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EXPERT OPINION

Should academic therapeutic patents go to the highest bidder?

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Universities conduct biomedical research with the self-stated goal of disseminating the benefits to the global public. Licensing therapeutic patents to the highest bidder is counterproductive to this aim, as it prioritizes income maximization over dissemination. We believe that licensing strategies focused on promoting broad access to university-discovered therapeutics better serve both the mission of universities and the public good.

Keywords: access to medicine, biomedical research, technology transfer, university licensing

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1. Does licensing academic therapeutic patents to the highest bidder serve the goals of university research?

Universities play a central role in advancing biomedical innovation [1,2] and receive substantial public funding to support their research activities. They have an attendant responsibility to ensure that their innovations are deployed for maximum public health benefit. Academic leaders endorse this view, as expressed in this recent statement from the Association of American Universities:

"The academy has a responsibility to ensure the broadest possible access to the fruits of its work by publics both local and global. Faculty research and scholarship represent invaluable intellectual capital, but the value of that capital lies in its effective dissemination… Dissemination strategies that restrict access are fundamentally at odds with the dissemination imperative inherent in the university mission" [3].

Access is particularly crucial for medical technologies, which can dramatically impact morbidity and mortality in populations worldwide. To determine whether academic therapeutic patents should be licensed to the highest bidder, we must, therefore, examine whether this model promotes broad dissemination of university innovations to patients in need.

The highest-bidder model of university technology transfer gained international dominance after the U.S. Bayh-Dole Act of 1980, which authorized American universities to patent and exclusively license federally funded innovations for revenue. It was assumed that this financial incentive would increase commercialization of academic technologies, and in turn increase the public's access to the fruits of university innovation.

In practice, unfortunately, the Bayh-Dole model does not promote broad public access. On the contrary, making revenue maximization the primary goal of university licensing has disincentivized consideration of dissemination or affordability when licensing technologies. Universities seek to license to the highest bidder regardless of how that licensee plans to disseminate the final product.

This is a serious concern for university-discovered therapeutics, as exclusive licensing enables commercial developers to sell end products at monopoly prices far out of reach for most of the global public (**Table 1**). Bayh-Dole offers no incentive for universities to negotiate greater affordability or access to these technologies, especially if it would risk reduced licensing revenue. Some licensees do not even intend to develop a product: it was reported in Nature last year [4] that major universities were licensing to Intellectual Ventures, a 'patent aggregator' that earns

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Table 1. Market prices of selected university-discovered drugs.

Drug	Condition treated	Market price (USD)	University	Licensee
Remicade	Rheumatoid arthritis	$20,000 per patient per year	Columbia University and Stanford University	Jassen Biotech
Fuzeon	HIV salvage therapy	$26,000 per patient per year	Duke University	Roche
Gleevec	CML, ALL, myelodysplastic disorders	$75,000 per patient per year	Oregon Health & Science University	Novartis
Sofosbuvir	Hepatitis C	$80,000 per course of treatment	Emory University	Gilead Sciences
Yervoy	Melanoma, prostate cancer, lung cancer	$120,000 per course of treatment	University of California San Francisco	Bristol Myers Squibb

ALL: Acute lymphoblastic leukemia; CML: Chronic myelogenous leukemia.

income primarily by pursuing patent infringement litigation against others rather than developing patents itself.

In other cases, pursuit of maximum licensing revenue actually drives universities to seek reduced dissemination. When the high price of the BRCA1 and 2 diagnostics led to a challenge of human gene patents before the U.S. Supreme Court, academic institutions receiving licensing income from such patents filed amicus briefs supporting continued monopolies on genes [5]. In another high-profile legal case, Princeton University joined Eli Lilly in pursuing patent infringement claims against generic companies seeking to develop lower-priced versions of a Princeton-licensed cancer drug [6].

Revenue-focused licensing may also deter dissemination of research within the academy. A 2002 study in JAMA [7] found that one in four university geneticists and life scientists reported denying requests for post-publication data or materials due to requirements by industry sponsors. Researchers who withheld their own research were also more likely to report being denied research results by others [8].

Finally, a highest-bidder licensing system contributes to a research culture driven by income potential and private-sector interests rather than medical need – further impeding the public mission of universities. The government of India recently cautioned that 'over-emphasis on IP [intellectual property] may…deviate the focus of the Universities from basic research and teaching to that of meeting the commercial needs of the industry' [9]. Indeed, an analysis by Universities Allied for Essential Medicines found that in 2010, the majority of America's top 50 research universities devoted < 2% of their research budgets to diseases that primarily affect populations too poor to offer a lucrative return on private sector R&D investment [10]. While other factors certainly drive this disparity, especially high-income government and donor funding priorities, an academy focused on licensing technologies for maximum income has further incentive to neglect the research needs of the global poor.

Given all of the above, it is difficult to argue that a 'highest-bidder' approach to therapeutic licensing effectively achieves the academy's goal of disseminating research for global public benefit. Still, many academic leaders argue that reduced dissemination is a price that must be paid for continued innovation. Without the financial incentive of revenue-driven licensing, they contend that university innovations would not be transferred for development into publicly available products at all, and universities would be less likely to pursue future innovation [11].

Current evidence casts doubt on these claims. The argument that income from intellectual property monopolies is necessary to recoup R&D costs and invest in further innovation may apply in the private sector, but the vast majority of academic research is funded by grants and similar 'up-front' funding not reliant on IP. Licensing revenue actually accounted for < 5% of total funding for academic research in 2006 [12]. A 2013 Brookings Institution study further found that most universities do not gain any net income from licensing, spending more on their technology transfer infrastructure than it brings in. The report concluded that '[t]he license-to-the-highest-bidder model has yielded high income for only a few universities,' with such revenue coming not from a steady stream of licenses but a handful of 'blockbuster' patents.

Furthermore, while patenting of public research increased dramatically following Bayh-Dole, it is difficult to correlate this spike with an increase in innovative products coming to market. An analysis of post-1980 patenting and licensing practices by universities found that the main effect of Bayh-Dole has been to expand the university pool of inventions for which patents were obtained and licensees sought; this actually resulted in a reduction in the average yield of marketed inventions by increasing the denominator without significantly increasing the numerator [13]. Studies also indicate that many university innovations – particularly platform technologies – could have been effectively disseminated through nonexclusive means, by being placed in the public domain or licensed nonexclusively [12]. The cotransformation method claimed by Columbia University's Axel patents, for example, became widely used before the patents were even granted [14]. While drug licensing presents additional complexities, universities can still employ strategies to prioritize dissemination and facilitate broader access, as discussed below.

2. Expert opinion

We enthusiastically support the development and dissemination of university technologies – we want academic medical innovations to reach all who might benefit from them. The evidence above demonstrates, however, that a highest-bidder model is not sufficient and often counterproductive to this goal, particularly when it comes to patients and health systems that lack the resources to pay the high end-product prices that exclusive licensing typically yields. Patented academic innovations will reach these populations only if universities adopt licensing strategies that directly promote affordable dissemination, rather than assuming that it will be a secondary benefit of licensing for income.

One such strategy is 'Global Access Licensing' [15]. In this system, universities require licensees to allow affordably priced generic production of end products for low- and middle-income countries in exchange for exclusive patent rights in high-income markets. This can substantially expand access to university-discovered medicines for the global poor with negligible revenue impact, as approximately 90% of pharmaceutical industry income comes from high-income countries, and 98% from outside the lowest-income regions [16]. Nearly 50 universities worldwide have adopted this approach. They report successfully including global access provisions in licenses with no drop in licensing volume or revenue.

As noted above, many university innovations have been successfully licensed on a nonexclusive basis, and we advocate incentivizing such licensing as the 'default' approach, particularly for publicly funded research. Licensees could, for example, be required to demonstrate that exclusivity would increase the prospects of development or dissemination.

More comprehensively, universities should work with actors across all stages and sectors of therapeutic development to pioneer R&D models that do not depend on IP monopolies to recoup costs, particularly where research is neglected or pricing is a serious concern. India's Open Source Drug Discovery project and the international Drugs for Neglected Diseases initiative both aim to produce innovative and immediately affordable medicines through open-source collaboration with academic researchers. The World Health Organization is testing similar approaches. Greater public-sector support for late-stage R&D processes – particularly clinical trials – could also help reduce dependence on IP, as these are actually the most expensive part of the therapeutic development pipeline.

While some of these proposals will take time to fully develop, universities can act immediately to adopt innovative licensing strategies that prioritize global access over revenue. This will ensure that current therapeutic innovations reach the patients in greatest need, dramatically increasing the global health impact of academic research.

Declaration of interest

B Collinsworth is employed by Universities Allied for Essential Medicines, an organization that engages in policy and advocacy activities related to the subject matter but has no financial interest in academic patenting or licensing; SE Crager has no known conflict of interest associated with this publication. There has been no significant financial support for this work that could have influenced its content. The manuscript has been read and approved by all named authors.

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