provisioning terms but should never replace those terms.

4. Proactive licensing provisions are essential to ensure that follow-on patents and data exclusivity cannot be used to block generic production. Other barriers may need to be addressed for the licensing of biologics.

5. University technology transfer programs should facilitate future innovation by patenting only when truly necessary to promote commercialization, utilizing non-exclusive licensing, creating streamlined processes for materials transfer, and reserving broad rights to use licensed technology in future research.

A global access licensing policy should be systematic in its approach, sufficiently transparent to verify its effectiveness, and based on explicit metrics that measure the success of technology transfer by its impact on access and continued innovation.

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be required in all licenses:

1. Generic provision enlists competitive market forces to develop the most affordable, most efficient ways to get drugs to patients and providers. Generic companies sustainably supply

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including non-assert clauses, sublicensing agreements, patent pools, data waivers, and grantback provisions.[13]

At-cost or other access provisions are sometimes necessary, but they should never replace generic provisions.

At-cost provisions, which require the licensee to sell the licensed technology in resource-limited countries for no profit, may be necessary:

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, many biologics may require at-cost provisions.
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.

Additional barriers to access must be overcome for biologics.

While there is a clear paradigm for the production of small molecule generics, there are a number of

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products developed from upstream technologies, place taxes on downstream research that discourages commercialization and use of future technologies. Patenting also raises concerns about patent thickets, blockages that result when numerous patents on a product lead to bargaining breakdowns that can prevent downstream research and development from taking place. Exclusively held patents may also block useful follow-on innovation that can result in combination products that magnify the impact of a technology, or in products that are tailored to serve the needs of people in developing countries. Finally, the practices of patenting and licensing can have a negative impact on longstanding academic norms regarding the open, swift, and disinterested scientific exchange of knowledge.

To avoid these unnecessary barriers to innovation, universities should craft policies that allow for patenting only those inventions that would fail to be commercialized in absence of the patent incentive. For example, universities need not seek patents on research platforms, diagnostic tests, and other technologies that can be adapted for commercial use in a short period with little additional investment. Such patents hinder innovation while providing no social benefits beyond enrichment to the patent-holding institution. Where patents are acquired, such technologies should be licensed non-exclusively to encourage the broadest possible dissemination of university research. Universities should reserve rights to grant future researchers the right to work with products in order to make improvements and modify them for uses particular to developing countries. Finally, universities should work to foster the scientific exchange of knowledge by adopting streamlined processes for materials transfer and providing internal incentives for the exchange of knowledge among researchers.

Implementation requires effective governance: policies must be systematic, transparent, and utilize explicit access metrics

The dynamic nature of the technology transfer process means that no single set of mechanisms, policies, or commitments is likely to be sufficient to ensure the greatest possible access to university technologies in the long term. For this reason, universities must strive to continuously improve on existing licensing practices, evolving policies and practices in order to improve access to medicines for all people, regardless of income. Effective governance is essential to ensure the implementation of global access licensing policies and to help guide this evolution. Transparency and accountability are essential features to ensuring effective governance.

One way to ensure transparency and accountability is to make redacted licenses available through publication. Where such publication is not practicable, governance may be accomplished by committees that, like institutional review boards, have public stewardship and review responsibilities. Governance mechanisms should be accrt 2 is