POLICY FORUM

INTELLECTUAL PROPERTY RIGHTS

Public Sector Collaboration for Agricultural IP Management

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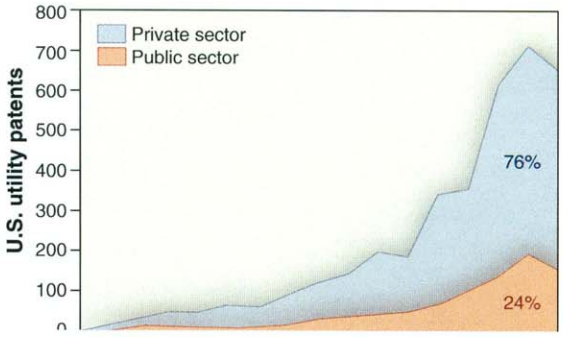
The impact of public-sector research is evident in many technology sectors, and this is particularly true in agriculture. Dating back to the establishment of the Land Grant College system in 1862, universities and other public-sector institutions have been the leaders in developing improved crop varieties that were transferred to farms and to the agricultural industry through cooperative extension services in the United States or equivalent organizations internationally. However, this model is changing rapidly because of increased intellectual property (IP) protection of agricultural inventions, as well as the development of a research-intensive private sector that is making notable contributions to enhancing the productivity of U.S. agriculture. The private sector logically focuses on crops such as corn and soybeans where markets are large, which leaves the development of small specialty crops for the United States and subsistence crops important to the developing world mostly in the hands of the public sector.

In the past 25 years, fundamental changes in the nature and ownership of innovations in basic and applied agricultural research have complicated the mission of our public research institutions. As the importance of biotechnology in biological research increased, the possibility of patenting and licensing biotechnology expanded through changes in the legal and policy framework. The Supreme Court decided in 1980, in *Diamond* vs. *Chakrabarty*, that living, human-made microorganisms can be patented. Also in 1980, the Bayh-Dole Act was passed to encourage U.S. universities to patent their innovations and to license them to private-sector companies in order to encourage their commercial use (*1*). Since that time, formal mechanisms for transfer of public research results to the private sector for further development have accelerated, and there has been a marked increase in the number of public-sector patents and the licensing of technology to the private sector.



Annual grants of U.S. utility patents in the area of plant biotechnologies.

Agricultural technologies pose a particular challenge for university technology transfer programs in balancing the objectives of technology commercialization with humanitarian purposes or for applications to specialty crops. Some offices have addressed these challenges by instituting licensing practices that foster commercialization while preserving rights for philanthropic purposes or by working to keep certain technologies in the public domain (*2*). Similarly, the U.S. Department of Agriculture continues its policy of making technologies broadly available (*3*). However, these practices are not universally applied across institutions, with the net result that, although many significant discoveries and technologies have been generated with public funding, these discoveries are no longer accessible as "public goods."

Our institutions have found that the public research sector finds itself increasingly restricted when wishing to develop new crops with the technologies it has itself invented, including so-called "enabling technologies"—the research tools necessary for further experimentation and innovation. In agricultural research, applied research and genetic improvement of crops are derivative processes based on pre-existing plant material, and each incremental improvement now brings with it a number of IP and germplasm constraints that have accumulated in the plant material. When IP rights for agricultural materials and technologies are held by multiple public- and private-sector owners, this fragmentation produces situations where no single institution can provide a commercial partner with a complete set of IP rights to ensure freedom to operate (FTO) with a particular technology (*4*). Along with major commercialization problems associated with public acceptance and regulatory approval, limited or conditional access to a wide range of patented technologies has been identified as a significant barrier to the applications of biotechnology in the development of new crops. This is particularly true for subsistence and specialty crops, the historically important work of public-sector research (*5*, *6*). A prominent example of the complexity resulting from fragmented technology ownership is "GoldenRice" (pro–vitamin A rice) in which more than 40 patents or contractual obligations associated with material transfer agreements represented potential constraints for commercial development (*7*).

Large agricultural biotechnology companies have assembled the IP assets needed to develop new crop products by investing in targeted research, by licensing important technologies, and by a series of strategic mergers and acquisitions. Several companies have effectively used these proprietary technology platforms to develop new varieties of major crops that enhance farm productivity and to reduce environmental impacts both in the United States and internationally (*8*, *9*). Meanwhile, work on crops of less commercial interest has progressed slowly. Therefore, we, as leaders of our in-

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stitutions, are now collectively asking whether institutions such as ours can do a better job in fulfilling our mission in support of agriculture in the United States and developing countries.

One of our institutions conducted research to evaluate the structure of IP ownership in the area of agricultural biotechnology (*10*). This study found that roughly one-fourth of the patented inventions were made by public-sector researchers (see the figure), which is substantially larger than the IP portfolio held by any single agricultural biotechnology company. It is, however, highly fragmented across institutions and across technology categories. And much of this IP has been licensed, often under terms that are confidential but which have likely resulted in greatly restricted access to the underlying technologies.

This study suggested that, apart from a few important exceptions, public-sector scientists have invented many of the types of technologies that are necessary to conduct basic biological research and develop new transgenic plant varieties. For instance, they have developed technologies to transfer genes into plant cells, have characterized specific DNA elements that drive unique patterns of gene expression; and have identified many genes that confer important plant traits. Such discoveries underscore the fact that public-sector research institutions have been significant sources of technological innovation in agriculture. They also suggest that, in the future, end products can still be delivered with FTO for specific purposes. A number of strategies can be envisioned to enhance FTO with public-sector IP. Informed decisions regarding dissemination of new knowledge via open publication or protecting it with a patent are clearly important. While new technology is judiciously patented, FTO can be enhanced if public-sector institutions systematically retain rights to use their newest and best technologies for subsistence and specialty crop development when they issue commercial licenses. It will also require that they systematically make their current and future technologies known and available to each other. We believe a collective management regime would enable an effective assessment of FTO issues and could begin to overcome the fragmentation of public-sector IP rights and re-establish the necessary FTO in agricultural biotechnology for the public good, while at the same time improving private-sector interactions by more efficiently identifying collective commercial licensing opportunities.

To develop this strategy and to realize what we believe will be significant benefits both for U.S. agriculture and for the world's food security, we are establishing the Public-Sector Intellectual Property Resource for Agriculture (PIPRA). We have been aided by the Rockefeller and McKnight Foundations who also see the importance of PIPRA for furthering their goals of achieving food security for the poor and excluded of the world.

Although PIPRA is a public-sector initiative, we recognize that continuing and enhancing our good relationships with the private sector will also be a critical component of developing and implementing a successful collective strategy. We have the following near-term objectives:

A review of public-sector patenting and licensing practices. We will explore and clarify the implications of our IP patenting and licensing practices. We will seek "best practices" that will encourage the greatest commercial development of publicly funded research innovations while also retaining rights that public research institutions need to fulfill their mission of research for the broader public benefit.

A collective public IP asset database. There are several efforts under way to develop databases of patented agricultural technologies so that public-sector researchers can be informed about FTO obstacles at the initiation of their research. Two of the most useful are the databases under development at the U.S. Department of Agriculture's Economic Research Service and at the Center for Application of Molecular Biology to International Agriculture (CAMBIA), located in Australia (*11*). These efforts, although extremely valuable, lack important information about the most current licensing status of patented technologies. PIPRA will complement them by developing a common database that provides an overview of IP rights currently held by the public sector, including up-to-date information about licensing statuses.

Shared technology packages. PIPRA is exploring the possibility of pooling specific public-sector technologies, making technology "packages" available to member institutions and to the private sector for commercial licensing or, at the very least, for designated humanitarian or special use. Patent pools have been used effectively by companies to expedite the development and diffusion of innovations that draw on many technology building blocks with multiple patents. Although we recognize that public-sector institutions have little prior experience with patent pooling, a well-known exception is Columbia University, which participated with nine companies in the pool of patents for MPEG-2 digital video technology, PIPRA will explore the feasibility of assembling complementary sets of key agricultural technologies that might help public-sector researchers obtain FTO in crop biotechnology and significantly reduce the transaction costs now associated with negotiating the large number of licenses required to develop a new cultivar. PIPRA will also explore whether such packages might create additional opportunities to generate royalty income to support public-sector research by providing convenient one-stop-shopping for commercial licensing.

Moving Forward

This is a new initiative for us, but one that reflects—and means to continue—the long-standing research collaborations that have naturally existed among agricultural scientists (among others) across institutions, while recognizing that significant progress in biological research now requires locating and negotiating for the use of multiple tools with many different IP owners. More planning, thought, discussion, and participation are needed to make this collective effort work, and our hope is that each of you who reads this Forum will initiate discussions within your institutions about IP management. What is the balance between the positive effects of IP rights on your institutional mission and the limitations these rights place on your research and your ability to apply your discoveries for the greatest public benefit? Open up the question for discussion, and let us know what ideas are generated. PIPRA seeks wide participation to mobilize the full scientific capacity as well as the underlying IP for public-sector agricultural research. Several organizations are beginning to express their interest and support, including the Board for International Food and Agriculture Development (BIFAD), an advisory board on agricultural development priorities to the U.S. Agency for International Development that involves many public-sector research institutions (*12*). We urge public-sector research institutions that are interested in joining this effort to contact us (*13*).

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13. For more information about PIPRA, including contact information, visit www.pipra.org.

14. We thank D. Delmer of the Rockefeller Foundation, A. Bennett of the University of California, R. Cahoon of Cornell Research Foundation, and J. Clough of the Meridian Institute for assistance in preparing the draft of this article.