

Managing Intellectual Property – Challenges and Responses for Agricultural Research Institutes

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Agricultural development has benefited from a long history of public sector/public good investment. However, public good investments in agriculture face an uncertain future because of (1) increased emphasis on market mechanisms forcing publicly funded organizations to respond to broader economic opportunities; (2) tendencies to limit freely germplasm for national agricultural research; and (3) changes brought about by the introduction of intellectual property rights (IPR).

The Changing Context for Intellectual Property

External forces are affecting agricultural research in developing countries and exerting pressure for change. These forces include the *integration of markets, growing activities of the private sector (including but not limited to multinational companies), and innovations in national and international legal and regulatory regimes*. Changes in research management and management of intellectual property are occurring in response to these global trends, each having the potential to redefine how agricultural research organizations will provide public goods to meet their country's food and agricultural needs.

In adjusting to these external forces and changing the management of IPR, a national agricultural research organization (NARO) must take into account (1) the policy framework guiding its mission, objectives and programs, (2) its stakeholders, and (3) its research scientists. Given these

various interests, and as the management of intellectual property (IP) attached to agricultural biotechnology is a relatively new phenomenon, developing, implementing and managing such a dynamic system can present formidable challenges and complications. The primary purpose of intellectual property ownership by NAROs, however, is to promote the fundamental research mission of the institute, keeping in mind the development of products available for use by small- and medium-scale farmers.

Clarification of ownership of assets and freedom to operate have important roles to play in this regard. Assets include research inputs, including patent rights for a gene sequence or for a laboratory or industrial process, and outputs. Copyrights and trade secrets may govern access to and use of experimental techniques and laboratory notes. Patents for research outputs may be sought for novel processes and products, while plant variety protection is sought for new crop varieties. Management needs to ensure that (1) ownership of intellectual property used by a research organization is respected by all who use the property, and (2) organizations are in a position to identify, secure, manage, and exploit the intellectual property that they generate.

Managing IP at the Institute Level

Various consultations, studies and related workshops have highlighted complexities regarding management of IP for NAROs, including several sponsored by the International Service for Na-

tional Agricultural Research (ISNAR), and reported in Cohen (1999). They have led to the identification of five tasks and associated responsibilities that help institutes structure responses to the challenges facing them with regard to the management of IP. The five tasks proposed here include the following:

1. *Clarifying institutional roles*
 - Relating legal status of the institute to relevant legal frameworks, regulatory regimes and stakeholders
 - Defining institutional policies for assembling and using an IP portfolio, including how research is conducted, and its publication and disclosure
 - Clarifying opportunities available for scientists between research financed for/by commercial sector versus that disseminated as public goods
 - Develop cost calculations and records for IP.
2. *Identifying IP*
 - Promoting general awareness and understanding of the importance of IPRs
 - Conducting an inventory of IP used in the institute
 - Disclosing IP generated to the research liaison office.
3. *Securing ownership*
 - Introducing IP rules as a part of contracts for research staff and visitors
 - Obliging the disclosure of IP generated by researchers
 - Attending to the registration of IPRs.
4. *Managing IP*
 - Liaison with IP suppliers
 - Policing licensed IPRs
 - Integrating IP policy with institute's mission to benefit expected end-users
 - Instructing researchers as "expert witnesses" in cases of infringement or other inquiries.

5. *Technology transfer and marketing IP*

- IP evaluation
- Liaison with IP exploiters (industry and commerce)
- Developing IP agreements (licenses and material transfer agreements-MTAs)
- Formulating a remuneration strategy.

Institutional Responses – Selected Examples

Research, case studies, and examples from national and international organizations have been selected to highlight challenges and responses regarding the management of IP. They also illustrate various aspects of the proposed tasks for IP management

Use of Proprietary Technology: Conducting Institutional Inventories

One of the changes affecting agricultural biotechnology research is the successful development of new tools and inputs from the private sector. These technologies and materials are finding wide utility in global agricultural research. IPRs protect most of these inputs.

Proprietary technologies and materials are those that are privately owned, managed, or protected through some sort of IPRs. Developers of such materials and technologies may place restrictions on their use during the research stage or in a later stage, when products derived from the protected materials are ready for wide dissemination. A growing number of research inputs are protected as intellectual property. This section focuses on the use of such protected or proprietary materials and technologies among seven CGIAR centers and from five countries in Latin America. It documents the difficult and often confusing situation that institutions face regarding the use and dissemination of products resulting from proprietary science where others hold IP rights.

The studies aimed to (1) assess the extent to which proprietary applications of biotechnology (technologies and materials) are being used in NAROs and CGIAR centers, (2) present potential legal implications regarding use of the identified proprietary technologies and materials, and

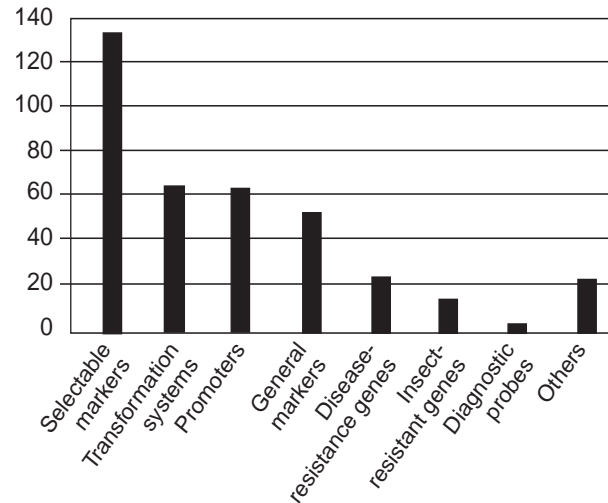
(3) synthesize findings and recommendations to stimulate further discussion.

CGIAR study. Every center responding to the survey currently uses proprietary inputs (technologies and materials) for biotechnology research. In total, 46 discrete technologies and materials were reported, covering eight technology categories. These included transformation systems, selectable markers, promoters, genetic markers, disease resistance genes, insect resistance genes, diagnostic probes, and other technologies or materials. As most centers apply these technologies and materials in several commodities, we recorded 166 specific applications of proprietary research inputs. Of the eight technology categories surveyed, selectable marker genes, promoters, and transformation systems show the broadest utility across centers, indicating the role that proprietary technologies and materials have assumed in research at the international agricultural research centers (IARCs), as is true for advanced research centers globally. Most, but not all, centers are using proprietary genetic markers, a set of disease- and insect-resistance genes. Some centers have integrated these technologies more than others across their research portfolio (Cohen and others 1998).

NARO study. In 1998, ISNAR conducted a similar survey among NAROs in Brazil, Chile, Colombia, Costa Rica, and Mexico. At the time of the study, none of the institutions that were surveyed had suitable institutional or legal frameworks for related IPR topics. With the exception of two research centers, none of the institutions had an office or person responsible for assisting the researchers in issues of intellectual property, access to adapted technologies, technology transfer, or ways to protect their own inventions. The researchers were functioning without the institutional support needed to address these issues for their research.

The range of proprietary technologies and materials used by the research organizations and the number of applications reported in each category are summarized in Figure 1. In total 34 different technologies and materials as well as 386 specific applications of proprietary research inputs were reported. While not all proprietary inputs pose difficulties regarding intellectual property ownership and the dissemination and use of resulting products, this study has helped

Figure 1 Proprietary technologies and materials covered in Latin American study



research organizations explore areas where potential difficulties may occur.

With regard to proprietary technologies and their permission for use, the Latin American study found that MTAs accounted for 25 percent of acquisitions, being the most common means, as is true for the CGIAR centers. This study highlighted the importance of international collaboration and purchase of proprietary technologies, totaling 35 percent of acquisitions. Other applications either lacked formal written agreements or information was not available (35 percent). The use of licenses, as another form of technology transfer, was very limited, accounting for only 5 percent.

IPR and proprietary science

As demonstrated by these studies, international and national organizations using biotechnology for agricultural development are operating in a complex environment, reflecting a transition from earlier periods where products and processes for research resided in the public domain. The increasing acquisition of proprietary technologies, their use in research serving the public good, and the vast array of developing countries where such use occurs, raises questions regarding appropriate IPR arrangements. However, for many scientists and institutions, such concerns are overwhelming. Yet their work continues, trusting that as final products are developed, no

legal instruments will block the dissemination of improved materials to their clients.

Adopting a more proactive strategy requires significant time and investment in taking steps to find institutional mechanisms to address these complex challenges. Such advancements are being made by both the CGIAR centers and by larger national research organizations in developing countries. National and international institutions are exploring whether they should invest in IP management or adopt a “wait and see” approach. They realize that no one clear position has been given by commercial biotechnology providers, as owners of much of the IPR for applications identified, regarding the use of third-party IP used for or with developing countries.

Practitioners Workshop in Costa Rica

Institutional inventories, such as those described for selected CGIAR centers and Latin American agricultural research organizations, present a first approximation regarding use of proprietary inputs. They provide a source of common information, allowing for analysis that is more detailed and formal IPR audits, and serve as a foundation for work regarding the institutional management of IP.

The data from the Latin American study were reviewed and verified before presentation to a workshop held by ISNAR in Costa Rica, in September 1999, of key individuals having institutional responsibilities for IPR (Falconi and Salazar 1999). Participants included senior research scientists and program coordinators from five NAROs. The purpose of the workshop was to discuss and analyze the results of the survey of proprietary technologies among selected Latin American research organizations, and to identify management needs. The specific objectives were to:

1. Review in detail the study’s findings and recommendations
2. Assess the legal implications of related IPR developments
3. Assess individual and institutional needs with regard to study findings
4. Identify future case studies in the management of IPR and review the case study approach.

Identifying practitioner and organizational needs

Practitioner needs refer to knowledge that scientists need to help address the problems identified in the study. These needs are classified as either technical (acquisition of skills and abilities) or those that are related to management and policy. Priorities emerged with regard to managerial/policy needs to:

1. Promote/support the creation of institutional IP units
2. Promote/motivate the development of institutional IP policy/strategy
3. Promote IP management parameters during research planning
4. Promote negotiation needed for licensing proprietary assets at institute level
5. Introduce new criteria for the management of information related to proprietary technologies in research institutes (for example, confidentiality, timing of publication).

Identifying organizational constraints

After analyzing and prioritizing individual practitioner needs, participants were asked to identify organizational restrictions regarding the management of IP at the institutional level. These included the following:

1. Lack or limited development of an IP unit to handle technology transfer, licensing, institutional negotiations, training, protection of assets/cultivars, processes and products of research
2. Lack of clear policies related to internal and external use of proprietary assets
3. Lack of economic studies to support the licensing in or the protection of technologies and products
4. Lack of clarity in present legislation, such as TRIPs requirements and definitions of terms such as natural process, discovery and invention, and part of the total plant.

Institutional Responses – Selected Examples

Embrapa, Brazil

Since 1995, the Brazilian Agricultural Research Corporation (Embrapa) has developed and begun to implement a new internal policy for intel-

lectual property protection. Embrapa has given high priority to its responsibility for protecting intellectual innovations, thereby helping to ensure that they become institutional assets. Its institutional IP policy published in 1996 states the following basic principles:

- Embrapa has to maximize its capacity to use intellectual property rights to facilitate the transfer or the licensing of technology, processes, and products without sacrificing its social mission
- Embrapa has to seek legal protection for the technologies, processes, and products derived from its research program, giving credit to employees as inventors
- Embrapa may authorize the use of its protected assets through a royalty-free license only when its social commitments are at risk and only after approval from its Intellectual Property Committee
- Embrapa research centers cannot release a new cultivar or disclose any process or product without previous analyses by the designated committee of the possibility, convenience, and opportunity for protection.

Following implementation of the policy, the institute began to discuss necessary internal changes by considering the economic and social consequences of forthcoming policy changes (Sampaio, This volume; Sampaio and Brito da Cunha 1999). The following challenges regarding intellectual property protection were identified:

1. *Implementing an internal intellectual property policy that requires legal support.* Embrapa has been implementing an internal policy, in conjunction with Congress approving the necessary legal framework.
2. *Raising awareness of intellectual property.* The institute has launched an internal awareness-raising campaign through lectures, courses, and workshops to promote and diffuse the new intellectual property policy. This campaign would also help researchers understand that they should have their research results prescreened for possible intellectual property protection before publication.
3. *Creating assets from intellectual property.* Embrapa should protect all assets coming from its research programs. Thus, revenues

can be obtained through licensing, or the institute can allow a third (resource-poor) party to use an asset free.

4. *Establishing regulatory infrastructure.* Embrapa hired and trained personnel to manage the implementation of its policies and intellectual property laws. It took into account that this includes a learning curve for preparing and filing patents and negotiating and licensing a protected technology.
5. *Modifying licensing system.* Embrapa is in the process of modifying its cultivar licensing system and its basic seed production program to suit the IPR legislation and the growing presence of a much stronger and competitive private seed industry in the country.

AARD, Indonesia

Similar developments have occurred in the Agency for Agricultural Research and Development (AARD) of Indonesia. Here, a new office for intellectual property and technology transfer was established (KIAT), in July 1999. The overall task of KIAT is to manage IPR resulting from AARD center's research and to transfer technology to the private sector (T. Subagyo, pers. comm., 1999). The office has three main tasks:

1. Provide information and services for technology in agriculture
2. Serve as a "one stop" service for agribusiness and the private sector
3. Provide guidance on intellectual property rights protection.

With regard to the first task, that of providing information, KIAT searches and prepares research results from AARD centers that would indicate products ready for commercialization. Certain products arising from AARD research efforts have been patented and sold, such as *Rhizoplus*, a fertilizer for soybeans containing *Rhizobia* and several other microbes. KIAT functions in this way across the seven research centers that comprise AARD.

With regard to relations with agribusiness, KIAT hopes to better address services sought by the private sector and other investors, beginning by preparing feasibility studies and moving to marketing. Working in collaboration with the

Director of IPR in the Department of Justice, IP is sought for research results coming from the individual centers.

Regulatory Regimes and IP Challenges facing the IARCs

Preparing responses to specific regulatory regimes has also been important for the IARCs of the CGIAR. These have included responses to the CBD, FAO agreements on germplasm, and awareness regarding potential national responses to WTO, UPOV and TRIPS agreements (Hawtin and Reeves 1998). In this context, the centers have put forward *Guiding Principles for the Consultative Group on International Agricultural Research Centers on Intellectual Property and Genetic Resources*, which was adopted as an interim working paper by the CGIAR in 1996 (CGIAR 1999).

The CGIAR Panel on Proprietary Science and Technology reviewed these guiding principles in 1998. Most of the panel members were satisfied with the Guidelines, but it was felt that some changes were needed, particularly the use of clear mission-based guidelines when seeking IP protection, and some changes in emphasis (TAC 1998).

In addition, the Panel commented on the desirability of strengthening CGIAR and IARC capacity for managing IPR. An organizational plan was presented that could contribute toward an effective intellectual property management program. There would be two aspects of such a program, one helping with problems regarding access to proprietary science owned by others, and the second regarding protection of new developments made by CGIAR centers themselves. The report stated that, "any program developed would begin with a centralized resource center and would require a local liaison at each center."

Following the Panel's report, several developments have occurred to enhance center management of intellectual property and related issues. These have included implementing the Central Advisory Service (CAS) for Proprietary Technology for the CGIAR, based at ISNAR, The Hague (ISNAR 1999), individual centers undertaking formal IP audits, focused technology development and related IPR protection undertaken in association with CAMBIA, Canberra, Australia,

and the beginnings of "Intellectual Property Management Units" among selected centers.

Institute Responses and the Five Management Tasks

The previous examples, taken from NAROs and CGIAR centers, illustrate IP management challenges and responses, and their relation to the five management tasks identified earlier. An essential aspect for each example has to do with *clarification of institutional roles*. In taking on these actions, particularly in relation to legal frameworks, various cases cited stressed the need for their research organizations to make decisions regarding IP management and protection more transparent and responsive to stakeholders.

This includes the need to clarify the range of opportunities available to scientists. This becomes increasingly important as NAROs and the CGIAR centers explore strategic partnerships with the private sector, and the receipt of funds from a broader range of investors. Scientists seek clarity as to how and if they should enter these agreements, and how to balance such research with those targeting equity or sustainability objectives.

Management of IP means that there are increasing costs for research. This is true whether such management occurs in an ad hoc manner through consultations, a centralized service, or decentralized systems with research liaison officers at each center. Cost effectiveness of providing IP management is in need of study and clarification. Institutional needs for IP offices and professional staff, as well as the support required for associated actions, means that costs must be carefully considered and justified against other needs.

Issues regarding tasks 2 and 3 (*identifying and securing ownership of IP*) were explored in earlier sections, as to how institutional inventories mobilize more detailed analysis of IP, including formal IP audits, as well as provide educational opportunities for staff involved. However, resolving ownership and operational freedom will require further concerted action.

With regard to responsibilities described as *managing IP*, among developing country institutes, there are few examples as to how they will evaluate and protect IP arising from their scientist's efforts. However, there are examples

of subsidiaries or advanced research institutes that provide such evaluation services. Additional actions have not been discussed, including monitoring and enforcing relevant IPRs and the integration of IP policy with a given institutional mission.

Technology transfer and marketing IP has been mentioned in many of the cases cited. Institutions are exploring ways in which enhanced management of IP and institutional assets can facilitate technology transfer. Here, special attention will be needed to ensure that such transfer occurs not only to commercially able partners, but also to providers or suppliers that can address institutional needs for providing products addressing equity and sustainability.

NAROs and IARCs: Differing Needs, Different Responses

Responses with regard to IP management and the proposed five tasks will differ between NAROs and CGIAR centers. For example, there are greater expectations to patent inventions by the NAROs than by the international centers, especially given the intention that center patents, if needed at all, may be essentially defensive in nature, and not sought as an additional mechanism for finance.

Furthermore, these two systems, one national and one international, each have different policies and reasons for assembling and using IP portfolios. For the CGIAR centers, an emphasis has been placed on managing IP to achieve bargaining chips, in seeking to gain access to protected technologies and as a means to secure freedom to operate, not to obtain financial returns from public investments. As seen in the case of Embrapa and AARD, expectations regarding IP assets appear quite different, especially with regard to facilitating greater access to the private sector for commercialization and expectations of remuneration from technology that is commercialized.

Decentralized Research and IP Management

Developments cited in this paper describe advisory services for management of intellectual property conducted through centralized IP offices serving decentralized research systems. While

development programs strengthening national agricultural research increasingly emphasize greater decentralization, with regional and local decisionmaking, when it comes to providing IP expertise, a centralized office or service may be more economical and viable.

The centralized offices described in our case studies provide agricultural research organizations with an economy of scale by investing in one unit to work with designated counterparts at their local research centers, as is the case for Embrapa and AARD. The effectiveness of such arrangements will depend on the services that the centralized facility provides, its availability and responsiveness to the needs of the local client centers, and the ability to effect decisions taking into account both local and strategic needs. Similar considerations have been given to a centralized advisory service for IPR from the CGIAR centers (Reeves 1999).

Centralized offices assisting with IP management do not take over research functions. They exist to address specific responsibilities highlighted among the five tasks identified earlier, relieving local institutes, centers and scientists from the full burden of these responsibilities. The centralized facility can also undertake studies with regard to topics such as benefit sharing and alternative mechanisms to protection. Over time, a balance of responsibilities can be envisioned, moving from advisory services on the one hand, to more focused and centralized management practices on the other.

Such centralized offices will not replace the need for staff trained in IP issues at local institutions, but rather reinforce the need for communication between the local research institutions and the centralized offices. Agreement on a division of labor could be achieved by allocation of responsibilities based on the five tasks. Recently, the CGIAR's Central Advisory Service (CAS) (ISNAR 1999), reviewed such services for the CGIAR centers. The centralized services could provide for the following:

- Educational programs
- Organizing information and policy development workshops
- Maintaining a registry of expertise and an information base on new patents and IP developments

- Research on topics of system-wide importance
- Designing a system-wide patent disclosure form specific to CGIAR
- Assisting in negotiations with IP holders to protect a center's freedom of action
- Providing principles for strategic alliances with private sector.

As experience grows, the CAS may also begin to advise the NAROs on IP management in ways that would facilitate interactions with the international centers.

Enhancing Capacity for Scientists, Managers and Policymakers

Challenges lie ahead as institutes either begin or continue to define the means by which they will manage IP. Continued and expanded education opportunities are needed to address these challenges over the long term; addressing not only sweeping institutional changes, but also the new skills needed by individuals faced with such daunting challenges and responsibilities. The need for capacity and competency in the area of IP management is one of the new frontiers that agricultural scientists, managers and policymakers will face in the coming century.

The Scientific Challenge

Agricultural scientists are clearly affected by globalization trends and intellectual property regimes. For many, this means becoming more strategic and systematic in their collaborative research programs, and seeking clearer understanding of the institutional implications of their work. There are also many administrative matters to attend to, including the way in which laboratory or research notebooks are handled, and knowing when and how to make public presentations or disclosures of research results (Crespi 1998).

The Management Challenge

In many of the case studies cited, researchers function without the type of institutional support needed to properly manage IP. The examples provided from the NAROs, CGIAR centers, and universities illustrate the growing importance that such management has for research organizations

responsive to emerging IPR regimes and cognizant of the potential significance of their own assets. In this regard, gaps exist between scientists and institute directors, between directors and clients, and between institutions and policymaking bodies where modifications of IPR regulations are needed.

Serious attention is needed to address these management gaps to ensure that the primary purpose of intellectual property ownership by NAROs promotes their fundamental research mission. With regard to individual institutes, the opportunity to provide research liaison officers or contact points for the centralized service should be considered (Blakeney 1999). The research liaison officer can improve the understanding of legal rights given for protecting creative effort and will help to further the institution's research mission. Most importantly, this means protecting and maintaining the IP assets of the institute and developing awareness and appreciation of the use of patent documents and registered plant variety data as research resources.

The Policy Challenge

The previous examples have given indications of how national and international research systems are considering policy matters with regard to IPR. However, many questions are still left unanswered regarding *a research system's ability to provide public goods while working in the context of the three global trends: market integration, emerging private sector, and changing legal and regulatory regimes*. Further studies addressing the provision of public goods by national and international research organizations, in relation to globalization trends, are urgently needed. Such studies can help define modalities or scenarios for agricultural research and explore means for appropriate benefit sharing among stakeholders, including alternative treaties to UPOV and opportunities for implementing "farmers' rights" as well as "breeders rights" (CoFaB 1998).

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