RESEARCH AT A GLANCE

Biotechnology and Genetic Resource Policies

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Accessing Other People's Technology

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Public and private nonprofit institutions worldwide engaged in agricultural research and biotechnology are increasingly active participants in intellectual property transactions, interacting with the for-profit sector and even spawning private entities of their own. Notably absent from the group of nonprofit institutes seeking patent protection are the 16 centers of the Consultative Group on International Agriculture Research (CGIAR). Located primarily in developing countries, only a few centers have obtained patent protection for their inventions.

Nonprofit research institutions are not in the business of selling products to consumers. If they are to realize a return on their investment, they must sell rights to their technologies to commercial entities or other research institutions rather than make them freely available. A nonprofit entity may, for example, exclusively license technology to a commercial partner, license the technology itself nonexclusively, or use the technology as the foundation for a spin-off company.

For all the benefits that nonprofit institutions receive from intellectual property, these same institutes are notorious for using other people's patented technologies without permission. A review of the intellectual property policies of several large universities in the United States with active licensing offices reveals that none discusses the need to obtain permission to use patented methods and materials, and only one provides guidelines on copying material that is copyright protected (Nottenburg, Pardey, and Wright 2002). In contrast, for-profit entities—especially in biotechnology—are not only generally more cognizant of intellectual property rights and rules, but also proactive in obtaining licenses, options for licenses, or collaborations that will assure their "freedom to operate," that is, their ability to practice or use an innovation.

Nonprofit research organizations need to develop and implement policies regarding use of other people's technologies. With a special emphasis on agricultural biotechnology, this brief discusses policies of intellectual property protection, de jure (by right) and de facto research exemptions, and the ways that research at nonprofit institutes fits with, and is at odds with, these policies and exemptions. We also present an overview of the steps necessary to abide by others' intellectual property rights (IPRs) and show how most nonprofits are ill equipped to undertake such measures. Finally, we present strategies for pursuing different options to obtain rights to use other people's technologies.

Protecting Intellectual Property

The major forms of legal protection available for agricultural biotechnology are patents, plant breeders' rights (known in the United States as Plant Variety Protection Certificates), trademarks, trade secrets, and contracts. Third-party trademarks and trade secrets, however, have relatively little impact on nonprofit institutions and so will not be discussed here.

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Protecting and controlling the use of intellectual property can also be achieved by technical means, like hybridization of crops such as corn and rice and genetic use restriction technologies (GURTs). These methods have the greatest impact on farmers by rendering the seed unsuitable for replanting or suppressing the expression of certain introduced traits in saved seed. They are dealt with in detail by UNEP/CBD/SBSTTA (1999).

A web of proprietary claims now envelops the transfer and use of patented biotechnologies, thereby limiting the freedom to operate of public and private agencies alike. Biotechnologies covered by these claims include (1) parent germplasm in the form of individual plant varieties; (2) germplasm constructs that include trait-specific genes; and (3) transformation technologies, such as a gene coding for a specific characteristic inserted into plant cells, selectable markers, and gene silencing or regulating technologies. Depending on the complexity of the transgenic product, dozens of identifiable proprietary claims can be involved in its development.

Patents

Patents protect inventions of tangible things and confer a legally enforceable right on their owners to exclude others from practicing the invention described and claimed in the document. These rights apply for a limited period of time, generally 20 years, and only in a specific legal jurisdiction.

A common misconception is that a patent awarded in one country confers rights in the rest of the world. This is not so; there is no such thing as an "international patent." Patents are awarded by national governments, and the protection conferred by a patent extends only to the national jurisdiction in which the patent is awarded. To protect an innovation in more than one country, a patent must be awarded in each. The cost of obtaining a patent varies from country to country, and the cost of obtaining protection in every important market can be substantial. In general, most inventions are patented in just one or a few countries, mainly the developed ones.

Plant Breeders' Rights

To be granted a plant breeders' right (PBR), an applicant must demonstrate that the variety is new, distinct from other varieties, and genetically uniform and stable through successive generations. The holders of a PBR have a legal monopoly over commercialization of their variety for a prescribed length of time. Generally, PBRs encompass the right to sell, reproduce, and import a new plant variety. PBRs in most jurisdictions contain a research exemption.

Forms of PBRs consistent with the International Union for the Protection of New Varieties of Plants (UPOV) now exist in most developed countries. Developing countries are adopting either UPOV standards or other forms of plant variety protection to comply with the requirement of the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) to grant a so-called *sui generis* form of protection to plant varieties. By December 2001, 50 countries (including, most recently, Bolivia, Brazil, China, and Kenya) had enacted PBR legislation.

Permission Issues

The nature of the patent right allows the patent holder to exclude others from making, using, selling, offering for sale, or importing the patented invention. To encourage basic research, countries have sought to facilitate access, either through a statutory exemption, a common law exemption, or compulsory licensing.

In the United States researchers generally assume that patent law does not apply to their basic research. Academic researchers are often shocked to discover that, except for some limited statutory exemptions, there is no general research exemption for using other people's patented technologies. Courts generally have ruled that using another's invention for research or experimental use is an infringement. Research at a university or other nonprofit institution, even if performed without any profit motive, would constitute an infringement.

The U.S. Congress has enacted only a few narrow exemptions. Yet there does appear to be a de facto exemption in the United States. Even absent a legal research exemption, it is unlikely that nonprofit institutions have more than a minor risk of infringement exposure, especially in cases where the nature of the research is clearly noncommercial. The number of patent suits filed against nonprofit organizations in U.S. District Courts is extremely small.

Commercially Oriented Research

The risk of infringement liability may be higher when commercially oriented research or services are

involved. In these cases the unauthorized user may receive a letter requesting that the activity cease and desist, an offer for a commercial license, or notice of an infringement action.

An important trend, however, is that the line between nonprofit and commercially oriented research is becoming blurred. An increasing amount of research is performed as part of private-public sector alliances. Substantial private sector funding also supports research conducted by government agencies and public universities in many developed countries, and in some developing ones as well. Public policies have encouraged this. In the United States, for example, the Bayh-Dole Act of 1980 mandated that the U.S. government cede ownership of intellectual property emanating from government-sponsored research to the recipient institutions. Under the auspices of Cooperative Research and Development Agreements (CRADAs), specifically designed to speed the commercialization of federally developed technology, the government and its collaborating partner may share patents and patent licenses, allow one partner to retain exclusive rights to a patent, or assign licensing rights to facilitate licensing to third-party users.

What Is "Free Access"?

Given the risk of using other people's patented technologies, some in the nonprofit research world may want express permission to use the technologies. Permission may be obtained in a variety of ways, but the recipient should be vigilant in identifying the hidden costs of access. Sometimes agreements widely characterized as onerous are actually far less restrictive than apparently "free" deals and traditional consulting arrangements between private firms and individual academics.

Determining Freedom to Operate

As nonprofit research becomes more commercially oriented, the risk of serious consequences for infringement may well increase. As risk increases, the need to scrutinize the intellectual property landscape and the freedom to operate will become more pressing. There are various reasons why determining freedom to operate can be a daunting task, especially for the nonlegal professional.

- A freedom-to-operate analysis is, by design, a snapshot of the current patent situation; however, patenting and disclosing inventions is a dynamic process. A review of emerging publications is integral to such analyses given the continuous stream of patents and applications being published.
- The challenges inherent in an ever-changing landscape are further complicated by the difficulty of determining which entity will triumph, and with what claims.

A patent's claims—not its text—define the parameters of the patent right conferred on the patentee. Hence, to delineate the extent of the right, a potential user must interpret these claims. In the United States claim construction is a matter of law and centers on an objective test of what a person of ordinary skill in the art at the time of the invention would have understood the claim to mean. Infringement is determined by examining whether the alleged infringing product or method falls within the scope of the claims.

The development of any product in biotechnology requires a multitude of technologies and reagents. This is especially true in agricultural biotechnology, where the delivery system includes germplasm. Typical reagents include vectors for transformation of plants, components of vectors, elite plant varieties, and the like. In the case of *Golden*Rice™, an analysis estimated that 70 patented technologies were used during research and development (R&D). This analysis illustrates the complexity of intellectual property in agricultural biotechnology.

Several databases with differing amounts of information are available on the Internet; some are available by paid subscription and some are free. For nonlegal professionals, a problem common to all the existing databases is the interface, which caters to individuals with a substantial knowledge base concerning intellectual property. Furthermore, with the exception of the database of the Center for the Application of Molecular Biology to International Agriculture (CAMBIA; see www.cambiaIP.org), none provides an explanation about patents, how to read a patent, or other information to assist the naïve user.

Options for Gaining Access to Other People's Technology

Various options are available for gaining access to proprietary technologies. Some of the more important

ones are discussed here, mainly from the perspective of a nonprofit agency. This discussion emphasizes developing countries, although most of the issues are relevant in developed countries too.

Cross-Licensing

At CGIAR centers, licensing would have to be restricted to property other than landraces and other plant varieties designated as "in trust" material (under a 1994 agreement with the Food and Agriculture Organization of the United Nations) that must be made available to the world at large. Through a material trust agreement (MTA), recipients of in-trust material distributed by CGIAR centers agree not to seek intellectual property protection on that material, though they may seek protection for derivatives.

Despite these severe constraints, candidates for cross-licensing have already been identified. The near-isogenic lines of rice germplasm potentially useful in plant breeding and developed at the International Rice Research Institute are examples of plant breeding that might be licensed via an MTA or other contractual agreement. Fischer and Barton (1999) proposed a model MTA in which a CGIAR center would offer such material to another institution at no cost in exchange for access to information about subsequent discoveries and zero-cost nonexclusive research licenses to CGIAR centers and agricultural research agencies operating in developing countries. If this example leads to successful cross-licensing, it is likely to be the exception that proves the rule. The number and value of intellectual property resources held by most public agencies operating for developing countries are often overstated, which puts them in a relatively weak negotiating position.

Research-Only Licenses

A free research license that does not permit commercialization can make a research tool the "cuckoo's egg" of technology transfer. If the project succeeds, then the bargaining for permission to commercialize must begin. On the one hand, researchers have already incurred the sunk cost of all the research, placing them in a highly disadvantageous bargaining position. On the other hand, even in refusing to allow commercialization, the IPR holder gains valuable information about the technology and its downstream applications.

Market Segmentation Strategies

All CGIAR centers engaged in biological research are in developing countries. Patents are usually filed in, at most, a select group of countries. Indeed, until recently few developing countries allowed patents on life forms. To the extent that research agencies use technologies and cultivars that are not patented or otherwise protected where the agencies are located, they can and should legally proceed without obtaining permission from the IPR holder. Even after compliance with TRIPs, the breeding of new cultivars using prior cultivars protected in developed countries may be legal under the sui generis protection that is being adopted in many developing countries.

The new regime of the World Trade Organization (WTO) might facilitate a kind of indirect market segmentation, in which developing countries get the new technology for free, and proprietary claims are enforced in developed countries. Further, cultivars incorporating genes patented in developing countries may not be subject to effective intellectual property claims if those countries have neither the legal means nor the will to enforce them.

In the near term, research agencies in developing countries are likely to have considerable freedom to operate, if they operate judiciously. Because retroactive patenting is impossible, most of the technologies usable by the CGIAR and its developing-country partners over the next half-decade or so are likely to be unencumbered by relevant intellectual property rights. Mistakes, however, could result in catastrophic legal liability. To reliably implement a strategy of obtaining intellectual property only where necessary, those who make research commitments must have access to adequate information and to expert legal counsel. Such access does not exist for most developing-country researchers and research institutions.

A promising initiative to provide intellectual property information services for developing-country organizations is being pursued by the Australian nonprofit corporation CAMBIA. The aim is to develop interactive software that can help researchers identify prior patent claims and areas of freedom to operate and thus travel more safely through the international patent minefield. If adequately funded on a continuing basis, such an initiative could reduce the uncertainties about prior claims to useful biotechnology.

Markets for intellectual property can also be segregated on grounds other than geography. With technology licenses, common segmentation strategies include delineating fields of use, length of time, certain claims of a patent, limitations to specific uses of the technology, research use versus commercialization, or restrictions on third-party services. Another option is to charge license fees based on an ability to pay or expected profit streams.

Mergers or Joint Ventures

Mergers can be a way to avoid an expensive patent fight. In agricultural biotechnology, mergers are a prime private sector solution to minimize the private costs of transactions in intellectual property. Mergers and outright privatization of previously public research agencies are characteristic of public sector agricultural R&D reforms in countries such as the Netherlands and the United Kingdom. But much of this change seems to have been driven by policy reforms and public budget cuts, not by a consideration of intellectual property.

Joint ventures are often viewed as a more promising and flexible alternative. For example, Monsanto is marketing transgenic cotton in China in a joint venture with a provincial public seed-producing organization.

Cost-Free Licensing of Technologies

For many minor crops, private and public IPR holders might be persuaded to allow international agricultural research centers and public research agencies in developing countries to develop proprietary biotechnology for use by farmers without any direct compensation. This situation is more likely where there is obviously little risk to the significant commercial markets that are the focus of the IPR holders' hopes for profits. Such cases have already occurred in these noncommercial crops, including several under the auspices of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

Direct Programmatic Research Support from the Private Sector

For-profit corporations might be persuaded to give more general support to collaboration with public research. Important examples of such support on the part of corporations with significant market power have already occurred. In the genomics field, a consortium of corporations has supported creation of a public database of genome markers in preference to partaking in a competing private sector initiative. Such cases suggest that private firms might, on occasion, choose to support public or private research initiatives in areas complementary to their own endeavors.

In another case Monsanto donated technology for the transformation of corn by *Agrobacterium* to the University of California. As part of a divestiture of assets ordered by the U.S. Justice Department, Monsanto was persuaded to give this technology to the university, allowing the university to license access to the technology to third parties. The details of this case illustrate the important point that prospective recipients must exercise flexibility and initiative to take advantage of such opportunities.

Patent Pools

A patent pool is an aggregation of intellectual property rights that are cross-licensed and licensed to third parties. In the United States the two critical features of a patent pool are that (1) the pool integrates complementary patent rights, and (2) the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program. Thus, patents in the pool must be essential to practice the technology.

Such joint agreements are probably not feasible as a regular modus operandi for pooling agricultural biotechnologies on a one-by-one basis. A better option is to coordinate a joint commitment by the major biotechnology providers and public agencies (including the CGIAR) to provide royalty-free licenses on all IPRs in agreed terms of application. In negotiating and drafting any such agreement, attention should be paid to national antitrust laws. This type of negotiation is difficult and costly to all parties and requires high-quality legal advice.

Clearinghouse Mechanisms

An alternative means of lowering the cost of technology transactions in biotechnology is the creation of an Internet-based clearinghouse (Graff and Zilberman 2001). This clearinghouse could identify relevant intellectual property in specified technology endowments, its availability, and how it could be obtained. It could also establish prices or pricing indicators, facilitate negotiations, and offer mechanisms for arbitration of disputes and monitoring of compliance. An agricultural biotechnology intellectual property clear-

inghouse could bundle together sets of complementary patents from different patent holders into complete "biotechnology or agronomic systems" contracts. Through such strategies, it would be possible to create customized licenses that could greatly increase the use of inventors' technologies and make multipatent technology systems readily available and affordable to researchers.

Independent Development of Research Tools

A quite different approach is to sponsor the creation of substitutes for existing proprietary research paths. For example, CAMBIA seeks to generate new biotechnology tools for agriculture, unencumbered by restrictive property claims. These tools are in turn made available on an ability-to-pay basis. The licensing revenues are used to fund further research and to support transfer of the technologies to developing countries.

Pressure for Sharing of Technology

International research institutions, including the CGIAR and FAO, should continue to press for including the interests of international and developing-country nonprofit research collaborations in measures designed to address the interests of domestic research institutions in the leading countries.

One form of pressure is a boycott of companies demanding "unreasonable" terms for key enabling technologies. Making common cause with more powerful allies in applying pressure on IPR holders might help ensure that any concessions by IPR holders are extended to nonprofit international agricultural research and that intellectual property is disseminated to noncommercial markets.

Conclusion

Designing policies and operating procedures to ensure that public science has sufficient freedom to operate is becoming increasingly important in the developed and developing worlds. Freedom to operate will be crucial for public and nonprofit agencies intent on developing improved seed varieties and other technologies destined for commercial release, albeit in markets that may generate large social gains but are not necessarily privately profitable. Various options are available to improve the efficiency of public-private relationships—particularly options that could lower the transaction costs of tapping proprietary technologies to further public research. Paradoxically, for developing countries the short-run importance of freedom to operate has been exaggerated by well-publicized donations that generate inferences that the multinational life science oligopoly holds extensive portfolios of intellectual property that block further research in those countries. Ironically, in developed countries nonprofit researchers often believe themselves exempt from infringement suits. Worldwide, institutions need to better understand their rights and responsibilities regarding intellectual property.

As things stand now, intellectual property does not appear to be the binding constraint on science in developing countries, but it is becoming a constraint on nonprofit research in rich countries. The real problems facing many countries and agencies, especially in developing countries, are lack of local investment in science and limited experience and expertise in gaining access to, using, and regulating modern biotechnologies. Developed countries are not immune to these problems either. Also suffering are the agricultural biotechnology industries in developed countries like Australia and Canada, which have comparatively small investments in domestic R&D but are highly dependent on exports to countries that have strong intellectual property protection (such as the United States and European countries). Furthermore, the implementation of TRIPs as currently formulated will likely affect the freedom to operate in the next generation of biotechnologies. Guiding these changes in intellectual property regimes and responding creatively to the new environment are pressing challenges for those interested in the future of scientific research, including agricultural biotechnology.

References

Fischer, K. S., and J. Barton. 1999. Gene discovery in rice: The exchange of IRRI's biological assets. Stanford Law School, Stanford, California. Photocopy.

Graff, G., and D. Zilberman. 2001. An intellectual property clearinghouse for agricultural biotechnology. *Nature Biotechnology* 19 (12): 1179–80.

Nottenburg, C., P. G. Pardey, and B. D. Wright. 2002. Accessing other people's technology for non-profit research. *Australian Journal of Agricultural and Resource Economics*, 46(3): 389–416.

UNEP/CBD/SBSTTA (United Nations Environment Programme/Convention on Biological Diversity/Subsidiary Body on Scientific, Technical, and Technological Advice). 1999. Consequences of the use of the new technology for the control of plant gene expression for the conservation and sustainable use of biological diversity. Paper presented at the fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice, Montreal, June.

For a more detailed version of this summary, see C. Nottenburg, P. G. Pardey, and B. D. Wright, Accessing other people's technology: Do non-profit agencies need it? How to obtain it, EPTD Discussion Paper No. 79 (IFPRI, Washington, D.C., 2001). http://www.ifpri.org/divs/eptd/dp/papers/eptdp79.pdf

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