LICENSE FOR DISCOVERY

Exploring the commercialization of university inventions.

BY DANIEL W. SHARP AND DAVID J. PALMER

A noisy and high-stakes patent fight between universities over a path-breaking gene-editing technology known as CRISPR-Cas9 has reignited a debate over whether universities should really be in the business of patenting inventions that come from their research. CRISPR-Cas9 promises inexpensive and accurate editing of the human genome. Following its discovery, a major dispute arose between the University of California, Berkeley and the Broad Institute over the institutions' entitlement to patent claims covering the use of the technology in eukaryotic cells. The ultimate resolution of the case will determine how much of the substantial royalties expected from licensing the invention will flow back to these institutions and their inventors.

The ability of universities to patent and license inventions made on campus was greatly enhanced by the 1980 passage of the Bayh-Dole Act, which allows universities to patent inventions made in the course of federally funded research and to license those patents to private industry. Bayh-Dole has allowed universities to capture a small percentage of the profits generated from commercially marketing university-developed inventions, rather than allowing private industry to capture all the value. Significant returns to educational institutions have been used to support additional research or other university expenditures.

Opponents of universities' involvement in patent licensing see the CRISPR litigation as a demonstration of the pitfalls of Bayh-Dole and an illustration of why they think universities should be kept out of the patent business. They argue that potential profits from university inventions inhibit the free sharing of scientific discoveries that push knowledge forward and introduce incentives that can distort and corrupt scientific research. They believe the mission of universities and the cause of scientific and technological advancement would be better served if the institutions simply allowed the products of their research to be available for any private entity to use or sell, without restriction or royalty obligation.

For the University of Texas at Austin, licensing rights to inventions developed during university research has brought tremendous benefits back to the university and to the public at large. Opponents of university patenting may overlook that in some industries, the research and development time necessary to bring products to market is so lengthy, expensive, and uncertain without patents allowing for the ability to exclusively profit from resulting products, no firm would invest in the research and few products would ever be brought to market. This is true for many pharmaceuticals and other life sciences discoveries, such as products that must be put through clinical trials for approval by the Food and Drug Administration or products with particularly small target markets. By filing patent applications before these discoveries are made public, universities can preserve potential exclusivity as an incentive for private firms to invest in the long process of commercialization once it becomes apparent that an invention has commercial promise.

UT-Austin has seen valuable inventions commercialized that would not likely have attracted investment were the inventions not patent-protected. For example, more than 10 years ago, researchers at the university developed an antibody that binds to a component of the anthrax toxin. The antibody neutralizes the toxin's activity, greatly mitigating the tissue damage that can result from an anthrax infection. Although infections are not common, anthrax spores can be used as a biological weapon, as we saw in 2001, and society certainly benefits from having an antibody stockpiled and readily available. UT-Austin officials licensed the patented antibody to Elusys Therapeutics, which, with exclusive access to the technology, was willing to invest what was necessary to bring the product (now called Anthim) through the lengthy FDA approval process. The antibody was approved in 2016.

As another example, UT-Austin associate professor Jennifer Maynard, who helped create Anthim, has also developed a vaccine and therapeutic antibody for pertussis (commonly known as whooping cough) that can be administered to infants. Previous vaccines could not be administered before a child is about four months old, and as a result, the World Health Organization estimates that about 300,000 primarily unvaccinated infants die of pertussis each year. UT-Austin was able to obtain patent coverage for a new treatment that could serve as both a vaccine and therapy for vulnerable populations. The intellectual property covering the new therapy is licensed to Synthetic Biologics, which, with the promise of exclusivity and a grant from the Bill & Melinda Gates Foundation, is investing in the clinical trials necessary to bring it to market.

In addition, Christine E. Schmidt and other researchers at UT-Austin helped develop technology used in nerve grafts to enhance the regeneration of nerve tissue. The university licensed that intellectual property to AxoGen in order to secure necessary investment. As a result, the technology has now been translated nearly all the way from the lab to clinical practice.

No doubt there are inventions that arise from university research that would attract the investment necessary for commercialization even without patents offering exclusive rights to the technology. In such cases, the public still benefits from universities protecting the inventions with patents and licensing them to commercial partners by bringing money back into university labs to support additional research, which can lead to further discoveries.

UT-Austin professor Adam Heller's research into the "electrical wiring" of enzymes formed the technological basis of the first blood glucose monitor that used blood samples so small that they could be painlessly obtained. The product, called FreeStyle, was commercialized through the company TheraSense, which was co-founded by Heller and eventually sold to Abbott Laboratories. The university benefited greatly from royalties received from commercializing the intellectual property created by Heller, and his continued research at UT-Austin has more recently led to the development of the FreeStyle Libre, a new technology for continuous blood glucose monitoring that does not require any blood samples at all.

UT-Austin professor John Goodenough's research led to the invention of the lithium-ion rechargeable battery. That technology has been of enormous benefit to society, as lithium-ion batteries are nearly ubiquitous in everything from consumer electronics to electric vehicles. More recently, Goodenough and his collaborator Maria Helena Braga have continued to push the envelope on battery technology, reporting significant improvements in battery capacity and stability using a solid electrolyte material. Their new discovery is attracting great commercial interest and the university hopes to bring in significant additional research support as a result of licensing the technology to industry.

Royalties received from patent licensing at UT-Austin are typically shared between the university and the inventors, which may help keep productive researchers who work on lucrative technologies inside universities, where their research is promptly disclosed to the public. If university inventors of valuable inventions like CRISPR-Cas9 could not share in the profits from commercializing those technologies, it might become much more attractive for such researchers to work instead in the private sector, where such profit-sharing may be available but where the scientists' advancements may well be kept secret for a period of time in order to maintain the employer's competitive advantage.

In some cases, money UT-Austin receives from patent licenses is earmarked for specific sponsored research. As an example, researchers in the Department of Petroleum and Geosystems Engineering developed surfactants and methods to use them to capture unrecovered oil from existing reservoirs. The university licensed patents covering these inventions to a major oil company and in exchange has received millions of dollars of direct research support for the department. The university has also been able to obtain substantial research support through commercializing technology for using lithography in semiconductor fabrication through a startup called Molecular Imprints. As a result of licensing the university-owned patents to that company, the university was able to establish the Nanomanufacturing Systems for Mobile Computing and Mobile Energy Technologies research center to allow university researchers to continue to pursue advancements in semiconductor manufacturing technologies. The university has also received targeted research support from patent licenses for a variety of other technologies, including a promising enzyme for rare disease and cancer treatment that served as the technical foundation for a startup, Aeglea BioTherapeutics, which went public not long ago.

Many of the inventions made at UT-Austin would not likely have been commercialized had there been no patents through which a commercial partner could be offered exclusive rights to products it could develop out of the research. And the university and society as a whole have benefited from the additional research funding that has flowed back into the university's labs as consideration for many of its licenses. At UT-Austin, the prospects for enabling new products to be developed based on licensing university patents and bringing funds back into the labs to support future research look brighter than ever. **TBJ**

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