Global Health and University Patents

Universities have long been important in the development of life-saving medicines and technologies, and they once considered patenting to be antithetical to academic science and public health. Now a fierce debate rages about whether and when patents promote innovation, but in practice, the patenting worm has turned: Seeking revenues and ways to commercialize their inventions, U.S. universities are taking out patents in unprecedented numbers. In 2001, they were granted more than 3000 of them.

But patents bring more than revenues. They also bring controversy, when they ensure power over commodities that are the very currency of life itself. Today, universities hold important patents on many life-saving drugs, including the antiretroviral drugs stavudine (Yale University), abacavir (University of Minnesota), lamivudine (Emory University), and enfuvirtide (Duke University). As the AIDS pandemic has demonstrated, patents and exclusive licenses typically drive prices up and thereby impede access to life-saving medications. Low prices alone cannot solve the global crisis in access to medicines, but they are necessary, particularly for those in low- and middle-income (LMI) countries, where governments have limited resources and people often pay for part or all of their health care.

We have seen firsthand the effects of university patenting and licensing decisions. In February 2001, Doctors Without Borders sought Yale’s permission to use a generic version of stavudine in South Africa. This prompted global attention and intense discussions between the university and Bristol-Myers Squibb (to whom it had exclusively licensed the drug). The result was the first patent concession on an AIDS drug and a 30-fold reduction in the price of the patented drug in South Africa. This action was taken without negative consequences to the university, financial or otherwise. Recently, a local company began selling generic stavudine in South Africa at up to 40% less than the reduced patented price.

A group of experts recently convened at Yale concluded that universities can improve and save lives by working collectively to adopt access-friendly intellectual property (IP) policies (see Access to Essential Medicines and University Research: Building Best Practices at http://cira.med.yale.edu). This will require developing specific licensing and patenting strategies that are applicable to LMI countries. Such strategies must be tailored to the technology and partner, but broadly speaking, they fall into two categories. First, universities could not patent their discoveries in LMI countries. This will promote generic competition as long as all the IP necessary to produce a generic version of a product stays in the public domain and no patent barriers exist in important source countries for generics (such as Brazil, India, and Thailand). Today, universities rarely patent in most developing countries because of the expense, but some will do so if a licensee requests it or if there is a market or potential generic competitor in the country. If universities already hold patents in LMI countries or want them for leverage (for example, over companies who might take out improvement patents), they can still promote competition by granting nonexclusive licenses to these patents. Second—and regardless of where they hold patents—universities should negotiate clauses in their licensing agreements that require the resulting products to be made available in LMI countries quickly, in sufficient quantities, and at an appropriate cost.

Such actions should not hurt universities’ bottom line, diminish their ability to strike licensing deals, or discourage innovation for one simple reason: There is very little profit at stake. For 2002, Africa was projected to make up a mere 1.3% and Southeast Asia, China, and the Indian subcontinent only 6.7% of the world pharmaceutical market. These markets are too small to significantly influence revenues or, unfortunately, innovation. Universities can, however, seek creative ways to bridge the innovation gap; for example, by licensing compounds that may be useful against neglected diseases to new, nonprofit, drug development initiatives. A few have already done so.

Issues of access and IP will be with us for years to come. Some progress has been made in the past few years at the World Trade Organization and by governments, but this provides little comfort when so many people still lack essential medicines. Where lives and health are at stake, universities should not pass the buck. University research is intended to advance the common public good. It is time that it consistently do so globally, as well as locally.

Amy Kapczynski, E. Tyler Crone, Michael Merson

Center for Interdisciplinary Research on AIDS, Yale University, New Haven, CT.