Intellectual Property Resources for International Development in Agriculture

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Scientific advances in many fields were historically treated as public goods. This was particularly true in agriculture. Universities and other public sector institutions were leaders in developing improved crop varieties that were transferred to farms through cooperative extension services in the United States or equivalent organizations internationally (Conway and Toenniessen, 1999). However, this model has changed rapidly in the last few decades due to greater utilization of formal intellectual property protection of agricultural advances by the public sector and the development of a research-intensive private sector that now makes major contributions in enhancing the productivity of U.S. agriculture (Kowalski et al., 2002). The growth in patents related to agricultural biotechnology can be seen in Figure 1. These data indicate a strong growth in the issuance of patents by the U.S. Patent and Trademark Office to both private companies and to public sector institutions, most notably the land grant universities. Similar trends are also apparent in patents granted by patenting organizations of other countries, suggesting that this is a global trend. Several changes in the legal and policy framework greatly expanded the possibility of patenting and licensing biotechnology inventions over the last 20 years. For example, in 1980, the Bayh-Dole Act was passed that encouraged U.S. universities to patent their innovations and license them to private sector companies to encourage their commercial use (Council on Governmental Relations Report; http://www.ucop.edu/ott/bayh.html).

All research institutions, whether private or public, now face increasing intellectual property restrictions that can influence the development of transgenic crops. This is particularly true of so-called "enabling technologies"—the research tools such as *Agrobacterium tumefaciens*-mediated transformation and the use of selectable markers, which are necessary to produce transgenic plants. The fragmented ownership of intellectual property rights across multiple public and private sector owners produces situations where few single institutions can provide a complete set of intellectual property rights to ensure freedom to operate (FTO) with any given technology, giving rise to the development of a so-called "anticommons" (Heller and Eisenberg, 1998). This situation is particularly true for subsistence and specialty crops, the historically important work of public sector research, where only isolated efforts have been made to assemble complete intellectual property portfolios for applications in these fields (Wright, 1998; Conway and Toenniessen, 1999). A prominent example of the complexity resulting from fragmented intellectual property ownership is the case of "Golden Rice" in which over 40 patents or contractual obligations associated with material transfer agreements represented potential constraints for its commercial development (Kryder et al., 2000). Many of these patents are not valid in some countries in the developing world, but clearing the path for FTO for this project has required considerable investment of time and resources and the good will of several companies.

Overall, the ownership of critical intellectual property and the rights to practice or use certain technologies is becoming a major issue confronting researchers in all areas of science, including agricultural biotechnology. The recent Federal Circuit Court of Appeals ruling in the Madey v. Duke case emphasized that academic research is not protected by an "experimental use" exception from patent infringement, even when the research is purely fundamental (Eisenberg, 2003). Thus, even pure research may become increasingly entangled in access to intellectual property rights. Although the importance of intellectual property is becoming better recognized in both the public and private sectors that focus on agriculture, many researchers, business people, research and development (R&D) decision makers and policy makers are still relatively uninformed of the means to find, understand, and utilize intellectual property information, including published patents and patent applications. In addition, the ability to obtain rights to use patented technologies has remained uncertain even for projects that have little commercial impor-

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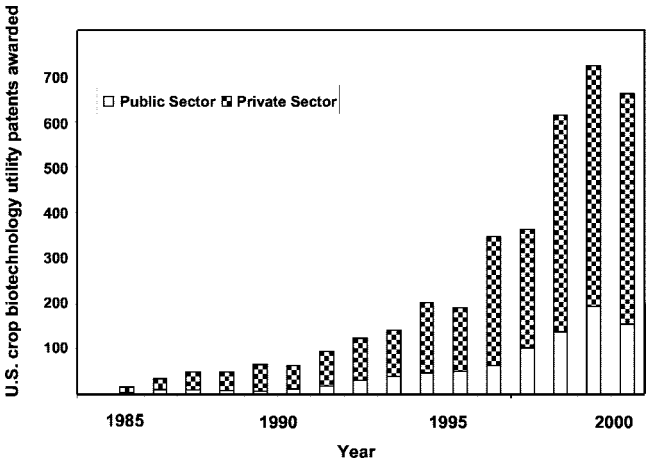

Figure 1. Patents awarded by the U.S. Patent and Trademark Office in the area of crop biotechnology assigned to either private sector or public sector institutions between 1985 and 2000.

tance but may have large impacts in subsistence agriculture. Several organizations have formed recently to address the relative inaccessibility of intellectual property information and to provide a clear path to access intellectual property owned by either the public or private sector, particularly for subsistence crop applications in the developing world. These major activities are described below and, collectively, they are beginning to provide a framework to ensure that intellectual property rights do not block important applications of agricultural biotechnology and to facilitate the advancement of projects that can have broad humanitarian benefits.

CAMBIA IP RESOURCE

CAMBIA is a private, nonprofit research institute located in Australia whose overarching goal is to provide technical solutions that empower local innovators to develop new agricultural solutions. CAMBIA invents, develops, and delivers new technologies in agricultural biotechnology through licensing to companies and transfer to national programs and universities in developing countries. CAMBIA IP Resource (http://www.cambiaIP.org) is an activity within CAMBIA that is designed to provide tools and information to assist researchers and policy makers in understanding the intellectual property landscape influencing R&D in agricultural biotechnology, particularly in issues relevant to international agricultural. The IP Resource provides the background and framework necessary to formulate IP-based strategies for the development and deployment of research activities and, in particular targets, scientific researchers and business-associated personnel in national programs, universities, small companies, and international institutions.

The CAMBIA IP Resource was publicly launched in July 2001 and provides three primary elements: (a) a database containing searchable full-text patent and patent application data that are relevant to biotechnology, (b) white papers providing overviews of the patents in selected topical areas of interest to agricultural and health-related biotechnologies, and (c) tutorials designed to bridge the gap between theory and practice of IP.

Patent Databases

Four major datasets are either currently or soon-to-be available: (a) full text and image data of European granted patents, (b) full text and image data of Patent Cooperation Treaty international applications, (c) full text U.S. patents and patent applications, and (d) full text and images of Australian patents. For each of the data sets, that subset of the patents and applications that was most related to agricultural biotechnology was chosen.

The search interface is structured to guide the user in making choices. The user can choose one or more of the datasets, whether full text or cover page data is to be searched, and type in terms to query the data. Tutorial and help screens are also posted to assist the user. For the output, a list of patents and applications are presented in table format, with the publication number and the title of the application. The user may select a publication by clicking on the number, which will bring up more details about the particular application, or obtain the entire text of the publication in a format that can be read with a word processing program or in PDF format.

White Papers

The CAMBIA IP Resource also provides a series of "white papers" that present and analyze the patent landscape in key areas of biotechnology with the top one to three tiers of patents summarized and analyzed for each area. The analyses also contain an introduction, explanation of the science behind the subject matter including schematics and diagrams, and some information about the patent owners. The white papers are available for viewing online or can be downloaded in a variety of formats for the user to read. Three papers on *A. tumefaciens*-mediated transformation of plants, antibiotic resistance genes and their uses, and promoters and their uses are currently available; several others are about to be released. In addition, the user will also find several articles on patent policies and their effects on trade of staple crops and on basic scientific research.

Tutorials

Several tutorials have also been developed to provide pragmatic guidance and to assist users of the CAMBIA IP Resource in evaluating the significance of patent information. These tutorials, including

"How to Read a Patent" and "Top Ten Things to Know about Patents," provide a concise approach to addressing the lack of legal knowledge in much of the scientific research world.

The coming phase of the CAMBIA IP Resource will expand and improve the site in four specific ways: (a) add Health Sciences and Chemistry patent data that were previously excluded, (b) further develop the search interface to guide and assist users to find their desired data while only requiring a minimum amount of knowledge about patents, (c) greatly expand the tutorial section in the areas of pragmatic information and advice to increase understanding of what patents mean and how to strategically use them, and (d) continue researching and presenting white papers on major controversies in timely topic areas.

The outcomes from this project are intended to provide national programs and research institutions with a strategic framework for dealing with both national and international IP issues associated with biotechnologies. In particular, the expertise gained from this resource will increase capabilities for dealing with various IP issues for negotiating with private companies, raising public awareness, and forming policy decisions.

PUBLIC SECTOR INTELLECTUAL PROPERTY RESOURCE (PIPRA)

An examination of patented technologies related to agricultural biotechnology illustrated the large increase in both public and private sector patents since 1982 (see Fig. 1), and further evaluation indicated that public sector institutions initially owned 24% of patents in this technology sector. This represents a substantially larger intellectual property portfolio than that of any single agricultural biotechnology company (Graff et al., 2003). In addition, public sector scientists have invented many of the fundamental enabling technologies that are necessary to develop new transgenic plant varieties. For instance, they have developed technologies to transfer genes into plant cells, characterized specific DNA elements that drive unique patterns of gene expression, and have identified many genes that confer important plant traits. However, the public sector portfolio is highly fragmented across institutions, and much of its intellectual property has been licensed, presumably under terms that have restricted general access to the underlying technologies.

A number of public sector research institutions and the Rockefeller and McKnight Foundations have found that the public research sector itself is increasingly restricted in its ability to develop new crops with the technologies it has itself invented. As a result, a consortium of institutions, including the University of California, the Donald Danforth Plant Science Center, North Carolina State University, Ohio State University, Boyce Thompson Institute for Plant Research, Michigan State University, Cornell University, University of Wisconsin (Madison), University of Florida, the U.S. Department of Agriculture, Rutgers University, Texas A&M University, and Purdue University in conjunction with the Rockefeller and McKnight Foundations have held discussions that led to the development of PIPRA (http://www.pipra.org). Recently, the leaders of many of these institutions have made a public commitment to participate and promote the goals of PIPRA within their own institutions (Atkinson et al., 2003).

The primary purpose of PIPRA is to explore strategies to collectively manage public sector intellectual property in support of both U.S. and developing country agriculture. A number of strategies can be envisioned to enhance FTO using public sector intellectual property. For example, informed decisions regarding dissemination of new knowledge via open publication or protecting it with a patent are clearly important, and FTO certainly can be improved if public sector institutions systematically reserve rights to use their newest and best technologies for subsistence crop development when they issue commercial licenses. For U.S. agriculture, it is also important to retain rights for use in development of small specialty crops that are not currently within the commercial interests of large private sector companies. The anticipated benefits of a collective intellectual property management regime are to enable an effective assessment of FTO issues, to overcome the fragmentation of public sector intellectual property rights and reestablish the necessary FTO in agricultural biotechnology for the public good, and to enhance private sector interactions by more efficiently identifying collective commercial licensing opportunities.

PIPRA is in its early developmental stage and has established a series of near-term objectives aimed at demonstrating the feasibility of this initiative and laying the groundwork for collective public sector intellectual property rights management. These objectives are as follows:

Review Public Sector Patenting and Licensing Practices

A series of "best practices" will be developed 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 public benefit and to support subsistence crop development.

Develop a Collective Public Sector Intellectual Property Asset Database

There are several efforts underway to develop databases of patented agricultural technologies so that public sector researchers can be informed about FTO obstacles at the initiation of their research (see CAM-

BIA IP Resource, above). PIPRA will develop a common database that provides an overview of intellectual property currently held by the public sector, including up-to-date information about licensing status, information not usually available in other current databases.

Explore the Development of Consolidated Technology Packages

PIPRA will explore the possibility of consolidating groups of specific public sector technologies, making technology "packages" available to member institutions and to the private sector for commercial licensing or for designated humanitarian 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. This effort also will test whether such packages might create additional commercial licensing opportunities by providing a convenient one-stop shop.

AFRICAN AGRICULTURAL TECHNOLOGY FOUNDATION (AATF)

Although PIPRA is trying to address issues of access to proprietary agricultural technologies from the public sector, there is also a clear need to develop easier paths for gaining access to similar technologies from the private sector for use in the developing world. The Rockefeller Foundation, with additional support from U.S. Agency for International Development and the UK-based Department for International Development, have been involved in another new initiative that is focused on access to private sector technologies specifically for sub-Saharan Africa. This new initiative, AATF (http://www.aftechfound.org), is, like PIPRA, still in its early stages of development. In a series of discussions over the past few years, representatives from many of the large private sector companies with large portfolios in the area of agriculture have indicated an increased willingness to share these technologies for humanitarian goals, particularly in regions and for crops and markets that do not overlap significantly with their own commercial interests. However, the companies have made clear that their willingness to engage in such negotiations relies upon several important factors: (a) The goals of any project using their technologies must be well-defined, scientifically sound, and clearly focused on a goal that can meet a clear need for resource-poor farmers; (b) the project must have a clear way to ensure proper stewardship for the use of these technologies in ways that also limit the liability of the donor companies; and (c) the agreements should allow for clear protection against use of the technologies in ways that interfere in the company's (ies') own commercial spheres of interest.

After extensive discussions and planning with a broad range of African, North American, and European stakeholders, the concept of AATF was created. The fundamental concept is to bring together private companies (and perhaps also public sector institutions such as PIPRA) in developed nations with African stakeholders, including the National Agricultural Research System and other agricultural R&D institutions, farmers associations, non-governmental organizations, and national private sector agribusinesses. The goal is to access advanced scientific and technological resources and adapt them for use in specific projects for the development of agricultural products for sub-Saharan Africa. To ensure that the best interests of Africa will be advanced, the AATF will be an African-based, -owned, and -led entity. It has already developed a business plan, become incorporated as a nonprofit entity, assembled a Design Advisory Committee, and is establishing its offices in Nairobi. A prominent African scientist, Eugene Terry, is now functioning as its Interim Director until a permanent Director can be chosen. An official launch of the AATF is scheduled for the spring of 2004 in Nairobi.

The AATF has, as a first goal, to engage in extensive consultations with African stakeholders to identify priority crops and traits that are important to poor farmers and to identify scientific partnerships that would be capable of carrying out such projects. Specific technologies that are needed for these projects will be identified, and the AATF will be the entity that negotiates with the relevant technology providers and potential users to help develop specific project business plans that take into account technology needs, requirements for proper stewardship including proper regulatory measures, provision of safeguards against piracy, and many other issues that need to be planned to carry any project from the lab bench to the farmers' fields. The AATF will negotiate royalty-free licensing agreements with the companies for such projects and will be the primary holder of such licenses. These will then be sublicensed to the partner institutions in Africa that will carry out the projects. The AATF will not fund projects itself but rather will provide the matchmaking, stewardship, and guidance at all levels to ensure the development successful projects that will be carried out in responsible ways. Although AATF will undoubtedly consider projects that involve genetic engineering, it will not be limited to these approaches but rather intends to promote access and use of all types of technologies relevant to enhancing agricultural productivity.

Clearly, Africa is a good choice to try such a new approach to public-private partnerships for agriculture. The need for improved crops and other technologies related to agriculture is clearly critical, and the size of current markets makes it unlikely that the private sector alone will enter into R&D and com-

mercialization of many crops that are important to the region. If the AATF can demonstrate the success of such an approach, it may serve to strengthen agricultural markets in Africa, and it may also serve as a model for the establishment of similar partnerships in other parts of the developing world.

CONCLUSION

The awareness of intellectual property as a key ingredient in the development of research projects that seek to develop new crop cultivars for international agricultural development has increased significantly. As a result, a number of organizations have begun to address new approaches to inform researchers about the intellectual property landscape impacting agricultural biotechnology and to design strategies that will improve access to intellectual property, particularly for humanitarian purposes. The organizations described here are all in their early stages of development but promise to provide a framework for how the public and private sectors can work independently and collaboratively to ensure that the full benefits of agricultural technologies are realized. These organizations have a common theme of providing cooperative strategies to overcome intellectual property hurdles to innovation in agricultural biotechnology. Major hurdles in gaining regulatory approval for transgenic crops lie beyond innovation in research. Perhaps similar cooperative strategies that involve access to regulatory information and public-public and public-private consortia may help overcome these hurdles also.

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