Intellectual property clearinghouses as an institutional response to the privatization of innovation in agriculture

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Abstract

Intellectual property clearinghouse organizations such as the Public Intellectual Property Resource for Agriculture (PIPRA, Davis, California, USA) and the African Agricultural Technology Foundation (AATF, Nairobi, Kenya) have been created to help agricultural researchers navigate access to agricultural technologies protected under intellectual property rights.

Introduction

For well over a hundred years, public-sector research programs at universities or government institutions around the world have been providing service of developing new crop varieties. Once developed, new crop varieties were typically released publicly; made available to seed companies, nurseries, and farmers without restrictions on use, whether for commercial agriculture or subsistence agriculture. In the last two decades however, the nature of crop variety innovation has changed dramatically in response to both the breakthroughs of biotechnology and legal innovations in the area of intellectual property (IP). While the United States has been at the lead in both respects, the resulting privatization of innovation in crop genetics has had global implications affecting and in fact constraining the technical options available to public sector crop development programs everywhere, including Africa.

Plant genetic engineering, pioneered in the 1980s, has led to new technical possibilities for altering the traits of crop plants in a controlled manner, but the technologies involved are very advanced and constantly evolving. Three distinct types of technologies emerged as essential to developing new biotech crops: genetic transformation techniques themselves, specific genes, and elite breeding materials or germplasm. The new paradigm of biotechnology introduced a technical ability to separate and recombine these three component technologies to create new crop varieties with new and powerful capabilities. Public sector researchers were often in the vanguard making the research breakthroughs that enabled plant genetic engineering.

In the United States in 1980 two landmark legal and legislative events occurred that would come to impact upon public sector agricultural research. First was the decision of the Supreme Court in *Diamond v. Chakrabarty* to allow the patenting of microorganisms that embodied man-made biotechnological inventions. The decision was extended in 1985 to cover plants, introducing new possibilities to exploit commercially the emerging recombinant DNA technology in agriculture by patenting a new biotech crop variety itself. Second was the passing by the U.S. Congress of the Bayh-Dole Act (Public Law 96-517, 1980) to allow and encourage universities in the U.S. to patent and license newly invented technologies to the private sector. This legislation led to institutional policy shifts at many universities and the establishment of technology transfer offices (Graff, Heiman, and Zilberman, 2003). Outside of the U.S., while patenting of crop varieties is not widely practiced by other governments, the combined influences of international agreements, including the Trade Related Intellectual Property Rights Agreement (TRIPs) agreement of the WTO, bilateral trade agreements, and the Union for the Protection of New Plant Varieties (UPOV), have led to general strengthening of the IP environment for all of the technologies essential to the development of biotech crops. More recently other countries have been adopting laws and regulations that, like the Bayh-Dole Act, allow and encourage their universities to patent inventions.

Following *Diamond v. Chakrabarty* and the Bayh-Dole Act in the U.S. and similar policies in other countries, university-developed technologies have been increasingly protected by intellectual property rights in accordance with the new policies. Agriculture has been one of the fields—along with medicine and engineering—to be most affected. Some fundamental tools used for plant genetic engineering have been licensed by the universities to companies in the private sector under exclusive terms. While this has encouraged and been accompanied by an increasing level of private sector investment in crop variety development, one result for public sector researchers, however, is that once a technology is patented and exclusively licensed it is no longer available for the development and public release of any new biotech varieties by university based developers (Wright, 1998).

It is true that use of patented technologies further upstream in the research activities of universities continues to be allowed in most countries under formal "research exemptions". In U.S. patent law, there is not a formal research exemption, and university researchers using patented materials are operating in something of a legal grey area, under a *de facto* research exemption arising from the fact that there is simply no precedent for companies to sue universities for patent infringement. This *de facto* exemption has been circumscribed and narrowed in a recent decision by the U.S. Supreme Court in *Madey v. Duke University*.

During the mid 1990s the seed industry in the U.S., and to a lesser extent in Europe and Latin America, saw the entry of many larger chemical and pharmaceutical companies attracted by the potential of selling genetically engineered crops in combination with or in place of agricultural chemicals, their core line of business. Large agrochemical firms eventually acquired most of the smaller R&D companies and all of the major seed companies in the U.S., significantly consolidating the agricultural inputs industry (Graff, Rausser, and Small, 2003). This development towards larger companies was driven, in part, by the difficulties and high transaction costs of licensing technologies, combined with the valuable synergy effects of integrating the different component technologies (including plant transformation tools, genes, and plant germplasm materials) needed to develop biotech crop varieties.

Agricultural research today is increasingly characterized by incremental improvements of the existing transformation tools, trait genetics, or plant materials, with each advance yielding new and increasingly overlapping IP rights. In the current environment a robust corporate patent portfolio that spans all three areas of technology not only allows an optimization of technical synergy effects, but in some cases merely provides "freedom to operate" (FTO) in the marketplace. Freedom to operate is defined as owning or otherwise having access to rights to use the full range of technologies embodied in a product, minimizing or eliminating the risk of infringing patents held by others. The mergers in industry have resulted in a handful of large firms that control most of the vital IP.

The public sector has been left in stewardship of a highly fragmented IP-portfolio and an ever diminishing public domain. Today, at least in the U.S., neither the public domain nor the patent portfolio of any single public sector institution can offer all of the necessary key technologies to enable the development or commercial sale of a new transgenic crop variety. The upshot is a situation in which public sector actors and small entrepreneurs are restricted, lacking access to the full set of IP necessary to bring new crops to market. One highly publicized example of this problem was the development of "Golden Rice" (pro-vitamin A) which was constrained by 70 different patents or contractual obligations associated with material transfer agreements (Kryder, Krattiger, and Kowalski, 2000).

Yet, considered as a whole, public sector organizations in 2001 owned a large proportion of the industry's technology (24% of all agricultural biotechnology patents), more than any single firm. (Monsanto at 14% was the largest.) It was reasoned that this 24 percent of the industry's patents should contain variants of all or most of the key technologies needed to enable the development of new transgenic crops. The difficulty lay in coordinating access to all of those different technologies. Actors in the public sector and others restricted by lack of access to IP could thus benefit from collaboration between universities and other public research institutions in the management of their collective IP to identify and bring together those technologies (Graff et al, 2003). This realization fueled the formation of PIPRA, the Public Intellectual Property Resource for Agriculture (Atkinson et al, 2003).

2. The formation of PIPRA as an intellectual property clearinghouse

PIPRA was established in 2004 as a coalition arising out of a dialogue among a dozen major universities and research institutes, with catalytic leadership and funding provided by the Rockefeller Foundation and the McKnight Foundation and expertly facilitated by the Meridian Institute. After a competitive review of proposals, the University of California, Davis was chosen as the host for PIPRA's headquarters. PIPRA currently has a staff of seven located at UC Davis. PIPRA can be found online at www.pipra.org.

The organization is growing quickly—now consisting of over 40 member institutions from eleven countries, including several of the leading international research institutes of the CGIAR. When joining PIPRA, a member institution signs a Memorandum of Understanding whereby the institution agrees to cooperate with the other members on a number of issues. First they agree to help develop guidelines or "best practices" for licensing to encourage product development across as wide a range of applications as possible for the broader public benefit, practices such as retaining rights for research use and humanitarian use of a licensed technology. They also agree to contribute non-confidential in-house information to a common database that provides an overview of what agricultural technologies across all PIPRA member institutions portfolios are available or unencumbered. Finally, in the MOU they agree simply to explore the possibility of bundling certain technologies to facilitate commercial and/or humanitarian uses. (A copy of the MOU is online at http://www.pipra.org/docs/Memorandum%20of%20Understanding.doc.)

The fundamental mission of PIPRA is to make agricultural biotechnologies more readily accessible for the development and distribution of subsistence crops for humanitarian purposes in the developing world and neglected commercial specialty crops everywhere in the world.

3. The services provided by PIPRA

To fulfill that mission PIPRA's efforts are roughly divided into four general platforms: Information and Analysis, Educational Services and Outreach, Biotechnology Resources, and Collaborative IP Management.

3.1 IP information and analysis

One of the long-term aims of PIPRA is to provide freedom to operate (FTO) for public sector research and commercialization activities within the key technologies of agricultural biotechnology. In the short term, the organization works to reduce uncertainty concerning the IP status of commonly used technologies, identifying where there may be FTO or how it might be achieved. This requires intensive study of the scope of existing IP claims and detailed comparison of what is available and what is not. Such analysis is routine in corporate patent divisions and law firms. It is not common in the public sector however. The rationale of PIPRA is to specialize in this work on behalf of the range of member institutions, undertaking the analysis of common tools of biotechnology, and making the resulting insights and recommendations known to the entire membership, and beyond.

The PIPRA patent database: PIPRA has launched a public database in collaboration with M-CAM, a company providing premier web-based products and services for patent data search and analysis. The PIPRA patent database contains the agricultural portion of the patent portfolio held by PIPRA member institutions and gives a clear picture of the availability of the technologies developed across the full set of PIPRA institutions. The database contains the patent text, patent status information (such as whether it is in application, in force, or expired), and licensing status (such as whether it is available for license, licensed exclusively, non-exclusively, all or some fields, and whether a sublicense is available). PIPRA has plans to expand this database to include entries on technologies which are (verifiably) in the public domain, in order to give a more complete overview of agricultural technologies that can be accessed and used.

Preliminary FTO research: PIPRA conducts preliminary searches of patent and non-patent art to support FTO analyses of important technologies, looking globally at the ownership situation. Identifying potentially relevant patents, mapping licensing information, and even making validity assessments are all part of this work. The end result is a set of reports containing recommendations for public sector researchers on how to proceed with research or commercialization activities, such as suggestions on strategies to "invent around" blocking patents, patents under which licenses can be obtained, and what technologies are in the public domain. While PIPRA engages in the background research, anything requiring legal analysis is referred on to an attorney. A number of law firms support PIPRA in this by providing FTO analyses on a *pro bono* basis.

Patent landscape analyses: The patent landscape analyses at PIPRA are mappings of the IP across broad sets of technology. These can vary in degree detail but generally do not go into the same depth as an FTO analysis. Rather, a patent landscape of a broad set of technologies, such as plant genes, would be part of or provide a starting point for FTO research on a narrower subset of technologies, such as plant promoter regulatory elements.

Industry and policy analyses: PIPRA conducts and publishes research on industry trends and structural shifts and also on developments in government policies, all with an eye to affects on IP in agricultural R&D.

3.2 IP management education and outreach

In order to facilitate public-private R&D partnerships and promote technology transfer to developing countries, PIPRA offers a number of educational services within IP management to researchers, administrators, technology transfer staff, sponsors, policy makers, industry, and farmers. These include:

IP management handbook: PIPRA is collaborating with its sister organization in the medical field, MIHR (www.mihr.org) also established through efforts of the Rockefeller Foundation, to put together an exhaustive handbook and accompanying web-based resource on IP management for policymakers and professionals in the developing world. PIPRA is working to improve IP management in agricultural R&D, and understanding the rules of the game are essential to being able to play. Lack of access to agricultural biotechnologies, especially in developing countries, often simply results from a lack of professional expertise in IP management in those countries, knowing how to access the technology. Lack of access can also result—even unintentionally—from overly broad terms of commercial licenses executed by universities and institutes in the North.

Research publications: Much of the work being done by PIPRA in FTO research, landscapes, as well as industry and policy analyses are being adapted (such as redacted to remove confidential information) for public access on the PIPRA website. Their publication is intended to allow the broad clientele at member institutions and others to benefit from the research and analyses done by PIPRA.

Professional training opportunities: PIPRA is seeking to educate IP professionals in the agricultural sciences by accepting short term interns to engage in the full range of work ongoing at PIPRA.

Short courses: Plans are in formation to formalize short courses on specific topics involving PIPRA's approach, IP analysis results, and recommended best practices.

3.3. Biotechnology resources

PIPRA is also working actively toward providing freedom to operate for neglected market applications of agricultural biotechnologies through the development of a suite of enabling biotechnologies for plant transformation.

Plant promoters: Laboratory based analysis is being carried out at PIPRA to discover where non-patented or accessible biotechnology components might be substituted for those with legal restrictions. PIPRA then integrates its systematic understanding of promoter effectiveness with

Intellectual property clearing houses may bring the benefits of modern agricultural technologies to African farmers at an affordable price

what it has learned about the IP status of the various promoters to come up with optimal recommendations for a variety of research contexts.

Plant transformation vectors: The first project underway involves vectors for the insertion of DNA into plant cells. This is a very important tool and one that is burdened with IPRs and to a large extent inaccessible for use outside of the major corporations. In order to avoid this bottleneck, PIPRA is attempting to develop a novel transformation vector in the PIPRA lab using technologies for which FTO has already been established, whether they are in the public domain or owned by a PIPRA member institutions and available for license. PIPRA may need to include one or two components that are proprietary to a commercial company, but the terms of any such agreement would be settled ahead of time, so as not to encumber the PIPRA vector system. PIPRA envisions making the vector widely available under a pooled non-exclusive license, with separate terms for research, humanitarian, and small-scale commercial uses.

This work requires a close collaboration between the lab, PIPRA staff performing IP searches, and supporting law firms doing the FTO analysis. If the project is successful, vectors, packaged with the license, will be distributed free of charge within the public sector and for humanitarian use. Private companies will pay a fee to use the vectors commercially. This degree of IP "self awareness" guiding research design is unique in the public sector.

3.4 Collaborative IP management

Reservation of rights in order to segment markets: PIPRA is also promoting among its member institutions a common licensing language that can be used to encourage and manage market segmentation. More precise licensing terms can be used to allow commercial licensing of technologies to firms to encourage them to invest in developing the technology for major commercial markets, while reserving rights in order to then license smaller firms to develop the technology for use in minor commercial markets such as specialty crops and, even more importantly, to allow non-market or humanitarian uses of the technology, such as in subsistence crops.

Greater precision in licensing terms aims to target the transfer of rights to those parties that are most likely to utilize the technology across a range of commercial and non-commercial contexts. PIPRA has participated in a consultative process with university attorneys and external legal counsel to develop licensing language for retaining "humanitarian use rights". PIPRA member institutions are encouraged to use such language as part of their standard license agreements in agriculture. (PIPRA's proposed language for humanitarian use reservation of rights is online at http://www.pipra.org/docs/HumResLanguagePIPRA.doc.)

Bundling or pooling: The models for bundling or pooling IP being developed in PIPRA's transformation vector project can also be used in other areas. Current activities include development of a licensing model where rights over complementary technologies are pooled and can be accessed through a single non-exclusive license. Much of the effort here is put into discussion and negotiations with technology owners, including PIPRA's own member institutions, to find a model that preserves commercial interests while carving out space for public research and humanitarian uses.

It is important to point out that, while PIPRA already plays a role in identifying and defining the mutually-complementary technologies involved in IP coordination bottlenecks, PIPRA is still exploring models for bundling or pooling of technologies. One model being contemplated would be to take licenses to these technologies and then offer sublicenses. Another would be for PIPRA to assist in the set up and management of a pooled licensing arrangement signed directly between the owners of the technologies and the users. Arrangements for different technology pools indeed are likely to differ markedly depending on the nature of the technology involved, who owns the IP, in which countries the rights apply, and its commercial potential.

Exploring open source: PIPRA has likewise explored open source licensing models for biotechnology. In open source models, the owner (or owners) of a technology make it available for research and commercial use under a license where one of the basic terms is an obligation to license back to the owner(s) and/or other licensees (the "open source community") any improvements made on the technology. In biotechnology, the open source model has posed challenges in terms of finding an effective balance between the obligation to license improvements back to the open source community and any other obligations that might be in place to others with IP claims over parts of what is a typically involved in a complex R&D project. In addition, the cost of maintaining the open source commons based on a licensing of patent-protected technologies is significantly higher than in the classic case of open source based on licensing copyright-protected technologies like software. When a large investment is put into paying the fees to secure patent protection, it is often predicated on an expectation of commercializing the technology. Few are likely to be willing to cover the expense of patent fees, simply to "donate" the technology to the open source community. Indeed, for academic or public sector researchers in biotechnology, the lower cost and more likely option is simply to publish the improvement, thus leaving it to the public domain rather than to the open source commons.

Defensive publishing: Putting a technology into the public domain is, in fact, another IP management tool being researched and advocated by PIPRA. This is not always as straightforward as it sounds, however, given that many aspects of technologies as published may in fact be dominated, at least in part, by claims of existing or future patents. Still, in many cases it makes little sense to incur the costs of patenting a minor component technology when the prospects of licensing it as a stand-alone invention are small. Or, an inventor or their academic institution may simply choose to make their invention broadly accessible by publishing it instead of patenting it. In both cases, certain steps can and should be taken, with an eye on the patentability requirements established by patent law, to disclose as much as possible in terms of methods and possible applications. The intention is to make the publication as effective as possible as "prior art" to preclude encroachment by patent filings on improvements of the published technology or on similar technologies.

While the privatization of innovation has led to immense gains, there still exist many areas in which the social or humanitarian value of introducing an innovation may be high but potential market returns are almost non-existent. At present, campaigning for this shift in awareness and licensing practice is perhaps where PIPRA is having its greatest impact, preventing IP from creating future bottlenecks for agricultural R&D and crop variety development that is still clearly the mandate of public sector institutions.

4. Partnering for IP management in Africa

Economies in Africa continue to be highly dependant on their agricultural sectors. Subsistence or small scale agriculture still employs a majority of the working age population in many African countries. Agricultural innovation is therefore of high relevance to economic development and improvement to the human condition. When the needs of smallholder growers are analyzed with a critical eye, a number of viable solutions can be found that depend upon new agricultural technologies that are proprietary, registered under patents in some countries.

In most cases, questions of access to new technologies when considered from the African context are very different from those typically confronted in the U.S. or Europe. Most of the technologies that might be of interest in Africa have not been registered by their inventors under patents in African countries, and they are therefore by default in the African public domain.

An immediate legal issue arises only if the crop is to be exported to the U.S., Europe, or other country where patents may be in force. It is at the port or the border crossing that such traded commodities would come under the patent laws of those lands and thus might become infringing (Binenbaum et al, 2003). While this constraint does not, in principle, prevent the use of the technology in Africa, for African purposes, it does restrict the feasibility, in an increasingly globalized economy, of using technologies to produce crops that may at some point in time be traded. Also, practically speaking, proprietary technologies may not flow as readily through the research community to become an approach that might be experimented with in Africa's agricultural research institutions. Control of the technology may be maintained by the owners controlling access to biological materials, and the owners may be reluctant to release or transfer those materials for a variety of reasons often revolving around concerns over liability and stewardship.

In seeking to make the proprietary technologies owned by the PIPRA member institutions available for use in Africa, PIPRA has partnered with the African Agricultural Technology Foundation (AATF), hosted in Kenya on the campus of the International Livestock Research Institute (ILRI) in Nairobi to explore opportunities to provide royalty free licenses to African institutions (www.aatf-africa.org). The mission of the AATF is to identify innovation priorities based on an understanding of the real constraints confronting African farmers and facilitating access to any proprietary technologies that might be needed to create innovative solutions to overcome those constraints. Examples of technologies being developed through the facilitation of AATF include a maize variety able to overcome the choking weed striga because it is tolerant of imidazolinone herbicides, as well as a nutritionally biofortified sorghum.

While the AATF searches everywhere in the world for appropriate technologies, sourcing them from industry or from research institutes in both developed and developing countries, the PIPRA member institutions represent a wealth of technologies that may one day be used in Africa under a royalty-free humanitarian use license. The identification of opportunities, negotiations, and licenses can be facilitated through the partnership between PIPRA and AATF. While coming from a different corner of the world, a good example of the kinds of agreements that are feasible is a recent license signed by the AATF with *Academia Sinica*, a public research institute in Taiwan, for use of an anti-bacterial protein to combat banana leaf wilt (Academia Sinica, 2006).

5. Conclusions

In a world where knowledge and technology are both increasingly valuable and increasingly denominated as intellectual property assets, the role of IP clearing-houses, such as PIPRA and AATF, become crucial to the function of public sector institutions. They are navigating an often uncharted shoreline between the open seas of the public domain of knowledge and the fertile lands of proprietary technology.

The role of PIPRA might be best characterized as that of a "supply side" IP clearinghouse, primarily making the IP that is held by a group of inventing institutions more readily and broadly available for a range of commercial and non-commercial uses. The role of the AATF might be best characterized as a "demand side" IP clearinghouse, primarily facilitating use of IP by a group of applied research institutions seeking to be responsive to the needs of the end users within African agriculture, clearing the way on their behalf to use proprietary technologies. The ultimate goal of IP clearinghouse institutions is to help find an optimal balance between incentives that mobilize private investment in agricultural innovation and the effectiveness of public investment in agricultural innovation. They are an attempt to properly adjust the public-private mix in the engine of innovation that is driving today's economies and that has the power to transform the human condition.

Authors

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6. References

1. Academia Sinica, "The Application of Amphipathic protein-1 for Anti-Banana Wilt Licensing and Collaboration Agreement Signed," August 11, 2006. [Online at http://ipmb.sinica.edu.tw/events/events_2.html.]

2. Atkinson, R.C., et al., "Intellectual property rights. Public sector collaboration for agricultural IP management." *Science*, 2003. 301(5630): p. 174-5.

3. Binenbaum, E., C. Nottenburg, P.G. Pardey, B.D. Wright, P. Zambrano, "South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops," *Economic Development and Cultural Change*, 2003. 51(2) 309-335.

4. Graff, G.D., G.C. Rausser, and A.A. Small, "Agricultural biotechnology's complementary intellectual assets." *Review of Economics and Statistics*, 2003. 85(2): p. 349-363.

5. Graff, Heiman, and Zilberman, 2003

6. Graff, G.D., S.E. Cullen, K.J. Bradford, D. Zilberman, and A.B. Bennett. "The public-private structure of intellectual property ownership in agricultural biotechnology." *Nature Biotechnology*, 2003. 21(9): p. 989-95.

7. Graff, Gregory, Amir Heiman, and David Zilberman. "University Research and Offices of Technology Transfer," *California Management Review*, Vol. 45, No. 1 (Fall, 2002), pp. 88-115.

8. Kryder, R.D., S.P. Kowalski, and A.F. Krattiger, *The intellectual and technical property components of pro-vitamin A rice (Golden Rice): A preliminary freedom to operate review*. 2000, ISAAA (International Service for the Acquisition of Agri-biotech Applications): Ithaca, NY.

9. Wright, B.D. "Public germplasm development at a crossroads: Biotechnology and intellectual property" *California Agriculture*, Vol. 52, No. 6 (1998), pp. 8-13.

SIGNATORS OF PIPRA MEMORANDUM OF UNDERSTANDING

1. Agricultural Institute of Genetics, Vietnam
2. Agriculture and Agri-Food Canada
3. Arizona State University
4. AVRDC - The World Vegetable Center, Taiwan
5. Boyce Thompson Institute
6. Cornell University
7. CIMMYT - International Maize and Wheat Improvement Center, Mexico
8. CIP - International Potato Center, Peru
9. Donald Danforth Plant Science Center
10. Fundacion Chile
11. Hanoi Agricultural University, Vietnam
12. Iowa State University
13. IRRI - International Rice Research Institute, Philippines
14. Kansas State University
15. Michigan State University
16. North Carolina State University
17. Ohio State University
18. Oregon State University
19. Parco Tecnologico Padano, Italy
20. Purdue University
21. Rutgers University
22. Salk Institute for Biological Studies
23. St. Augustine University of Tanzania
24. The Samuel Roberts Noble Foundation
25. University of Arizona
26. University of Arkansas Division of Agriculture
27. University of California, Berkeley
28. University of California, Davis
29. University of California, Riverside
30. University of Florida
31. University of Georgia
32. University of Kentucky
33. University of Idaho
34. University of Missouri-Columbia
35. University of Saskatchewan, Canada
36. University of Tennessee
37. University of Wisconsin (WARF)
38. Virginia Tech
39. Washington State University