POLICY

Implementing Socially Responsible Licensing for Global Health: Beyond Neglected Diseases

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Global health efforts require socially responsible licensing that permits wide-ranging access to inventions that address health challenges beyond the so-called neglected diseases. Our analysis suggests that universities that excel in global health innovation are less likely to have global-access licensing policies in place. This trend can slow access to new clinical products and diminish the ability of universities to address their public missions.

As recipients of national and regional public funds, universities have an ethical obligation to the publics they serve and a responsibility to comply with their self-declared mission statements. Their mission includes education of students, performance of research, and service to the wider community through the pursuit and dissemination of knowledge (*1*). However, national and regional governments increasingly perceive universities as engines for economic development (*2*) that are expected to commercialize research, contribute to local job creation, and serve as hubs for high-technology clusters (*3*). Concomitantly, public funding models for academic-industry partnerships encourage research in the service of industry or that addresses specific problems (*4*–*6*) and emphasize direct social and economic benefits as returns on research investments (*7*). Assisted by institutional technology transfer offices (TTOs), researchers actively pursue patents, license technologies, collaborate with industry, and create spin-off companies—activities that are the primary indicators of success for TTOs and, increasingly, for researchers as well (*8*, *9*). In this Commentary, we move beyond decrying the shift to commercialization and translational science in the mandates of funding agencies and research institutions. Instead, we pose two questions: First, what might be done to harness these imperatives so that they incentivize innovation directed at important global issues beyond neglected diseases? Second, how might researchers and research institutions implement policies and guidelines on the management of research outputs, especially those generated with public funds, to reflect university mission statements, which continue to promote traditional goals of public good and social benefit?

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TRICKY TRANSFER

TTOs manage what is known as the triple helix model of research, involving government, universities, and industry (*10*–*12*). The model brings costs and benefits. It results in increased funding and infrastructure for university researchers beyond what is available from purely public sources. It enhances the ability of university researchers to leverage public funds in order to address questions of importance to industry. However, the corollary is a narrowing of research agendas because of the focus on immediate needs and problems from specific stakeholders.

Although this model attracts substantial criticism, it would be a mistake to overlook how valuable it is when pathways are developed to translate research into practical application. Indeed, there is considerable merit in applied research—in focusing the world's brightest minds on solving the most pressing problems, such as finding and developing clean energy sources, tackling noncommunicable diseases, and implementing innovative methods to address issues of food security. Unfortunately, depending on the source of funding, expectation of a return on research investment may be overly focused at the national or regional level (*3*, *7*). This focus belies the global nature of the greatest challenges facing humanity and acts as a disincentive for critical research for which there are no clear economic gains (*13*)—such as devising public health interventions for tobacco control or injury prevention—and may hinder universities from fulfilling their traditional mandate: to serve the public interest.

To this end, we advocate for global-access policies that promote an increased awareness and use of socially responsible licensing (SRL), which is the practice of licensing products in a way that is considerate to global needs. It promotes access to innovation for those who need it, whether for health, broadly defined, or further research and innovation (*14*).

Although private universities may have greater latitude to consider global needs as part of their missions, we argue that it is short-sighted for regional (state/provincial) universities to ignore an increasingly globalized world, in which the economic power and population demographics are moving to emerging economies and the developing world. Thinking globally has a number of benefits: It supports research partnerships with global funders, such as the Li Ka-Shing and Bill and Melinda Gates Foundations; it enhances the reputations of universities, most of which actively recruit international students; it addresses innovative challenges that confront developed and developing countries alike; and it opens markets for innovation in regions with growing economies and populations. Beyond self-interest, researchers at public and private universities receive funding from a range of sources, including national funders, philanthropic sources, and industry. These funders commonly attach values and obligations to research that do not perfectly align with, and indeed broaden, localized mandates.

Nevertheless, pitfalls may arise when universities traverse the split goals of public good and commercialization in a global context. The Yale University–Bristol Meyers Squibb (BMS) controversy that took place starting in 2001 illustrates this conundrum (*15*). Two researchers from Yale discovered a compound that was effective against HIV/AIDS in the late 1980s, and the university filed for and received a patent shortly afterward. Yale gave to BMS, which had sponsored the research, an exclusive license to file foreign patents related to its antiretroviral compound. BMS filed patents in developed countries but also in South Africa. The discovered compound became part of the crucial and life-saving triple antiretroviral treatment for AIDS sufferers, which was unaffordable to the majority of South Africans, where the disease was rampant at the time. Public pressure and protests eventually drove Yale to reconsider its licensing policy, which nongovernmental organizations pointed out did not align with the uni-

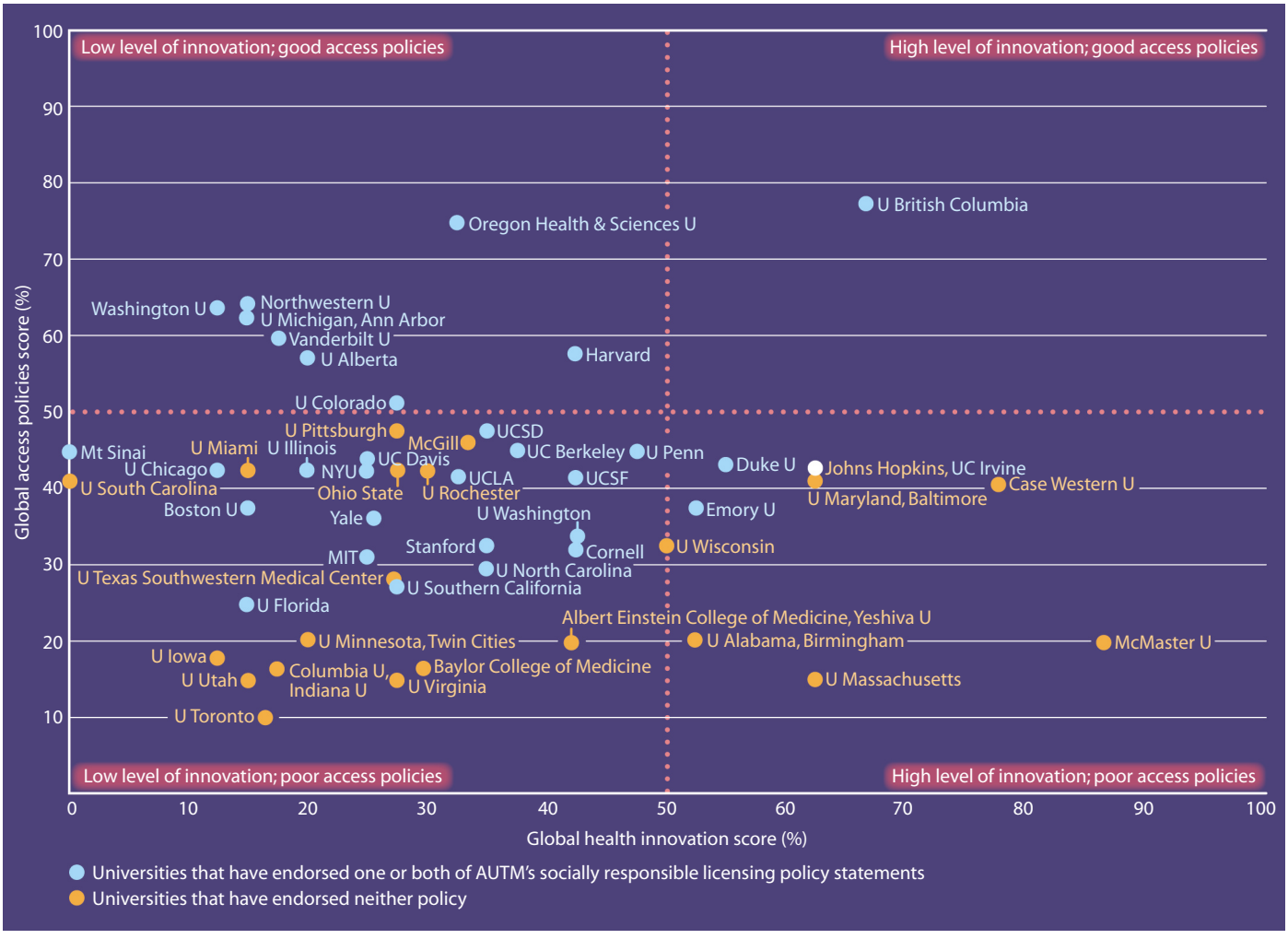

Fig. 1. Good grades. Global access policies (on a scale from 0 to 100%) versus global health innovations, with a focus on neglected diseases (on a scale from 0 to 100%), is shown for 54 North American universities. Data were compiled from (*16*, *17*, *21*).

versity's own mission statement (*15*).

The key problem, however, did not arise from the seeking of patents, which are simply legal instruments that vest in the owner control over the invention. Indeed, patents may be desirable as a defense mechanism if guidelines are in place for licensing practices that promote the core mission of universities. Instead, issues arose from the management of that intellectual property (IP), which may be solved through greater awareness of SRL.

SRL is encouraged by the Association of University Technology Managers (AUTM), which recommends TTOs to ensure that licensing agreements account for neglected individuals or communities, particularly with respect to medical and agricultural innovations (*16*). AUTM encourages TTOs to promote policies for the equitable dissemination of medical technologies, to prevent IP from becoming an obstacle to access in developing countries and to support research and development into neglected diseases (*17*). Similarly, the Bill and Melinda Gates Foundation requires projects to have predefined global access strategies in place, based on SRL, to achieve the goal of developing essential medicines for the developing world (*18*).

In practice, SRL includes sets of terms that promote access to innovation (Fig. 1). Such terms may include nonexclusive licensing of technologies with differential access or pricing for developing countries; a liberal reservation of rights for further noncommercial research by the originating university or all research institutions; and the return of benefits (not necessarily monetary) to countries that contribute resources or expertise to the research (*16*, *19*). The latter concept is most forcefully captured under the "access and benefit-sharing for genetic resources" provisions in the *Convention on Biological Diversity* (*20*) and the accompanying *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity* (*19*), which came into force in October 2014.

GLOBAL ACCESS REPORT CARD

In response to calls for universities to improve their global access policies and practices, Universities Allied for Essential Medicines (UAEM), a student-led group that arose in response to the Yale-BMS controversy, issued a report in April 2013 that assessed the global health impact of 54 top-funded North American universities (*21*, *22*). The report evaluated (i) investment in global-health innovations with a focus on

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Table 1. Policies and practices that promote global access

SRL

- License nonexclusively
- Use terms that limit geographic area or field of use so that technologies may be licensed differentially in developed and developing countries
- Require licensees to further develop products or technologies for developing countries
- Require licensees (exclusive or nonexclusive) to provide differential access or pricing for developing countries
- Ensure licenses include a liberal reservation of rights for further noncommercial research by the originating university or all research institutions
- Include Access and Benefit Sharing terms as appropriate.

Research contracts and IP management

- Promote innovation through nonenforcement of patents against other universities
- Ensure the return of benefits (not necessarily monetary) to research partners in developing countries that participated in research and/or contributed resources or expertise to research
- Ensure that research contracts include mechanisms to build research capacity in developing country institutions
- Develop and adopt commercialization metrics that capture the social, cultural, and institutional value of research and development.

Data sources: (*2*, *13*, *15*, *16*, *19*)

neglected diseases, (ii) whether policies were in place to ensure discoveries had global reach, and (iii) the level of emphasis placed on empowering and educating future global health leaders (*21*). The report included the 60 universities that received top levels of funding in 2011 from the U.S. National Institutes of Health (NIH) and the Canadian Institutes of Health Research (CIHR). UAEM's analyses of these three outcome measures were based on (i) publicly available sources, such as university Web sites and online databases, and (ii) a standardized survey that was sent to all institutions (*21*). The quantitative measures included in the report were normalized to account for funding, and predefined categories were used to uniformly evaluate the institutions (a detailed description of the UAEM methodology is available at http://globalhealthgrades.org/methodology).

There are clear limitations to UAEM's report and methodology. For instance, Wirtz *et al.* note that the report "seeks to measure the extent to which universities are licensing health technologies developed through research grants to encourage practical application of results. Yet it does not present information on the number of licensing opportunities related to medicines (whether or not they are related to neglected diseases). If a university does not have a research center on health technologies for neglected or any other diseases, we should not conclude that it has no commitment to global health" (*23*). This concern is somewhat overstated, as an inclusion criterion was the most highly funded research institutions by national health funding agencies, NIH and CIHR; however, some of these institutions may not have strong global health programs, which would have an impact on their position in the UAEM ratings. Further, there is indeed a lack of detail on licensing opportunities, a statistic that is almost impossible to compile from TTOs. This bottleneck points to the need for greater transparency and accountability for TTOs in the licensing of technologies developed with public funds.

Despite its limitations, however, there are several interesting observations to be gained from the report. Although several universities scored well in one category, the University of British Columbia (UBC) was the only institution to receive an overall grade in the A range. Only three universities—Vanderbilt, Harvard, and Northwestern—received an A in more than one category. Not immediately apparent from the report, however, is that universities that excel in the area of global health innovation are less likely to have global-access policies in place, and vice versa (Fig. 1). With the exception of UBC, the most innovative universities scored poorly on access (*21*). This observation suggests that although most of the 54 universities publicly endorse AUTM's global-access policies premised on SRL, endorsement has not necessarily equated to improved access (Fig. 1). This pattern is troubling and indicates the need for further research to assess the relationship between innovation, global access, and SRL in universities.

In addition, UAEM's, and AUTM's policies have been criticized as overly focused on neglected diseases, even though it is now recognized that global health is a much broader concept (*23*, *24*). We agree with Wirtz *et al.* (*23*) that "Global health, as proposed by the Consortium of Universities for Global Health Executive Board, is much broader than the topic of the survey, which focuses on innovation for, and technology licensing of, medicines to treat neglected diseases" (*23*). Indeed, it is clear that beyond infectious diseases, global health innovation focuses on noncommunicable diseases, injuries, maternal health, the amelioration of health inequities, improved health systems, and the social determinants of health. Thus, global health solutions stem beyond the fields of medicine and public health to include the environment, education, agriculture, water, energy, and animal health. All of these fields should be considered when adopting and implementing SRL policies.

PUTTING POLICIES IN PLACE

This conclusion suggests that universities and researchers should make a stronger case to governments that global access policies and SRL practices are consistent with their core mandates. SRL enhances opportunities for the translation of publicly funded research. Beyond meeting an ethical imperative to reduce health inequities, there is also evidence that SRL may open opportunities for global partnerships and nontraditional funding sources. The experience of UBC suggests that, in the words of one of its TTO officers, "no company has walked away from a potential deal with UBC because of the global access principles it adopted" (*25*).

Adopting global-access policies (Table 1), however, requires TTOs to become versed in SRL practices and more assertive with industry partners. This may be accomplished through greater cross-institutional learning about SRL negotiations and deals, accompanied by metrics that capture SRL practices for both TTOs and the innovators they serve. The University of California, Berkeley (UCB) was one of the first universities to adopt an SRL program (in 2003) through which UCB partners with industry, start-up companies, and not-for-profit

agencies for research and development into technologies that lack traditional profit motivations (*26*). UCB's TTO Web site provides SRL guidance and model clauses as well as descriptions of projects in a wide range of areas, including traditional neglected diseases—malaria therapies, tuberculosis drug targets, diagnostics for dengue fever and other infectious diseases, and new antiviral compounds—but also broader applications in agriculture (protein-enhanced sorghum and pesticide-free crops) and sanitation (water purification filters).

Implementation of SRL also requires the development of better metrics for the social, cultural, and institutional value of university research, such as those developed and deployed at UBC, which assesses all of its licenses on a scale from negligible to outstanding for academic and social benefit and economic, financial, and political impact (*2*, *27*). It is time for universities to move beyond the mere adoption of global access policies to their implementation, combined with strategies for evaluation of impact.

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