

CGIAR Research Strategies for IPG in a Context of IPR

Report and Recommendations Based on Three Studies

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COMMENTARY AND RECOMMENDATIONS

arising from the Joint Science Council-Genetic Resources Policy Committee Study¹

Background

The CGIAR last approached the issue of intellectual property rights (IPRs) in 2000 when the Genetic Resources Policy Committee (GRPC) drew up guidelines for the System's position regarding its own intellectual property (IP) and the IP of collaborators relating to genetic resources.² This document was criticized by certain stakeholders for its overemphasis on defensive patenting by the CGIAR and was never formally adopted.³

In the intervening six years much has happened: the Centers have found, increasingly and particularly in the molecular biology area, that they need to be able to use proprietary technologies; the need for and the implementation of humanitarian licences have become much debated; biotech crops, with varying levels of statutory protection, but still under the control of an increasingly consolidated international plant breeding industry, are now being grown widely in a number of developing countries; and, the System has had its first experiences of third party IP in its own biotech crops. Within the System, the Central Advisory Service for Intellectual Property (CAS-IP) has been established as a resource. Other internal initiatives include that by the CGIAR Private Sector Committee with the Scientific and Know-How Exchange Program (SKEP) to promote interchange between the CGIAR and industry. The Science Council (SC) itself includes a new Standing Panel on Mobilising Science to promote increased interaction between the CGIAR and scientists outside the System in academia and industry. There are also new challenges on the horizon, particularly involving the international transfer of non-Annex 1 species (crops not listed in Annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture, ITPGRFA4) while the 'access and benefit sharing' provisions of the Convention on Biological Diversity (CBD)⁵ have still not been resolved.

Given these changes and the continuing requirement for the CGIAR to act as a provider of international public goods, the SC and GRPC believe that the CGIAR should attempt again to move towards an agreed policy.

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¹ Mike Gale (Science Council), Carl-Gustaf Thornström (CGIAR Genetic Resources Policy Committee) and Stephen Smith (Board of Trustees, IPGRI & Pioneer, DuPont Agriculture & Nutrition)

² GRPC (2002) Guiding Principles for the Consultative Group on International Agricultural Research Centers on Intellectual Property Relating to Genetic Resources. Appendix 3 in the Report of the 11th Meeting of the GRPC for ICW2000. http://www.cgiar.org/corecollection/docs/icw0009.pdf

 $^{^3}$ Thornström, C-G (2002) CGIAR revising intellectual property guidelines 2000 -A non-event with geopolitical boundary and sector transgressing content. $\underline{\text{http://www.cbm.slu.se/eng/perseng/cg.htm}}$

⁴ http://www.fao.org/ag/cgrfa/itpgr.htm

⁵ http://www.biodiv.org

With this in mind, three papers were commissioned to investigate the current status of: IP management within the Centers;⁶ means by which CGIAR scientists can identify third party IP that they might like to access and the terms under which that access might be granted;⁷ and, the humanitarian licence movement and intermediary organizations that have been formed to facilitate the transfer of IP between the private and public agricultural sectors.⁸ Concurrently the International Food Policy Research Institute (IFPRI) has convened and documented a series of meetings to explore public-private partnerships in the context of food security in developing countries.⁹

In this commentary we have attempted to extract some of the key messages of these studies that might be incorporated into an agreed policy and updated version of advice to the CGIAR on IP and access. We also attempt to identify other information, presently lacking, that is needed to allow CGIAR scientists to manage IP in an optimal manner.

Scope

IP is complex and extends well beyond just germplasm and patents, involving: copyrights; plant variety protection systems;¹⁰ database rights (in Europe); trade secrets and confidential information; contractual obligations; and, trademarks and geographical indications. All have the potential to impinge on the CGIAR's freedom to operate with the best and most appropriate technologies. Discussions and agreements at the international level on germplasm are also relevant, particularly the ITPGRFA and issues covered within the CBD, because they impinge heavily on the ways in which Centers must manage germplasm and associated IP. The CGIAR's task is to understand IP and work within the legal boundaries while producing and distributing international public goods, which is an extremely difficult and demanding task. This complexity notwithstanding, the commissioned papers concentrate on access by CGIAR scientists to third party IP and this dominates the discussion below.

The Millennium Development Goals of the UN¹¹ highlight the need to cooperate with the private sector to "make available the benefits of new technologies". In view of emerging new legal boundaries for use and exchange of germplasm, technologies and research tools, the CGIAR System must clearly position itself as regards International Public Goods (IPG) and these new contexts.

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⁶ Apollonio-Henson, V (2005) Strategies for the CGIAR to conduct Research and deliver Technological Innovation that benefit the Poor in a Context of Intellectual Property Rights. http://www.sciencecouncil.cgiar.org/publications/pdf/GRPC-SC_IPStrategiesRep

⁷ Chojecki, AJS (2005) Access to information on agricultural biotechnology property rights and the availability of technology for the CGIAR's international public good research. http://www.sciencecouncil.cgiar.org/meetings/meeting/SC4/SPPSaccess.pdf

⁸ Toenniessen, G & Delmer, D (2005) The role of intermediaries in maintaining the public sector's essential role in crop varietal improvement.

http://www.sciencecouncil.cgiar.org/meetings/meeting/SC4/SPPSintermed.pdf

⁹ IFPRI (2005) Proceedings of an International Dialogue on Pro-Poor Public-Private Partnerships for Food and Agriculture. http://www.ifpri.org/events/conferences/2005/ppp/pppproc.asp

¹⁰ Universally required as of 2000 by the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).(http://www.wto.org/english/thewto_e/minist_e/min99_e/english/about_e/10trips_e.htm)

¹¹ http://www.un.org/milleniumgoals/

General

Some CGIAR scientists view patents as a potential impediment to fulfilling their mission. Excessively broad claims, multiplicities of patents, and unethical abuses of the patent system live on as perceived obstacles. Nevertheless there is willingness in both academia and industry to collaborate with the CGIAR. Plainly, a continued culture shift within the System is required and the CGIAR needs to develop means by which that external goodwill can be tapped and grown.

While it is clear that proprietary information and materials will often be made available, it is also clear that the world will not come to us. The System must become more proactive and a common, and communal, IP policy would be a step towards this. The indications are that universities, public research organizations (advanced research institutes) and the private sector are waiting for the CGIAR to approach them. This will involve yet further change in the CGIAR culture, as has already happened in the public sector in the North over the past decade. Moreover, balance needs to be struck between, on the one hand, promoting the awareness that IP could be utilised as an opportunity, while, on the other, preventing abuses and distortions of the IP system as applied to genetic resources in IPG research in agriculture. This balance must also be extended to our partner national agricultural research systems (NARS). Both CGIAR and NARS are going to have to learn to skilfully negotiate the terms and conditions of IP licences, which is a challenging task.

The CGIAR's and NARS' understanding will have to include the realities of confidentiality; statutory regimes; biosafety; competitive pressures; uneven IP protection worldwide; monitoring and impact assessment; and arguably most importantly, segmented markets in defined territories. The private sector partners' requirements will involve all of these components of 'product stewardship'. The CGIAR partners will have to be clear that, in this environment, IPGs are compatible with IPRs, albeit with new legal boundaries that change the terms of access and exchange.

Optimal management and stewardship of products of third party IP will require close partnerships between Centers and individual NARS in the earliest stages of research and product development. NARS can no longer be mere recipients of near-finished varieties. This same observation emerged from a recent SC biosafety study¹² where it became clear that active involvement of NARS partners is required in a CGIAR Biosafety Network as well as in collaborative development of 'business plans' for biotech products destined for release. The involvement of NARS representatives in the CGIAR Biosafety Network should inform NARS and System scientists alike of general regulatory and transgenics product stewardship issues. Similarly, close relationships between Center researchers and industry (or academia) will need to be fostered if the benefits of the partnership are to extend beyond the simple transfer of IP, or 'narrow-sense IP'.

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¹² Johnson, B, Persley, G, Chopra, V, Kapuscinski, A & Olembo, N (2004) A Report of the biosafety panel to the CGIAR SC on biosafety policy and practices of the CGIAR Centers. (Final Report to be published)

Access to technologies by Centers and the System

While Chojecki's study stresses that there are avenues through which much IP, either in the form of information or material, could be made available to Center scientists, its release for research purposes and its use in products for the developing world agriculture will involve informed negotiation.⁴ For these purposes it is also plain that the System's decentralisation and autonomy is not helpful in dealing with the private sector, particularly while industry is already 'centralised' through consolidation. Deals must be initiated and struck by individual Centers, but they should accommodate the future participation of other relevant Centers. This, of course, also requires that Centers participate in coordinated and mutually supported research. The role of CAS-IP and Center-based IP units will be vital in this respect, with CAS-IP providing corporate memory so that every negotiation, on the CGIAR side, does not have to start from scratch.

CGIAR Systemwide principles are needed. These could ideally include the notion of other Centers as 'preferred partners' so that, for example, third party IP can be used in other Centers for other commodities without having to revisit the original arrangement. The private sector must have confidence in the technical ability and processes, such as laboratory and record management, of the CGIAR recipient. Industry is likely to insist on specific projects with defined fields of study and defined countries under confidentiality terms. However, each new project must have feasible outcomes with clear and credible benefits over reasonable periods and it will be necessary that that the CGIAR partner will have a clear idea of costs and risks and benefits and the relative benefits of alternative approaches. Further third party access to proprietary technologies after an agreement is in place is likely to be very difficult.

Almost certainly all arrangements will continue to be on a case-by-case basis, at least until precedent and "tried-and-tested" System-industry relationships allow a more generic approach. Industry does not hold all the cards. We may be past the time of 'sweet deals', but the System still has much to offer public-private partnerships for the use of proprietary IP in the production of IPG. Among the obvious assets (legally defined under the ITPGRFA) that the CGIAR administers are the breeding programs and the detailed knowledge of the material and the intimate understanding of the crop plant germplasm collections that the Centers hold. Less obvious assets are our networks and regional experience built up, in some cases, over the past 40 years.

It is probable that individual agreements will cover the transfer and use of specific technologies. Trade secrets surrounding that technology will not be included. Such 'secrets' that will be most valuable are knowledge of industry's failures which could save considerable Center time and resources by avoiding the same mistakes. This information may be available but will only follow real partnerships sustained by individual researchers.

In general, however, agreements will come about only with the private sector partner's commitment to participate in the betterment of the world, independent of its own financial interests and the desire to be seen as a good corporate citizen, and possibly, a desire to make research that is no longer of strategic value to the company available for use in developing countries for food security purposes.

Requirements of suppliers of IP

Underlying the CGIAR's approach to negotiations must be a clear understanding of the various organizations with which we will interact. The needs and expectations of different partners will vary: multinational industry is usually a supplier of IP; smaller national companies are also potential suppliers of IP, whilst some, particularly private sector seed companies, will be recipients of CGIAR products. Academic institutions such as members of the Public Intellectual Property Resource for Agriculture (PIPRA) and other independent public sector organizations will similarly differ in their aspirations and approaches. The range of 'humanitarian licence' options available is described in the study by Toenniessen and Delmer.⁵

Industry is likely to be less bothered by low or non-existent royalty returns from CGIAR usage; they are more likely to be concerned by issues of product stewardship, liability and their own reputation within specific national boundaries or by market segmentation where they expect most demand for their products. Academic suppliers are likely to be concerned about ownership retention and tangible recognition in the event of a 'commercial' outcome. Restrictions on applications in certain crops and practises are also likely. Everybody will want access to further IP developments arising from CGIAR-mediated use.

Each negotiation for individual technologies must be accompanied by a clear proposed route for research and deployment. In particular, the weak points in the chain, both for product success and IP product stewardship, must be understood. These routes will vary case by case for trait, associated proprietary knowledge and/or technology. The later stages of any IP's itinerary will almost always be in the hands of NARS, and this again requires the very early involvement of NARS in product development.

The International Treaty on Plant Genetic Resources for Food and Agriculture

During the period in which the negotiations for the ITPGRFA took place, the 1994 agreement between FAO and CGIAR Centers, and the subsequent Joint Statements, had governed the exchange and distribution of designated germplasm under agreed MTAs for plants and non-plants. As demonstrated in a recent IPGRI study, however, uncertainty has led to a greater reluctance in a number of countries to provide new germplasm under the 1994 FAO/CGIAR regime. This inertia has created problems for Centers wishing to extend and update *ex situ* collections of the CGIAR's crops. ¹³

Some of the problems of international exchange might be overcome by the adoption of a new standard MTA (SMTA) during the First Meeting of the Governing Body of the ITPGRFA in June 2006, and the pending agreement between the Centers and the Governing Body scheduled towards the end of 2006.¹⁴ Annex 1-listed crops and associated information, including traditional and farming systems knowledge (TK) will be available under the terms of the new standard MTA. Non-Annex 1 crops and

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¹³ Halewood, M, pers. comm. (2006)

¹⁴ Commission on Genetic Resources for Food and Agriculture (2006) Report for the First Meeting of the Governing Body of the ITPGRFA. (GB-1/06/REPORT) http://www.fao.org/ag/cgrfa/gb1.htm

associated TK, i.e. genetic resources and TK under national sovereignty, will be available at the discretion of the provider. The Harvest Plus and Generation Challenge Programs are already gaining valuable experience in facilitating international movement of non-Annex 1 crops. With the move towards income generation and research on high value crops, as identified in the New CGIAR Priorities, the Centers are likely to have to deal increasingly with a growing number of non-Annex 1 species. ¹⁵

Traditional knowledge

TK is a complex topic that cuts across many different policy areas including IPR. While there is still some debate on the precise definition of TK, discussions have been continuing within CBD under Article 8(j) on the implementation, particularly on: the development of an ethical code of conduct; facilitating participation of indigenous/local communities in deliberations; treatment of *sui generis* systems; and how TK relates to the Access and Benefit-Sharing provisions. This discussion is relevant because CGIAR materials and skills that are brought to the bargaining table may include TK. It is most important that a good faith attempt is made to identify all these elements in all negotiations, while keeping up-to-date on the details of the CBD debate.

The CGIAR must value traditional knowledge and endeavour to work with the holders of traditional knowledge through participatory research. Furthermore the CGIAR must respect the rights of traditional knowledge holders and aim to seek their consent for the use and publication of their traditional knowledge.

Conclusions

It is clear that the CGIAR must increase access to IP from both the private and public sectors if we are to maximize the benefits of our work for the lives of the world's poor. Although we must continue our efforts to build effective partnerships with the private sector, it is also particularly important at this juncture that we work ever more closely with other members of the public sector the world over to involve them in projects benefiting developing countries. With both private and public organizations the key is partnership, meaning sustained relationships, involving several Centers where appropriate, in an environment of informed product stewardship.

The System can no longer expect to impact developing country agriculture on its own and must work with initiatives such as PIPRA, CAMBIA's Biological Innovation for Open Society (BIOS) and the African Agricultural Technology Foundation. Staff exchanges with industry - as are being promoted by the CGIAR Private Sector Committee's SKEP initiative - will be important to build up understanding and trust and to share lessons on Product delivery.¹⁷

SC (2005) System Priorities for CGIAR Research 2005-2015. http://www.sciencecouncil.cgiar.org/activities/spps/pubs/Priorities%20Dec%2005.pdf

¹⁶ See http://www.biodiv.org/programs/socio-eco/traditional/default.asp

¹⁷ Wollweber, D. (2005) Intellectual property rights and public-private partnership collaborations in the CGIAR Report of a SKEP project between Bayer CropScience and IFPRI. http://www.ifpri.org/themes/ppp/SKEPCoverNote.doc

Partnership is the future but while the world may be willing to partner with the CGIAR, the CGIAR must actively seek out and cultivate well considered opportunities. This does, however, mean the CGIAR must, at the same time, develop and demonstrate corporate leadership in effective stewardship for the benefit of the world's poor.

Recommendations

These notes and the associated Studies^{5,6,7} that follow demonstrate clearly that all the partnerships, information and tools that the CGIAR and its partner NARS need for credible and effective use of third party IP are not to hand. Clear recommendations for improved IP management at the Center level are given in the study conducted by Apollonio-Henson.³ Below we append suggestions for more coordinated and effective IP management at the System level.

1. CGIAR Guidelines for Centers and Challenge Programs for managing and accessing IP are redrafted. These guidelines should deal with all aspects of IP belonging to third parties and the CGIAR itself. While the scope should extend beyond germplasm issues, GRPC is the appropriate drafting body. Consultation with all relevant stakeholders, including of course all the Centers themselves, will be necessary to avoid the problems encountered in 2000. A secondary role of the document would be to develop an IP 'language' that would be common to all Centers, understood outside the System, and, consistent with common practice.

And to inform the drafting process;

- 2. Stewardship is key, by both the CGIAR itself and its NARS partners who will deploy the products of collaborative science. Guidelines to credible product stewardship regimes are urgently needed, which could either be a separate document, or part of the above Guidelines for Centers and Challenge Programs for managing and accessing IP. These will be based on CGIAR and NARS experience to date and the expectations of the private and public sector IP donors. Product stewardship will include responsible management of third party IP and the special situation of transgenics and regulatory issues. Drafting by CAS-IP, probably together with a consultant from industry, is one way forward.
- 3. 'Liability', which is still not tested for biotech crops, is key in relationships with the private sector, who are likely to require a clear and stated willingness to accept liability for CGIAR and NARS actions. While issues regarding liability should be part of the above guidelines, action is needed in order to ensure *clearer understanding of liability at CGIAR and NARS level*. This may require inputs from an independent expert in the form of a Study, including some form of training/awareness sessions possibly with support from CAS-IP.

Other tools and incentives to help CGIAR researchers:

4. Patent databases and search facilities including the PIPRA M-CAM database and BIOS are discussed below. However a database of patents relevant to developing country agriculture which have expired (which is often not a simple data for all territories) or are due to expire would be most valuable for CGIAR scientists. CAS-IP should be asked to investigate the feasibility and cost of developing and maintaining such a tool.

- 5. Another *specialized* patent database that would be of value to many CGIAR scientists is a list of *marker-assisted selection patents*. Further discussion is required to consider the feasibility and modality of establishing this and other such specialized tools (e.g. by the Genomics Task Force and other players).
- 6. Corporate knowledge. A database of current and past CGIAR partnerships, best practises and formal evaluations is needed so that such information does not get lost as personnel leave the System. The home for such 'lessons learned' information, much of which will be confidential and sensitive, must be CAS-IP. This will not be a public document.
- 7. Incentives may be needed to speed the culture shift that is still required within the System. One possibility is a new CGIAR award for exemplary Center-industry partnerships involving the use of proprietary technology in developing countries. Both partners should be at AGM to receive the award.

The legal boundaries for access and exchange of germplasm, technologies and research tools have changed considerably in the last decade. In order to respond to the increasing needs for IPR guidelines, tools and services, the CGIAR should strengthen its overall capacity in these areas. The CGIAR must proactively meet the challenges involved in public-private partnerships and clarify the conditions under which it will collaborate with the international public and private sectors. Inaction is no longer an option.

CGIAR RESEARCH STRATEGIES FOR IPG IN A CONTEXT OF IPR SUMMARIES

This report is based on three studies:

- Strategies for the CGIAR to conduct Research and deliver Technological Innovation that benefit the Poor in a Context of Intellectual Property Right by CGIAR Central Advisory Service on Intellectual Property (CAS-IP);
- Access to Information on agricultural biotechnology property rights And the Availability of Technology for CGIAR's international public good research by J. Chojecki; and
- The Role of Intermediaries in Maintaining the Public Sector's Essential Role in Crop Varietal Improvement by G. Toenniessen and D. Delmer.

The first study was jointly commissioned by the CGIAR SC and the CGIAR Genetic Resource Policy Committee, while the other two studies were undertaken at the request of the CGIAR SC. The three studies were commissioned separately and are self-standing, although they are paginated consecutively in this document. Each document has been summarized below.

In Strategies for the CGIAR to Conduct Research and Deliver Technological Innovation that Benefit the Poor in a Context of Intellectual Property Rights, CAS-IP examines the current understanding/management of IP and 'product stewardship' at CGIAR Centers. The report notes that many Center scientists are aware of the issues surrounding IP Management but they generally perceive them as obstacles to research. Although the benefits of good IP management have been clearly demonstrated, the development of a solid IP management practice has been ad hoc and uneven at System level. Only a few Centers have established IP Management Units, either by donor request or as a result of a negative IP-related experience. The report underlines the need for increased efforts in conveying the importance of IP Management to Center staff. In-house IP Management Units, backstopped by CAS-IP, were vital in providing "resources for the production and distribution of public goods at all levels". The report also suggests that all future project proposals include a brief IP Management Plan.

In Access to Information on Agricultural Biotechnology Property Rights and the Availability of Technology for CGIAR's International Public Good Research, Chojecki explains the means available to CGIAR scientists for assessing existing patented technologies, and considers the terms under which access to technologies might be negotiated. He points out that much information on existing technologies and IP are available and "if a technology can be identified, then ways can probably be found to gain access". Large multinational companies are generally willing to make technology/IP available to the CGIAR System if their conditions are met. Nevertheless CGIAR Centers have expressed frustration with the increasingly complicated processes associated with IP. There is an obvious perception gap between the sectors in their preferred collaboration modes, but there have also been successful partnerships. Partnerships with public sector research organizations have been largely unexplored. The author concludes that the CGIAR Centers need to "engender culture that respects and understands international IP issues as part of routine research project management activities" in order to build a working relationship with the other sectors.

In *The Role of Intermediaries in Maintaining the Public Sector's Essential Role in Crop Varietal Improvement,* Toenniessen and Delmer review the relationship between public and private sectors within the changing landscape of ag-biotech research. They point out the current problems with the free flow of research results and knowledge between the two sectors in delivering improved crop varieties to the developing countries at no or low cost. While there is an increasing focus on IPR in trade and in the national obligations towards WTO/TRIPS, the authors warn that "a major IPR change that is threatening the operations of the international agricultural research system comes from public, not private sector research institutions." The public sector is constrained in its freedom to operate, making their products unavailable or highly IP encumbered and lacking avenues for commercialization. The authors underline the need for new mechanisms – perhaps through the formation of intermediary organizations - that re-establish the linkages between IARCs, academia, and the private sector in order to facilitate the technology transfer to developing countries. Three such intermediary initiatives are described in detail.

STRATEGIES FOR THE CGIAR TO CONDUCT RESEARCH AND DELIVER TECHNOLOGICAL INNOVATION THAT BENEFIT THE POOR IN A CONTEXT OF IPRS

CAS-IP

Part I: The CGIAR Center level^{18,19}

Summary

This report attempts to summarize observations and data from a variety of sources on IP Management practice in the CGIAR Centers as of mid-2005. Sources include Center and CGIAR historical documents, results of an electronic survey, anecdotal information from meetings with CGIAR staff and visits to the Centers, as well as information that is available from several other recent reviews and other publicly available resources. With consideration of all of this information a set of conclusions and recommendations are put forward by the authors in an attempt to encourage improvement of IP Management practice in the Centers, especially in this time of increasing interest in working with the private sector and an increased commitment to share attribution and other benefits, while keeping in mind that IP Management practice should be used to support trust and ethical practice.

Conclusions

- As a whole, individual scientists are aware of IP issues generally. However, the
 positive relationship between good IP management practice and the increased
 availability of public goods is not well understood. This frequently translates into
 thinking that the requirements of IP management are onerous and are just creating
 more paperwork for the scientists.
- 2. Most third party inputs are brought into the Centers under material transfer agreements (MTAs) or under informal arrangements (associated with inputs of data, survey responses, traditional knowledge, etc.).
- 3. Those Centers that have well-functioning IP Management Units have been able to realize the benefit of these units with regard to an overall improved research

¹⁸ This study was commissioned by the Genetic Resources Policy Committee and CGIAR SC as a joint project of mutual interest The CGIAR SC also has requested reports in other areas regarding Intellectual Property issues for the CGIAR, as described in the paper, "What strategies for the CGIAR to conduct research and deliver technological innovations that benefit the poor in a context of intellectual property rights? (June 30, 2004, the CGIAR SC-Secretariat, Rome).

¹⁹ The authors are Victoria Henson-Apollonio, Senior Scientist, Manager, The CGIAR Central Advisory Service on Intellectual Property, hosted at IPGRI, Rome, Italy, and B. Hanumanth Rao, Manager, the Intellectual Property Management Unit, ICRISAT, Pantancheru, India. This article reflects only the personal views of the authors and does not represent approval or agreement of the information by the CGIAR Centers or CGIAR System.

- management environment with pertinent project information readily available and accessible in one place.²⁰
- 4. In-Center events are the most popular way of helping staff learn about IP and product development/delivery/partnership issues.
- 5. IP Management practice is uneven among the Centers. A few Centers have been able to establish stable IP Management Units; a few more are in the process of establishing units, while many Centers do their IP Management in an *ad hoc* manner backed up by IP Committees that meet once a year or less.
- IP Management in the Centers (and the CGIAR System, as a whole), is underresourced.
- 7. Most Centers have learned their lessons about the need for IP Management, when something has gone wrong.
- 8. Donor attitude makes a big difference. When a donor requires a Center to carry out IP Management, it gets done. The Challenge Programs, in particular the Generation Challenge Program, have made a marked difference in advancing the thinking and practice in those Centers that participate in this CP.

Recommendations

- The Centers, (and those that fund the research of the Centers), must realize that IP
 Management is a crucial part of doing business and getting products distributed in
 today's world, especially, in the area of public goods. Resources must be set aside for
 IP Management.
- 2. Each Center should have an in-house IP Management Unit, with an annual operational budget, backed up by an IP Committee. (This might be a full-time or part-time need, depending upon the Center. Thus, Centers might be able to share personnel to fit this need.)
- 3. The Central Advisory Service on IP (CAS-IP) should continue with providing leadership and support to the Centers to standardize and institutionalize IP and technology transfer practices. CAS-IP needs to do more to help Centers streamline IP Management practices and to provide strategic help that results in an increase in the production and delivery of public goods.
- 4. The Centers need to develop guidelines on the acquisition and use of 3rd party information, especially information that is included in Center products such as databases and publications.
- 5. Centers ought to work with their host country partners, particularly developing country hosts of Centers or regional offices, to exchange IP Management ideas and practice, with a primary aim to foster a community of practitioners that provide support and act as resources for the production and distribution of public goods at all levels.
- 6. Every proposal prepared by Center staff, should have at least a brief IP Management Plan, as a part of the proposal document, emphasizing the public good nature of the anticipated project products and the usage of 3rd party inputs.

²⁰ For example, ICRISAT's IP Management Unit allows research managers to quickly pull together all necessary contractual/funding information regarding proprietary genes, while ILRI's IP Manager has been central in the management of the ECF project.

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- 7. Each Center should strive to have external access of all Center publications in a repository (either at the local level or, at a global CGIAR-wide level) in a manner that will facilitate the use of such publications databases as non-patent literature (NPL).
- 8. Every Center should schedule regular in-Center, awareness raising and interactive workshops to make note of the external environments.
- 9. All Center websites should have their IP policy statements accessible on or linked to the main page.
- 10. The Centers should encourage the CGIAR System to use language that is: a) understood by those that are external to the CGIAR and b) consistent with commonly used IP Management practice, in the scientific world, the business world, and at the farm-level.
- 11. Data sharing, data access, and database management issues are of major concern to all the Centers. Centers should promptly display copyright notices and/or disclaimer notices on their websites and include information regarding distribution and attribution as a part of the metadata supplied with data sets.
- 12. Expertise in product identification, development and delivery should be included on the EPMR panels and/or periodic independent IP Audits should be required of Centers.

Introduction

The mission of the Consultative Group on International Agricultural Research, the CGIAR, is: "To achieve sustainable food security and reduce poverty in developing countries through scientific research and research-related activities in the fields of agriculture, forestry, fisheries, policy, and environment." As the operational arm of the CGIAR System, the 15 Future Harvest Centers, also referred to as International Agricultural Research Centers, strive to generate public goods, that are accessible to all and that can be widely disseminated and used to benefit the resource poor and the developing world. In this study we examine the intellectual management practices followed by CGIAR scientists that: a) encourage innovation, b) support the use of cutting-edge technologies based on the latest scientific knowledge, tools and materials, as inputs for Centers' products and knowledge, and c) prepare the Centers for efficient and effective distribution and uptake of Centers products for the benefit of the poor.

Methodology

This report is based on: a) the results of an Internet survey commissioned by the CGIAR Genetic Resources Policy Committee (GRPC) and the CGIAR SC launched in December of 2004 and completed by all Centers and CGIAR Challenge Programs by August 2005; b) a series of informal consultations with a variety of Center staff,²¹ including discussions held at the recent meetings such as the 5th Annual IP-Strategy Meeting,²² the 18th Meeting

²¹ Recommendations from the IP Management Surveys that were carried out during the period of 1998-2001 have also been a part of these Center-CAS discussions.

²² Annual IP-Strategy Meetings of the IP=Strategy Group of CGIAR IP Managers/Focal Points, are organized by the Central Advisory Service on Intellectual Property (CAS-IP) to facilitate the exchange of

of the GRPC, and the recent meeting of the Private Sector Committee with the Executive Alliance of the Future Harvest Alliance; and, c) information regarding IP practice and technology transfer of the Centers, gathered from published articles.²³

The GRPC/SC/CAS-IP Survey²⁴

The GRPC/SC/CAS-IP Survey was commissioned at the 16th meeting of the GRPC in the spring of 2004, and followed up on by CAS-IP and the SC Secretariat, during the fall of 2004. GRCP member, Carl Gustaf Thornstrom and a SC subcommittee headed by Onesmo K. ole-MoiYoi, reviewed survey questions and the CGIAR Center IP Manger/Focal points were asked for input and review of the questions as well. After this review, CAS-IP engaged B. Hanumanth Rao, the IP Manager at ICRISAT, for the transposition of the survey to an on-line form that was subsequently adjusted to the "Survey Monkey" format²⁵ for the convenience of the respondents and to take advantage of the analytical aspects of this format. The "GRPC/SC Survey involving the CG Centers and Challenge Programs", consisted of 77 questions in a variety of formats (e.g. questions with responses listed in "pull-down" menus, responses as Yes/No "radio" buttons, free text space for responses, and responses where numbers could be used for rating suggested answers). After the introduction (Part 1), the survey questions were grouped into topics on: 2) Institutional Information, Q1-5; 3) Inputs used by your Center/Program, Q6-12; 4) IP Awareness in Your Center/Program, Q13-21; 5-7) IP Policy and Implementation in Your Center/Program; Q22-25, 26-28, and 29-62; and, 8) IP Strategy of your Center/Program (Q 63-77).

The survey was launched on a commercial site, http://www.surveymonkey.com, in December of 2004 and was closed in August 2005. This time window was needed to encourage full participation from all the Centers and CGIAR Challenge Programs.²⁶ All 15 Centers and 4 Challenge Programs completed a response to the survey.

Consultations with Center staff and Discussions at the IP-Strategy Meetings

Staff of the CGIAR Central Advisory Service on Intellectual Property (CAS-IP) has had an opportunity to visit all of the Future Harvest Centers of the CGIAR and to interact with the CGIAR Challenge Programs over the last three years. In the past year, Victoria Henson-Apollonio, Manager of CAS-IP, has visited nine of the Centers²⁷ and met with management of three of the Challenge Programs.²⁸ Interns with the "CAS-at-Cambridge"²⁹ project have been engaged in internships at an additional three Centers³⁰

experiences among the Centers. This year's meeting was held at CIAT, Cali, Colombia, 17-19 August with representatives of 11 Centers participating in the discussions.

²³ These reports are all publicly disclosed information and most are available through the Internet.

²⁴ Appendix 1 contains a printout of the questions that were included in the on-line survey.

²⁵ More information regarding the development and use of surveys, employing "Survey Monkey©" can be found at the site: http://www.surveymonkey.com.

²⁶ The CGIAR Challenge Programs include the 3 pilot Challenge Programs: GenerationCP, HarvestPlus, and the Water&FoodCP; and the one regular Challenge Program, the Sub-Sahara Africa (SSA)-CP.

²⁷ These Centers include: CIAT, CIMMYT, CIP, ICARDA, ICRISAT, IFPRI, IITA, IPGRI, and WorldFish.

²⁸ The Challenge Programs that have interacted with CAS-IP during the last year include: the GenerationCP, HarvestPlus, and the Water&FoodCP.

²⁹ "CAS-at-Cambridge" is (currently) an informal arrangement between CAS-IP and Dr. Sean Butler of the Law Faculty of St. Edmund's College of Cambridge University that has been on-going since 2003.

during 2004-05. These interactions have provided information that is related, in a general way, in this report. (No confidential information is disclosed in this report.)

Since 2001, the IP Managers/Focal Points of the Future Harvest Centers have had an annual meeting, organized by CAS-IP, where a summary of the year's Center-related IP Management practice is presented by each Center and current IP Management issues are discussed. Our meeting at CIAT, in Cali, in August 2005 provided for exchange of information from a majority of the Centers and CPs. Summaries of material from presentations and discussions from these strategy meetings, also inform this report.

Other fora in which Centers discuss IP policy and practice include meetings with national/regional partners, such as the "Workshop on Dissemination of Improved Fish Strains: Country-Specific Action Plans and 8th INGA Steering Committee Meeting", recently held in Shanghai and the Second Annual Research Meeting of the Generation Challenge Program, held in Rome, a meeting of the CGIAR Private Sector Committee and the Directors General of several Centers in Washington, DC.³¹

Publications in the public record

Over the past few years, several investigators have published reports containing information and opinions about the CGIAR Centers and/or System that is pertinent to the discussion in this report. These materials, along with other publicly available information, represent additional independent sources that bear on the topic and as such, materials from these reports are also discussed in the context of this current report.³² Sources are listed in footnotes and the bibliography.

Historical context

This current report builds on previous work that evaluated how the Centers were handling IP, proprietary materials, and other IP Management issues in the ~1998-2001 time period and that also contain advice for preparing the Centers for accessing and using 3rd party materials and information, ca. 1998, for "Mobilizing Science for Global Food Security", via agricultural research. The two main groups of documents include the "Report of the CGIAR Panel on Proprietary Science and Technology" and associated appendices/commentaries, presented at the 1998 CGIAR Mid-Term Meeting, and the in-Center IP Management audits, conducted from 1998-2001.

Report of the CGIAR Panel on Proprietary Science and Technology, 1998

This study, commissioned by the forerunner of the current CGIAR SC, the Technical Advisory Committee (TAC), was conducted by a panel of 14 external experts, over a period of time from September 1997 through March 1998.³³ The panel held an electronic

³⁰ 5-6 week, internships have been sponsored by CIFOR, WAFC/ICRAF, and IWMI during 2004-05. CIAT hosted the first intern in the summer of 2003.

³¹ CAS-IP representative, Dr. Sean Butler attended the Washington, DC meeting.

³² It is not suggested that the list of materials that have been reviewed for this report, is complete or exhaustive.

³³ Archived documents from the Mid-Term Meeting would suggest that the TAC, the Private Sector Committee, and the Center Directors, (as described in a meeting note from the Center Directors entitled, "Taking Biotechnology forward in the CGIAR", convened the Panel on Proprietary Science and

forum, consulted with Members of the CGIAR community and other stakeholders, held two meetings, and conducted two surveys. One survey looked at what $3^{\rm rd}$ party materials were being used by the Centers and the other survey took a cursory look at what $3^{\rm rd}$ party material was incorporated into Center products.

The survey of 7 Centers entitled, "The Use of Proprietary Biotechnology Research Inputs at Selected Centers", was conducted as a part of this panel study.

Conclusions of this survey were that:

- Proprietary (3rd party) inputs were being extensively used at the time of the survey (1998);
- Material Transfer Agreements (MTAs) were the most commonly used legal instrument for transfer of these inputs;
- Centers were not actively seeking IPRs over their products and innovations; and
- Centers could potentially benefit from additional technical expertise with regard to management of Intellectual Property.

Recommendations from the TAC-commissioned panel included: 1) That the CGIAR must be guided by its mission when using proprietary inputs; 2) that the CGIAR must acquire expertise for the Centers to deal with IP Management issues; and 3) that the existing "Guiding Principles on IP" should be revised.

Commentary on this study by the members of the 1998 Technical Advisory Committee supported and expanded on these three recommendations, to make note of the importance of the external environment in which the Centers work, particularly international treaties/agreements and the delicate, but important nature of Centers' considering the option of seeking protection over Center products.

In remarks provided by the 8th Meeting of Private Sector Committee (PSC) of the CGIAR, the PSC members indicated a certain amount of dissatisfaction with what they perceived to be a lack of decisiveness in the report which they felt would lead to an inability to implement the recommendations in a way that would allow Centers to work with the private sector. While the PSC took issue with the Panel's treatment of licensing IP in countries where no formal IPRs existed, they emphasized that a systemwide framework, consistency of approach to IPR issues and the CGIAR research mandate, centralized legal expertise, and an inventory of Centers' IP would augment the Panel's recommendations and further the successful acquisition of technologies from the private sector.³⁴

Technology, in order to help the CGIAR System understand what the situation was in 1997-98, and how the Centers could prepare themselves to access biotechnological tools and materials as research inputs. These documents, and others, can be accessed at the URL: http://www.worldbank.org/html/cgiar/publications/mtm97/mtm97.html.

³⁴ See the document, "Private Sector Comments on the Reports of Biotechnology and Proprietary Science Panels and Report of the Eighth Meeting of the CGIAR Private Sector Committee", 1998. Available at the URL: http://www.cgiar.org/corecollection/docs/mtm9805a.pdf.

Center IP Management Audits³⁵

Intellectual Property Management audits were conducted at 15 Centers during the 1998-2001 time period.³⁶ The audits were performed by a variety of institutions, including three non-profits (auditing four Centers), two academic faculty (auditing five Centers), and three private law firms (auditing six Centers). While the audits were initially based on a standard terms-of-reference that originated from the Chair of the IP subcommittee of the Center Directors Committee, individual Centers requested specific changes in these TORs and as a result, the uniformity of the exercise was not maintained overall; for example, very few Centers chose to inventory their IP. However, most of the recommendations made by all of the auditors had a common theme of identifying situations where Centers' rights and policies were unclear and needed to be addressed. A sample of specific recommendations from several audits includes:

- Wasted opportunities for improvement of IP Management need to be addressed by the Center.
- Modification of letters of agreement (LOAs) to include several clauses more protective of a Center's IPR.
- Addition of a paragraph that specifically addresses IPR in employment agreements, visitor, and consultant agreements.
- A standard MTA should be used for distribution of all materials, with the exception of those held in trust under the FAO agreement.
- Guidelines for data storage and management should be put in place.
- Clear instructions on delegation of authority should be issued for the signing all contracts and legal documents.
- Copyright protection notices should be put on all Center publications and websites.
- Mechanisms/structures, such as an IP Management Unit, should be put into place, so that scientists are free to operate on their tasks.
- Center should have an IP policy.
- Center should establish an agreement database as part of its file management strategy.

The auditors examined host country agreements, interviewed scientific and administrative staff, and researched specific issues for Centers. Some of the auditors gave in-Center seminars at the onset and/or at the finish of the auditing process. All of these interactions provided an opportunity for increasing awareness of Center staff about IP/IPR issues of importance to each Center and sensitized upper management at all of the Centers about the need for attention to IP Management. However, an overall interpretation of the exercise, expressed to CAS by many of the Directors General at the time of the completion of the audits was that the performance of the Centers was satisfactory in that no irregularities or serious problems such as infringement were discovered.³⁷ Thus the net effect of the IP Audits may have been to give the Centers a sense of comfort and a false impression that they did not need to markedly change their approach to the way in which IP Management was being carried out in their Centers.

³⁶ These audits are also referred to as "IP Audits", but the format departed substantially from the common practice of IP auditing as practiced by law firms specializing in intellectual property matters.

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³⁵ The Center Audit reports are confidential. However, one Center, CIP, published a public summary, in 2000, of the recommendations from its audit, performed by Prof. Neil Hamilton of Drake University.

³⁷ It is interesting to note that one of the Centers reported at the 2005 IP-Strategy Meeting that they had been prompted to assess whether they had acted the recommendations from their year 2000, IP-Audit, by the GRPC/SC Survey!

Results of Current exercises to assess IP Management Practices in the Centers

The GRPC/SC/CAS-IP Survey

All 15 Centers and 4 Challenge Programs responded to the survey. For most of the Centers/Programs, survey information was given by the Center's IP Manager/focal point or by individuals at the program manager, Deputy Director General (DDG)-level, with only a minority of the Centers choosing to include responses from a cross-section of Center personnel.³⁸ Most of the surveys were filled out in their entirety, although a few were missing responses for a majority of the questions. Some inconsistencies in the answers were also noted which could reflect confusing questions or problems with the use of the "Survey Monkey" format.³⁹

Of the choices given in the survey, the categories of the highest use inputs used by the Centers/Programs included: a) Plant germplasm, obtained under Material Transfer Agreements; (MTA); b) Gene markers, obtained under MTA, licenses, or with no accompanying agreement/contract; c) Nucleotide sequence information obtained under licenses; and d) Farming systems information, acquired under informal agreements or with no accompanying agreement/contract. While, of the choices given in the survey, the categories of the lowest use inputs used by the Centers/Programs included: a) Plant and animal cell lines; b) Isolated animal DNAs; and c) Isolated proteins.

In contrast to the survey conducted in 1998, the overall use of 3rd party material in research at Centers was noted to be low, and the overall incorporation of 3rd party material into Center/Program products was also judged to be low. Most Centers/Programs (82%) indicated that scientists are aware about the use of 3rd party IP in Center products. In consequence, one would expect that the levels of use in Center research and products are a true reflection of actual practice. In addition, those products listed as most likely to contain 3rd party material were given to be: a) Databases; b) Germplasm (improved); c) Publications, including websites; and d) Farm survey data/indigenous knowledge. These results are somewhat surprising, even taking into account that Centers may not be incorporating genes, gene markers, etc. in their products per se and that many of these reagents are synthesized in-house for use in marker assisted breeding or other molecular breeding strategies. The Centers seem to understand that information is a large part of the 3rd party material that they use, without the realization of the quantity of this type of 3rd party information that is included in their databases and publications.

It would also appear that the acquisition of 3rd party information will need to be monitored by the Centers in future, since most of this material is obtained through informal arrangements. A few of the Center IP Management Audits also noted the need for care in acquisition and use of traditional knowledge from local communities and CAS has also raised this issue with many Centers.⁴⁰

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³⁸ It would be fair to say that some Centers took the Survey as a serious exercise, while others did not. Several complaints were received from the Centers about the number of surveys, etc. that they are requested to respond to and that the time required to respond was not perceived to be well-spent, in that they did not often get feedback that would justify the time spent in answering survey requests.

³⁹ Clearly, some Center respondents did not like the use of the "Survey Monkey" format, while others found this format to be highly satisfactory.

⁴⁰ It should also be noted that the GRPC revised the CGIAR "Ethical Principles".

It was noted that use of material transfer agreements (MTAs), collaborative agreements, and prior informed consent were increasing in use, while the use licensing agreements had no discernable trend. The increased use of MTAs across the Centers for incoming materials is not surprising and confirms that most materials are exchanged in this manner in agricultural research situations, rather than the use of more conventional licenses. The System has put a good deal of effort into drafting MTAs for use with outgoing germplasm and other Center products, and this experience has led to an increased confidence on the part of the Centers in using these types of agreements. In fact the survey results indicated that out of a list of 15 commonly used terms in IP Management, the one term that over 75% of the scientists at Centers know is the meaning/use of the term MTA.

Of the other 14 terms queried, many of scientists (25-75%) at Centers know the meaning/use of: a) Assignment of rights; b) Public Domain vs. Public Good; c) Open Access; d) Open Source; and e) Memorandum of Understanding (MOU)/Memorandum of Agreement (MOA) - while, few scientists (<25%) at Centers know the meaning/use of: a) Freedom-to-operate (FTO); b) Invent-around; c) Background Art; d) Foreground Art; e) Database right; f) Defensive publication or defensive patent; g) Self-archiving; h) Grant back; and i) Humanitarian Use License. These results indicate that the level of awareness of IP is good and that scientists are gaining an understanding of terms they need to know.

One result that was unexpected was the fact that the overall awareness of the CBD, TRIPs, ITPGRFA, and other IP/IPR related laws and regulations was judged to be low. Perhaps this question should have been formatted in a manner similar to the question on the understanding of individual terms, in that perhaps the degree of understanding of these instruments should have been queried individually. Much effort has been made by the Systemwide Genetic Resources Program (SGRP), CAS and others to make sure that Center staff have a high level of understanding regarding the ITPGRFA. In fact, most respondents were aware that a new Center-wide MTA was in use by the genebanks. So, while it is not surprising that Center staff feel that their level of awareness of TRIPs or IP/IPR-related law is low, it is frustrating that the CBD and the International Treaty are not well-known. In addition, when this lack of awareness of these treaties is coupled with the fact that much of the 3rd party materials that the Centers use is information and knowledge associated with genetic resources or the use of genetic resources, we can see that more effort needs to be put into increasing awareness and understanding of these international agreements.

An interesting response, that is very relevant to increasing awareness and knowledge regarding IP issues, was that Center-sponsored events were judged to be the best way to increase awareness about IP/IPR/IP Management issues among Center staff. However, only 42% of Centers/Programs have seminars or meetings where these issues are discussed. Obviously, the Centers need more materials and support to run seminars and meetings for their staff, in order to make best use of these opportunities for effective staff education.

With regards to policy, all Centers have IP Policy Statements (2 are in the process of obtaining Board approval) that are based on the CGIAR guiding principles.⁴¹ Many of these statements are on the websites of the Centers. However, most Centers never or infrequently review their policy statement.⁴²

For implementation of policy, most Centers (68%) have an IP committee. Unfortunately, even in those Centers that have such a committee, the committee meets once a year or less. And while, six of the Centers reported to have an Intellectual Property Management Unit, it would seem that there is not a common understanding of what constitutes an IP Management Unit, as only three Centers had a person designated as an IP Manager at the time of the survey. This means that other Centers are trying to cope with the demands of IP Management on an ad hoc basis and this does not bode well for effective interactions with the private sector, let alone with the demands for an increase in the production of public goods by the donors. The cost of such a unit varies across the Centers, from a cost of "0", to a cost of ~US\$ 220,000/year (free text answer). Again, the Centers responding with a figure of no cost were those without a person with part-time or full-time responsibility for handling IP Management as their primary responsibility. Of those three Centers with IP Managers, the cost figures ranged from US\$ 30,000 to US\$ 120,000/year. One Center noted that in addition to assisting the formulation of the Center's policy on IPR, a Code of Conduct for interaction with the Private Sector, drafting and reviewing outsourcing contracts, licenses, and confidentiality agreements another main benefit of their IP Management Unit was to "provide a forum for information, dissemination and discussion for the wider community of the Center's beneficiaries".

Data regarding specific questions regarding IP Management practice indicate: a) a majority (60%) of the Centers/Programs said that their scientists keep lab notebooks, and of this 60%, 75% are checked by lab supervisors and of those, 38% are signed (witnessed) by the lab supervisors; b) half of the Centers/Programs hold exit interviews with parting staff; c) only 37% have a procedure for identifying intellectual products/assets produced by the Center/Program; d) the publications department/section in half of the Centers have procedures for clearing and/or identifying Center publications; e) most Centers rely on the genebank curators to document distribution of germplasm materials.

Survey data regarding the overall effect of an increased emphasis on IPR gave mixed results. While most of the Centers/Programs indicated that use of 3rd party materials and knowledge increased collaboration, a few Centers indicated that this increased awareness of IP issues made their scientists more fearful about collaborating and exchanging materials with colleagues outside of their Center.

Questions designed to understand what the Centers are doing with regard to the product delivery pathway give a picture of modest investment in this area. Distribution plans for Center products are included in 44% of the proposals that are submitted by Center/Program staff. And, only 44% of the Centers perform any sort of FTO-review

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⁴¹ The SGRP has published a compilation of various policy statements, guidelines, etc. approved by various CGIAR bodies.

⁴² The GRPC approved an IP Policy statement template that is recommended for use by the Centers, at its last meeting

before products are released. However there are some instances of Centers being able to negotiate FTO with providers of 3rd party materials when such a clearance has been necessary. In addition, programs at 3 Centers have had experiences of being unable to distribute products because of 3rd party, IPR issues, while two Centers have experienced a denial of funding due to IP issues.

Consultations with Center staff and discussion at the IP-Strategy Meetings regarding IP Management issues

CAS-IP has visited all the Future Harvest Centers since the office was established in 2000. We have had the opportunity to visit most Centers on more than one occasion and to talk with many staff, including scientists, administrative staff, management staff, as well as support staff at each Center. Discussions with Center staff allow several anecdotal points regarding the IP Management practice at the Centers to be made. For example:

- 1. More Centers are investing in the establishment of IP Management services, including the creation of IP Manager functions in their Centers (IITA, CIP, IPGRI, CIAT, to name a few) where information that is relevant to use of 3rd Party material such as agreements and licenses, tracking of the use of these materials in Center products, participation in product use and delivery planning and assistance to scientific staff in preparation of delivery plans, will be carried out.
- 2. At the same time several Centers have split the management of issues related to germplasm from other IP issues, e.g. ICRAF, IRRI, CIP and CIAT among others. However, both areas are represented on the Centers' IP Committees and exchange of information is actively sought.
- 3. Currently, (with one exception where the focal point recently retired in mid-July 2005), *all Centers have an IP Manager/Focal point*, as a central contact/IP Committee Chair, for all IP Management activities.
- 4. Centers and Challenge Programs are very concerned about product and knowledge uptake and utilization by users and beneficiaries. One Center (ICARDA) has established a program for developing effective knowledge and product transfer to stakeholders, called Megaproject 6, "Knowledge Management and Dissemination for Sustainable Development in Dry Areas". The Generation Challenge Program is focusing on Pathways for Products Delivery as an overarching theme for Subprogram 5, while the HarvestPlus Challenge Program is devoting resources to "reaching the end user" and has sought additional funding from the Bill and Melinda Gates Foundation for this purpose.
- 5. In conjunction with these efforts, *Centers are paying more attention to the issues of IP and the use of 3rd Party materials* as a result of donor requests to look at these issues, especially as they relate to distribution of Center products and knowledge. Examples are the McKnight Foundation's requirement for an IP Management plan as a part of a project proposal and renewal; the Bill and Melinda Gates Foundation's funding for the HarvestPlus Challenge Program and the Grand Challenge program utilizing cassava; the Generation Challenge Program's requirement for a list of background, (pre-existing IP and 3rd party IP) and foreground IP; and the CGIAR SC's interest in performance indicator regarding output targets and impact pathways.
- 6. Based on the recent participation at the 5th Annual IP-Strategy Meeting, where 10 Centers were represented and one Center participated via a telecon, most Centers have markedly increased their sophistication in dealing with IP issues as evidenced by the

professional level of discussions that were held this year. This includes some of the Centers thought of traditionally as "policy" Centers, such as IWMI and IFPRI. (The "Policy" Centers have traditionally been thought by many to have less concern with IP issues than the "Commodity" Centers.)

- 7. The resources that are spent on IP Management are inadequate. IP Management services are rarely budgeted for in Centers' annual budget plans, even though the cost of service functions such as financial auditing or human resources management are budgeted for in annual budget plans. (This is somewhat analogous to the cost of establishing and maintaining databases. For many years, budgets for genomics projects rarely included in the costs of establishing and maintaining databases, whereas today, this is an accepted part of any bioinformatics project proposal. ⁴³) IP focal points have had to use funding from other projects to support attendance at the IP Strategy Meetings for example.
- 8. Center IP Managers and Librarians (Information Managers) are increasingly aware of the value of Open Access as a way of ensuring access to Center publications. We are hopeful that the CGIAR will develop a strategy to support this effort.
- 9. Centers IP Managers tend to feel overwhelmed with work. Some Centers process as many as 15 agreements a week and the IP Manager is asked to look at all of these (and asked to pay particular attention to incoming agreements). In addition, IP Managers field questions from all the staff at a Center. It should be noted that it is not always easy for IP Managers to work with staff that look upon the IP Managers as an impediment to working in the way that they have done in the past. Based on the current IP Management Unit structure, the best arrangement seems to be to have the IP Management Unit housed in a senior management office such as the DDG-Research or Assistant DG Office to ensure support from top management. IP Managers are also very actively involved in capacity-building efforts locally and regionally.
- 10. Centers that have participated in the legal-internship program have felt they have greatly benefited from this program.

Publications in the public record

Several recent publications by a variety of authors have discussed aspects of Center IP Management. A recent paper by Chataway et. al. (2005) showcases the ILRI-based East Coast Fever initiative as a model for cooperation between public sector institutions (ILRI; the Kenyan Agricultural Research Institute (KARI)) and the Institute for Genomic Research (TIGR); the Ludwig Cancer Research Institute; the University of Oxford, and the University of Victoria (Canada); and the private sector, in this case the Merial Company, with support from the UK's Department for International Development (DIFD). This is an example of a program that incorporated local expertise into a project that has international partnerships. The basis for the partnerships in this initiative are supporting agreements that help the partners spell out responsibilities and also include requirements for tracking and protecting intellectual property resulting from this project. (Henson-Apollonio, 2005 contains a synopsis of this partnership arrangement.) The IP

⁴³ Early concerns about funds for the establishment and maintenance of public databases were raised by L.B. Ellis and D. Kalumbi, Bioinformatics 15:717, 1999. More recent reports regarding the sale of the BIND database by Canada are covered by AJ Cuticchia and GW Silk in Nature 425:7028, 2005.

Management Unit at ILRI has played a major role in drafting and reviewing the agreements associated with this initiative. The unit's work in this capacity has also raised the profile of the ILRI IP Management Unit in the East Africa region and has encouraged other local institutions such as KARI to take IP Management seriously. We need more of these examples where CGIAR Centers can provide effective leadership in building capacity in local institutions.

Binnenbaum, (2004) discloses several examples where exclusive arrangements were stuck by Centers, the CIAT-Papalotla license, the CIAT-based FLAR initiative distribution of rice varieties to consortia in Latin America and CIMMYT's arrangement with Syngenta (as Novartis, originally) in its work in apomixis, as examples of arrangements that have provided for or will allow distribution of Center products to the largest number of poor farmers. The apomixis work of CIMMYT has, so far, not yielded breakthroughs and the likely outcome of this partnership will be limited to benefits of scientific exchange between company scientists and CGIAR staff. While very important in keeping CGIAR scientists up to speed, this relationship is in a different category of partnership than one meant to encourage distribution of Center products.

Hall (2004) discusses several cases of CGIAR Center involvement with the private sector. Based on his research and experience he feels that successful partnerships have illustrated the importance of the local context and the social connections that are vital to success. This sentiment is echoed in the Chataway, et al. paper as well. However, all agree that key to making these partnerships work is a good understanding of the IP-related issues and the need for establishing appropriate agreements to underpin the trust in the relationship (see also, Henson-Apollonio, 2005). Spielman and von Grebmer (2004) indicate the difficulty is establishing trust. We would submit that much of this mistrust is based on a lack of proper IP Management ability on the part of the Centers and a lack of true understanding of exactly what IPRs are actually implemented and how they can be used to increase the production of goods available to the subsistence farmer.

A search of the European Patent Office publicly available patent database, "Espace" yields the following information regarding the patenting activity of the CGIAR Centers:

Patent applications/patents:44

 CIAT - Brazilian patent dealing with techniques used to propagate *Brachiaria*, issued Mar. 2003.

- CIMMYT Co-assignee on PCT filing related to Apomixis, filed in 1998 and a patent application, filed in Australia in Jan. 2005, and PCT filing related to Striga-control methods and compositions, filed in 2002.
- ILRI Has filed several patent applications related to ECF vaccine work in 2004, as required by partners.⁴⁵ Has a US patent on Theileria antigens that was issued in 1993.
- IRRI –apparently filed several patent applications with the Philippines. However, none has ever issued in the ~16 years that they have been pending.

⁴⁴ Information related to the patents/patent applications can be accessed through the European Patent Office (EPO) patent database site: http://www.espacenet.com.

 $^{^{45}}$ See the information contained in the article, "Collaborative agreements: A "how to" guide, by V. Henson-Apollonio, published by the Institutional Learning and Change(ILAC) Project in August 2005, to be available on the ILAC and CAS-IP websites in early September.

• WARDA—was co-assignee on PCT application filed in 2001, related to work on RYMV. The patent was abandoned prior to issue in France/by the EPO.

Plant variety protection has reputedly been issued over a few Center varieties. However, the only documented instance found by these authors is PVP awarded to the CIAT "Mulato" variety of *Brachiaria*, in the US and several Latin American countries.⁴⁶

Discussion of IP Management Practice in the Future Harvest Centers

In the years since these recommendations were made, the CGIAR has acted on all of these recommendations. Each Center has (or is in the final stages of having) a Board-approved IP Policy that underscores that the use of 3rd party inputs and IP Management at the Center is guided by the mission of the CGIAR. The Center Directors Committee voted to establish the CGIAR Central Advisory Service in 1999, which was initiated in 2000. The IP-Manager/Focal Points group, the IP-Strategy Group was convened for the first time in 2001. Attempts to revise the "Guiding Principles" were met with mistrust in 2000 and this revision has been dealt with in other forms, such as in implementation procedures, the ITPGRFA-MTA and FAO-Center Agreements, etc.

Conclusions

A summary of our observations are given below, taking into account the variability of the results and the anecdotal nature of much of the information.

- 1. As a whole, individual scientists are aware of IP issues generally. However, the positive relationship between good IP management practice and the increased availability of public goods is not well understood. This frequently translates into thinking that the requirements of IP management are onerous and are just creating more paperwork for the scientists. Many scientists would like to see the requirements associated with organizing information to just "go-away". There is little appreciation that much of the information that is sought in order to perform good IP Management practice is information that should be reported and organized as a matter of doing good science and good management of resources. For example, in CGIAR Centers, laboratory notebooks should not be kept because of the need to document prior art of dates of invention. They should be kept because that is how scientists document their work. Legal documents such as funding contracts, licenses, and other agreements set the rules for activities and expected behavior. Part of these activities will affect the disposition of intellectual assets and thus are strictly an "IP" matter. However, much of the other provisions in these contracts will also affect the production and distribution of CGIAR products and need to be heeded.
- 2. Most third party inputs are brought into the Centers under material transfer agreements (MTAs) or under informal arrangements (associated with inputs of data, survey responses, traditional knowledge, etc.). There seems to be little awareness that an MTA is a contract and thus falls under the realm of contract law, not IP law and thus the rules for enforcement are different. In addition, it is always possible to at least try to renegotiate contracts. If an MTA has been shown to be too restrictive, then a Center should enter into a new set of negotiations to obtain the desired result. Informal arrangements based on trust need to be backed up by written agreements. Changes

⁴⁶ Information from "Seedquest".

- of personnel at Centers and in local situations are too frequent to be able to count on verbal or informal agreements as a way of documenting the situation.
- 3. Those Centers that have well-functioning IP Management Units have been able to realize the benefit of these units with regard to an overall improved research management environment with pertinent project information readily available and accessible in one place.⁴⁷ Those Centers with IP Management Units are much better at helping scientists and administrators with partnership arrangements, contracts and agreements overall, and in helping local partners with IP-related issues. Sometimes the IP Management Unit will pay for itself because the services will be utilized and contracted by external contacts to perform work for them. Center experience with the stability of IP Management units is mixed. One Center, WARDA, had developed an IP Office by employing a spouse who was a lawyer. Unfortunately, with all of the disruptions caused by the civil unrest in Cote d'Voire, the IP consultant moved back to Burkina Faso, where she is now the head of the Copyright Office.
- 4. In-Center events are the most popular way of helping staff learn about IP and product development/delivery/partnership issues. This information is very helpful to CAS, as we develop additional materials next year, for use by the Centers in awareness-raising events.
- 5. IP Management practice is uneven among the Centers. A few Centers have been able to establish stable IP Management Units; a few more are in the process of establishing units, while many Centers do their IP Management in an ad hoc manner backed up by IP Committees that meet once a year or less. Little additional comment needs to be made here. IP Committees need to have someone to take up the action items they report out. Otherwise, IP Management is carried out at a very low level of priority.
- 6. IP Management in the Centers (and the CGIAR System, as a whole), is under-resourced. Compared to what other institutions spend on IP Management, both public and private, the CGIAR IP Management activity is woefully under-resourced. Just as financial resource management and reporting is necessary, so intellectual asset management and reporting are necessary. How has the money been used to generate public goods?
- 7. Most Centers have learned their lessons about the need for IP Management, when something has gone wrong. This is unfortunately the best way to bring about a change in behavior. It is also the way in which Centers have come to realize that data, software applications, datasets and databases are intellectual assets over which the Centers need to exert their rights so that they can be distributed in a manner consistent with their mission. Control doesn't necessarily have to take the form of direct ownership. Licensing is often a preferred route. The Centers are in the process of learning more sophisticated ways of managing IP.
- 8. Donor attitude makes a big difference. When a donor requires a Center to carry out IP Management, it gets done. The Challenge Programs, in particular the Generation Challenge Program, have made a marked difference in advancing the thinking and practice in those Centers that participate in this CP. This reinforcement of good IP Management Practice is one way of helping Centers value IP Management. Once Centers begin to organize

⁴⁷ For example, ICRISAT's IP Management Unit allows research managers to quickly pull together all necessary contractual/funding information regarding proprietary genes, while ILRI's IP Manager has been central in the management of the ECF project.

this information they will likely find that it is much easier to accomplish reporting overall and that it will be easier to demonstrate to donors (and the SC) their production of public goods. In addition, we believe this improved practice will lead to a wider use of CGIAR Center products and that obtaining feedback from users will enhance our ability to demonstrate the role our products have played in improving livelihoods of the poor that have been able to use CGIAR products.

PART II: The CGIAR System level

Summary

CGIAR Systemwide bodies dealing with IP/Technology transfer issues include the CGIAR Central Advisory Service on Intellectual Property (CAS-IP), the Alliance Executive (AE) of the Alliance of Future Harvest Centers of the CGIAR (the "Alliance"), the Genetic Resources Policy Committee (GRPC), the Private Sector Committee (PSC) and the SC. With the establishment of the Alliance and the standardization of the Medium Term Program (MTP) descriptions and reporting, there is an excellent opportunity for the development of tools and templates that will help to bring consistency to IP Management practice in the Centers and the System as a whole.

Descriptions of CGIAR Components dealing with IP Management Issues

The CGIAR Central Advisory Service on Intellectual Property (CAS-IP)

It was initiated by the Center Directors Committee (CDC) in 1999 and became operational in 2000 with the hiring of Victoria Henson-Apollonio as the CAS-IP Manager and Senior Scientist. Originally based at ISNAR, in The Hague, CAS-IP has been hosted by IPGRI since February 2004. The mission of CAS-IP as envisioned by the Centers Directors General was to raise awareness of IP Management issues, to assist the Centers in IP Management and to facilitate the exchange of experiences among the Centers. The CAS-IP staff now includes a legal specialist consultant based at IFPRI, Ms. Maria Ines Mendoza, and a Rome-based part-time Project Assistant. CAS-IP has established an IP Manager/Focal point group with representatives from all of the Centers (the "IP-Strategy Group) that meet on an annual basis for exchange of information and ideas. In addition CAS visits the Centers, ~5-6 Centers/year and meets with the CGIAR Challenge Program leadership, to provide face-to-face assistance and evaluation; publishes practice guides (see for example, the ISNAR Briefing Paper #53, "Defensive Publishing: A Strategy for Maintaining Intellectual Property as Public Goods" and the ILAC Brief #4, "Collaborative agreements: A 'how to' guide"); writes and presents workshop materials for the Centers and Center partners; reviews IP Management-related documents; maintains a "CASapproved" list of legal referrals; creates tools such as an on-line reporting system for inventorying Center-created public goods; and provides service to the Centers such as an internship program whereby law students from St. Edmunds College of the University of Cambridge (UK) spend a summer internship at a CGIAR Center. Funding for CAS-IP is provided by the Center Directors, DGIS, the Generation Challenge Program and the McKnight Foundation. CAS-IP is a unit of the CGIAR System Office, (http://www.cgiar.org/who/structure/system/index.html).

The IP Subcommittee and the Private Sector Subcommittee of the Alliance Executive (AE)

These are the two AE subcommittees that deal with IP Management/Technology Transfer-related issues for the Centers at the AE level. The IP subcommittee structure has been in place since ~1993, while the formation of the Private Sector Subcommittee is quite recent. The establishment of the Private Sector Subcommittee seems to be a response to link with the pro-active stance of the current Private Sector Committee. The Chair of the IP Subcommittee is a member of the CAS-IP Expert Advisory Committee (EAC), an oversight and resource committee for CAS-IP.

The Genetic Resources Policy Committee (GRPC)

It was established by the CGIAR in deliberations held at the Center's Week (ICW) in 1994. According to CGIAR documents the purpose of the GRPC is to: "advise the CGIAR on policy matters regarding genetic resources issues and to assist the Chairman or the CGIAR in his leadership role in this area." This committee meets twice a year to discuss policy issues related to genetic resources of the CGIAR System. After a favorable review, carried out in 2002, the committee membership was reconstituted. The committee looks at current and arising issues in the genetic resources policy area, carries out studies of genetic resource policy issues, and produces policy documents that are brought to the CGIAR membership.

The Private Sector Committee

It held its inaugural meeting in Washington, DC in 1995 and has included IPRs as a topic on its agenda in most meetings since its inception. Initial meetings documents indicate the tension that exists between the role of IP management in the private sector vs. the public goods sector and this stress is still obvious in the most recent documents that recount a meeting between the Private Sector Committee (PSC) and the Center Directors General, "A CGIAR-Private Sector High-Level Workshop", held at the National Press Club in September of 2005. In this meeting, the PSC stressed its desire to move from "talk" to "action" with regards to partnership with the Future Harvest Centers of the CGIAR and the meeting produced an action plan to generate a list of activities to be carried out jointly.⁴⁸ In addition, with the CGIAR-Secretariat, the PSC has developed the framework of the "Scientific Knowledge and Exchange Program" (SKEP), which is to be a project that fosters reciprocal exchanges of scientists from industry and the Future Harvest, CGIAR Centers. The first such exchange has taken place, with an industrial scientist visiting IFPRI during the latter part of 2005.49 An umbrella agreement, (renamed as the "guiding principles" document) was drafted with input from CAS-IP, and is meant to be used as the basis for bilateral agreements between private companies and CGIAR Centers that wish to participate in the program. A standard agreement template/form was **not** developed for the SKEP project.

The CGIAR Science Council

The CGIAR SC and its predecessor, the CGIAR Technical Advisory Committee (TAC) has had a long-standing interest in the role of intellectual property and intellectual property management in the way in which Centers use and distribute proprietary materials as a part of their research and product distribution. More recently, with a renewed energy to emphasize impact of the adoption and use of the international and global public goods products of CGIAR research, the SC is also beginning to integrate their analysis of IP Management and technology transfer practice into evaluations of Center management and review.

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⁴⁸ Meeting documents and action plans from these recent talks are not publicly available. The author has had personal communications that indicate a variety of activities have been identified including: workshops on project management, including IP considerations; studies of existing private-public partnerships within the CGIAR; development of partnership guidelines and requirements, drafting of standard agreements, etc.

⁴⁹ Additional information regarding SKEP is available from many sources including meeting reports of the PSC and the July 2005 edition of the CG Newsletter.

The CG Secretariat

The CG Secretariat has recently expressed an interest in the topic of "Hybrid IP Systems", or ways in which countries implement IP practice in their countries. The Secretariat has indicated that they would like to see how the experience of Brazil, with regards to the Brazilian government's pro-poor stance towards the holders of IP for the manufacture and use of anti-viral compounds and other HIV medicines, can be employed in the agricultural sector as well.

Recommendations

- 1. The CGIAR should formulate a strategic initiative to emphasize the public goods nature of their products and public access culture of the mode of distribution of products.⁵⁰ This is especially urgent in light of other initiatives that are being put forward by other groups that wish to involve the CGIAR Centers. The CGIAR is the largest producer of public goods, in the field of agriculture in the world. We need to make this much more visible. CAS-IP sees the establishment of the new Future Harvest Alliance of the Centers of the CGIAR as the perfect platform for bringing this initiative to life.
- 2. There is a need for increased genuine and open communication among all of the bodies that deal with IP/TT issues in the CGIAR System.
- 3. Adequate resources need to be brought to bear on IP Management in the system.
- 4. Standardization of IP Management practice/tools/agreements, wherever this would strengthen the negotiating position of the Centers and/or the System and/or would increase the understanding of CGIAR IP Management practice, should be accomplished.

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ACCESS TO INFORMATION ON AGRICULTURAL BIOTECHNOLOGY PROPERTY RIGHTS AND THE AVAILABILITY OF TECHNOLOGY FOR CGIAR'S IPG RESEARCH

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Background

This paper has been prepared at the request of the CGIAR SC through its Standing Panel on Priorities and Strategies. This derives from a general concern expressed in the CGIAR's own terms of reference for this study that the "rising global trend towards the exercise of IPR over material and knowledge could affect the capacity of the CGIAR to carry out its mandate for international public goods research on behalf of agriculture and poverty alleviation in developing countries".

The survey reported here conducted an assessment of resources and sites available for identifying IP/technology of relevance to CGIAR research and consulted agricultural biotechnology IP owners/providers in both public and private sectors about whether and on what terms they would consider providing access to their technology for CGIAR.

It is important at the outset to distinguish between "technology" or "intellectual property" in the broad sense (being results, physical or biological materials, know-how, methods, etc) and narrow sense "Intellectual Property Rights" (being registered patents/applications, trade marks, design right and copyright etc). The reason for this is that registered "Intellectual Property Rights" and their exercise or enforcement by owners should not be seen as the principal barrier to CGIAR accessing technology. Thus to ask the question "What agricultural biotechnology property is out there and protected by IPRs?" is to miss the point. For the generators of technology that might be useful to CGIAR researchers, the issues and concerns about cooperating with CGIAR go beyond narrow sense IPRs, and for CGIAR to limit its assessment of opportunities for benefiting from third parties technology to just "protected IP" would be to miss the much broader opportunities for sourcing valuable technology for CGIAR research. This is not to diminish the importance of narrow sense IP to the owning source organizations, nor to imply that CGIAR researchers should not assess the situation for registered IP (on the contrary!), but it is just that this whole area is about much more than narrow sense IP Rights. So for the purposes of this survey the section that follows on identifying technology opportunities for CGIAR research addresses the question "How can CGIAR researchers identify what agricultural biotechnology property is out there?"

The second part of this survey addresses a "review of the likely terms under which agricultural biotechnologies might be accessed by CGIAR scientists". This survey has been directed at technology generators both in the international public research sector and the private company sector, and has also sought input from CGIAR Research Institutes themselves, as to particular experiences and concerns. It was clearly apparent at the outset that technology generators (whether public or private) would be unlikely to be willing or able to be very precise about detailed terms and conditions in the absence of a specific request for a particular technology, with a defined application in mind. So this survey has sought to draw out the principal headline issues that would need to be

addressed in any access agreement, recognizing that almost all individual situations will have particular needs and conditions.

Most of the principal private sector companies involved in agricultural biotechnology research were contacted, as well as several smaller biotechnology providers, and selected public sector research organizations internationally. These were sent a background letter outlining the basic questions of the survey (as summarized in Appendix 1) which was followed up with further electronic mail correspondence and telephone interviews. In collating the specific responses to the questions posed in the survey, this paper attempts to represent the different perceptions and attitudes behind the responses, among the private and public sector IP/technology providers, as well as in the CGIAR system itself. It is hoped that understanding these perceptions and attitudes may help facilitate CGIAR's access to important technology in the future.

Part One

"How can CGIAR researchers identify what agricultural biotechnology property is out there?"

Quite how and where CGIAR researchers search for information about third party technology depends on the reasons for the inquiry in the first place, which could include:

- Technology Push Seeking serendipitous inspiration from what technology exists, to stimulate CGIAR research towards new product outputs or to remove research bottlenecks and increase research platform efficiency.
- Technology Pull Seeking to solve a particular product problem (e.g. unmet need in crop performance) or a known inefficiency in internal research platform (e.g. marker development or gene function analysis).
- Assessing third party technology from a strict IPR point of view to assess potential
 problems connected with access to unique and proprietary materials owned by other
 parties and even to dominating registered IP rights.

There is no single resource listing all existing agricultural biotechnology items and IP. It is probably stating the obvious to suggest that general searching on the internet using the popular search engines is one place to start, and traditional routes of communication and awareness to keep abreast on the international scientific developments through journals, conferences etc. As well as the general scientific literature, specialist bulletins and trade magazines and newsletters can usefully flag up emerging developments – for example (non-exhaustively):

- AgNET www.foodsafetynetwork.ca
- AgBiotech Reporter www.bioreporter.com
- Plant Biotech Projects www.pjbpubs.com/plantbiotech
- AGROW www.pjbpubs.com/agrow

AgNet is a near daily e-bulletin carrying a range of topical news items of interest in agricultural research, from GMO issues, to new molecular biology innovations, to topical crop problems internationally. AgBiotech Reporter carries articles and items on both plant and animal biotechnology and GM and regulatory issues, as well as private sector

news items and some summaries of patented technology news. Plant Biotech Projects (launched in 2004) offers a wide data source on plant biotechnology and IP, including searchable information on transgenic crop projects and patents. AGROW is more agrochemical focused but also carries useful information about the agricultural biotechnology private sector. Apart from AgNet these are subscription based facilities.

Such searching and monitoring of general technological developments via internet and via screening scientific research publications are the most likely tools for applying to "Technology Push" information gathering, but inevitably rely to a degree on serendipity. Moreover because of the wide technical spread across scientific disciplines (e.g. gene discovery/detection) through to (for example) crop agronomic performance or crop pathogen interactions, some cross discipline interpretative function may in some, if not all, cases enhance this technology seeking process.

Probably a more important issue with respect to accessing information about IP is the cultural attitude to IP within the CGIAR research system. CGIAR research has historically not been conducted in a culture of IP awareness. It is not generally perceived as the "scientist's job" to worry about IP; there is little time to assess IP backgrounds, with research funding requiring rapid proposal development; and there is reportedly an internal view in some parts of the CGIAR system that CGIAR research should "go ahead before spending time worrying about IP". While the outside public academic research sector has probably always been seen from within the CGIAR system as a potential source of technology and information, the potential for technology contribution by the private sector – with some notable exceptions – has perhaps been seen more as an obstacle rather than an opportunity. At least one company surveyed, commented that it appeared to them that the CGIAR saw the growth of the private sector and IP in general as a threat, and became defensive as a result.

Respondents to this survey from within the CGIAR network felt strongly that they need help to change to a more IP aware culture, and to one that is oriented more proactively and positively to acquiring technology both from the public and private sectors. The need for CGIAR researchers locally to become more aware of both IPR and technology ownership issues was reflected by private sector contributors. These issues are an object of the CGIAR Central Advisory Service (CAS, www.isnar.cgiar.org/cas), but there appears to be a need for provision of local expertise to help interpret intellectual property landscapes, not leaving this to individual CGIAR researchers to attempt to interpret alone.

This survey has not assessed the depth and quality of CGIAR information resources and facilities locally at research institutes (high-speed internet access, on-line journals, international conference travel budgets, staffing of dedicated internal information services functions etc) but these are all factors that will greatly affect the ability of CGIAR researchers to access information readily and routinely.

Timing of awareness to new developments is a further issue and CGIAR might consider whether it could develop even earlier awareness of relevant emerging technological developments (whether specific or strategic) coming from third party researchers such as by international collaborative research alliances (public and/or private sector), advisory panels or other external networking activity. For example some form of involvement in

or networking with national and transnational public research programs of relevance to CGIAR research might be beneficial to stimulate – for example:

"The ERA-NET Plant Genomics program PG brings European plant genomics together and for the period 2004-2007 comprises 12 national research programs from 11 European countries. ERA-PG is financed through the EU's 6th Framework Program with the aims to strengthen the European scientific base and to support the structuring of the European Research Area (ERA). The ERA-NET website (www.erapg.org) provides an access point to these programs."

Clearly far more focused monitoring and inquiry is possible in the context seeking applied solutions to a defined problem/target (Technology Pull) or for assessing narrow sense IPR and questions about proprietary materials, or patented processes and enabling technology - however some of these above broad issues again apply about quality and timing of CGIAR access to information on existing and new technology. Moreover – as David Hoisington of ICRISAT (pers. comm.) points out - some kinds of technology (for example useful molecular marker collections or breeding systems/technology) may not be easy to locate since they are often not patented and may not explicitly be published/promoted in scientific literature. Certain specific CGIAR initiatives for awareness and information gathering are already in hand - such as a plant patent database being generated by the CGIAR Central Advisory Service (CAS), and a database on marker-assisted selection patents being generated by Jonathan Crouch at CIMMYT under CGIAR Competitive Grant Program funding (J Crouch, pers. comm.). Several layers of information gathering are applicable together with and beyond such internal initiatives, internet search engines and monitoring of published literature and newsletters:

- Research organization websites public sector academic research groups' websites usually contain much information about ongoing research projects as well as previous publications and associated information. University and Institute technology transfer offices and some national research agencies (e.g. www.cnrs.com, www.frinnov.com) also have websites posting information on specific technology being "promoted" and usually patented by the generating organization. Also note certain public/private initiatives for example in plant genomics e.g. Genoplante in France (www.genoplante.com) and GABI in Germany (www.gabi.de).
- Other *public sector initiatives*, national and international networks or alliances of relevance to agbiotech, such as CAMBIA (www.cambia.org) and its intellectual property initiative, BIOS (www.bios.net) and PIPRA (www.pipra.org) (see below).
- *Specialist technology transfer organization* websites such as PBL (<u>www.pbltechnology.com</u>) or certain subscription-based websites such as Plant Biotech Projects (see above).
- Technology exchange sites e.g. CORDIS http://irc.cordis.lu/ these independent sites post technologies offered by providers, though are not specialized to agbiotech, though do carry technology of relevance. Some of these sites, such as the CORDIS "innovation relay centers" are public funded. Others are privately operated.
- Patent Databases searching (e.g. Delphion www.delphion.com, EspaceNET www.ep.espacenet.com, BIOS www.bios.net), through which international and national patents and patent applications can be searched, and monitored. Alerts can also be set up to monitor progress with individual patents/applications.

Specified consultancy projects for IP/technology searching and due diligence. Where a
particular, reasonably well defined need or inquiry exists, commissioning suitable
consultant services to conduct dedicated a technology search (perhaps also with IP
due diligence) may be an efficient route to pursue, and one that is or has been used
already by CGIAR.

Separately or in addition to the above, CGIAR researchers should maybe more often consider direct approaches to both public and private sector technology providers, even if somewhat speculative, especially as most respondents indicated a willingness to help CGIAR find technological solutions to their needs.

In USA, PIPRA (Public Intellectual Property Resource for Agriculture) is developing a database of agricultural bio-technology associated with its members and this will be searchable by CGIAR researchers through a web-based interface. Two CGIAR Centers (IRRI and CIMMYT) are PIPRA members, and Gerard Barry (IRRI) sits on PIPRA's executive committee. The portfolio described in the PIPRA database contains patents and patent applications from the PIPRA members. The database will include not only technologies that have active intellectual property protection, but expired and abandoned patents as well. For active patents and patent applications, the database has been designed to include licensing status information, as regards available rights. The database will be publicly accessible. PIPRA member institutions receive access to further software tools that can help in either the marketing of their technology, or evaluating freedom-to-operate questions.

In 2006 a new, Europe-based initiative will commence. EPIAGRI - supported by the European Commission - will bring together a number of public sector sources of agricultural intellectual property in a range of cooperative activities including formation of a shared database for intellectual property and technology, which will be accessible for others to search.

Certainly one conclusion from this survey is that while there is no single source of information about available IP/technology for all of CGIAR research interests, there are many places to search – including it would seem some considerable overlap and potential duplication (including CGIAR initiatives) – and that more attention should be given to encouraging/enabling CGIAR researchers to access and apply this information and helping them to do so, both directly and through CGIAR policies, management and cultural approaches.

Part Two

Terms under which agricultural biotechnologies might be accessed by CGIAR scientists. The preceding section of this paper focused on routes to identify whether a technology exists (plus or minus registered IP rights) that matches a need or opportunity for CGIAR research and development. Of course, identifying the existence of a particular item of technology of interest for CGIAR research does not mean it will be available. However – in most if not all cases – if a technology can be identified, then ways can probably be found to gain access. Almost without exception, respondents to this survey have indicated their willingness to make technology/IP available to the CGIAR system –

provided certain assurances can be given and conditions met. As indicated earlier in this

paper, the concerns of technology generators are much less to do with IP infringement issues and much more about stewardship, reputation and liability matters. It is also seems to be generally held (both in public and private sectors, as well as in CGIAR centers) that "IP pooling" and "clearing house" concepts are unlikely to provide a universal solution, as access is more likely in practice to be dealt with on a case-by-case basis. The following section considers likely terms under which agricultural biotechnologies might be accessed by CGIAR scientists.

The view from within the CGIAR System

Those involved within the CGIAR system in accessing third party technology for CGIAR research regard this (gaining access and establishing terms) as a "long haul" process based on experiences to date. There are even cases, giving concern, that some important platform enabling technology has not been made available at all to CGIAR system by the relevant licensors, and significant efforts are being diverted to seeking alternatives. It seems that at least in some circumstances there is no central channel being used by CGIAR researchers to raise such problems and gain CG assistance to achieve solutions.

There is also a feeling that the "public good crop breeding and seed distribution" mission is becoming complicated in practice by increasing private sector involvement. For example, one observation has been that SME's (small to medium size private companies) represent increasing proportions of CGIAR's product delivery agents (even in Africa), which, it is perceived, raises new issues with potential technology providers as to the "subsistence" versus "commercial" status of downstream activity from CGIAR research. For crop research programs, this is more acute a problem for some CGIAR Institutes than others, given the levels commercial interest in the crops they are involved in. Meanwhile, larger multinational private companies are seen to be taking increasing interest in CGIAR system target countries, on the one hand creating a tendency of CGIAR research to focus on increasingly niche agriculture and on the other potentially leading to complication of market/technology segmentation within such territories. This was always likely to happen, arguably, as a product of success over many decades of bringing subsistence systems towards market sustainable systems, but, at least in some regions, these are no longer so clearly bounded by national border envelopes. Whatever the cause/trend, it is cited by CGIAR researchers as reason for concern among private sector technology providers for providing technology to the CGIAR system.

Material Transfer Agreements ("MTA"s) are widely and routinely used in exchanges of materials between academic research groups and appear to have been a frequent start point for CGIAR center access to third party materials from both private and public sector providers. However the "typical" MTA format – granting a research-use license in return for the recipient agreeing to acknowledge the provider, hold them harmless from the recipient's activity, and not to transfer the materials to others without the provider's permission – is ultimately not sufficient for CGIAR's purposes if the materials are to be used to generate CGIAR outputs (e.g. crop germplasm), where a distribution (or commercialization) license may be needed, even if sometime later. CGIAR Institutes have spent - and continue to spend - considerable effort negotiating rights they may (or may not, if the research does not succeed) need later. There is an emerging view in some parts of the CGIAR system that MTAs should be avoided if the necessary materials can be sourced independently of an agreement from a provider. CGIAR should carefully consider its policy on this matter. This paper will return to this issue in the sections that follow.

Public Sector Technology Providers

Clearly, individual public sector research organizations (PSRO's) have widely varying restrictions on IP according to their own policies and the restrictions or requirements of their grant funding bodies. At the institutional level there is a fairly universal willingness among respondents to this survey to consider approaches from CGIAR system researchers wishing to access IP, particularly on a case-by-case basis. Such access would generally be provided on the basis that there was no cost to the provider, and that individual research staff whose participation was needed would be willing to do. In practice, there may turn out to be limitations on how much time individuals in PSRO's can or wish to contribute to support making IP/technology available for use by CGIAR researchers, unless specifically funded.

PSRO's will generally seek to retain clear ownership of their IP and if they do agree to make it available it would be by written agreement (e.g. an MTA or Limited-Use License) with a recognized body capable of performing and adhering to its obligations and undertakings under such an agreement. Issues to do with stewardship and liability were not highlighted as strongly by the PSRO's as by the private sector, but should nonetheless be expected to be part of any detailed transfer of IP/technology.

While not expecting (license) payments for use in resource-poor farming systems, PSRO's recognize that the CGIAR recipient's activities might directly (or indirectly) result in a "commercial" outcome of some significance that would at that point justify some tangible recognition of the PSRO's contribution. For example, export to and commercial sale of produce on international markets, or an application of the provided IP/technology developed by the CGIAR research that would have commercial use in the developed world.

PSRO's may be more reluctant to make IP/technology available to CGIAR researchers in certain crops, if to do so could jeopardize the PSRO's existing commercial licensees' activities, or a spin-out company of the PSRO, or even - it has been cited - other academic networks and collaborators working on similar aims. Moreover, while many/most PSRO's as organizations will now have general statements about humanitarian use policy, many PSRO licensing offices will be unlikely to make major commitments to a CGIAR research use until commercial sector opportunities have been thoroughly explored and the interests of actual or potential commercial licensees have been established.

Many of the PSRO's surveyed have not been directly approached by CGIAR researchers, while most have some experience of providing technology to developing country programs – usually from research under funding programs dedicated for such purposes (e.g. US AID www.usaid.gov or the INCO program in Europe www.cordis.lu/inco/home). However, in the past many, though not all, of these programs have been more about training, skills transfer and technology education than specific research and development projects.

PIPRA members have collaborated to develop licensing language for a "humanitarian use reservation of rights" (see Appendix 2). This language would be adopted "where reasonable" in the PIPRA members' licensing practices. For licensees whose use of a technology satisfies the definition of "Humanitarian Use", PIPRA promotes among its

members the use of a free, non-exclusive Humanitarian Use license and PIPRA staff are available to liaise between humanitarian-use recipients and PIPRA members' technology transfer offices and to assist in the licensing process. Quite how any particular use by CGIAR research of a PIPRA member's technology will map under the PIPRA Humanitarian Use definition will depend on individual circumstances. Moreover, membership of PIPRA does not require or indicate any guaranteed commitment by its members to make available any specific existing or future intellectual property or to a particular management approach with regard to interacting with, say, CGIAR Institutes and PIPRA members retain the right to determine licensing terms for their technologies, and ultimately decide whether or not to implement a Humanitarian Use license.

As well as encouraging a consistent approach to provision of IP/technology for humanitarian use purposes, PIPRA is facilitating the design and construction of certain materials – in particular a plant transformation vector – with "maximal freedom-to-operate", and this will be distributed on a royalty-free basis for humanitarian purposes. This may be of value where IP barriers are seen as an issue.

Private Sector Technology Providers

The private sector respondents included all of the six largest agricultural biotechnology companies and several smaller companies as well. Attitudes were similar to the PSRO's, with more or less universal willingness to assist CGIAR researchers achieve successful solutions, so long as certain requirements and conditions could be satisfied. The issues for the private sector are generally not about royalty payments, nor in the first instance about IP infringement (although the companies regard it as imperative that their IP rights are respected), but more about stewardship, reputation and liability matters.

Private sector respondents felt that there are still parts of the CGIAR system that, coming from the strong history of public goods creation largely without IP issues, believe that the CGIAR system ought to have free rights to use any IP, and even that there ought to be no place for IP in agriculture. The counter argument from the private sector (and perhaps from some parts within CGIAR) is that IP has been the driver of the greatest improvements in plant sciences in history, and that many technologies would not have occurred without IP driving the incentive for research investment. To extrapolate, the CGIAR system should recognize and take care of its own IP/property, at the very least as a tradable asset outside the subsistence and resource-poor agricultural systems that is its mission to serve.

Several companies were reluctant to make "general" policy commitments as to do so might raise expectations which could lead to disappointment. They also warn against the hope of a broad answer to a question about technology access that almost by definition needs to be answered on a case-by-case basis. It would appear from responses to the survey that many companies are unlikely to pre-commit to IP pooling or other such intermediary models and most felt that these initiatives were unlikely to be as productive as direct cooperation on defined projects with specified goals and responsibilities. The more defined such initiatives are (both technically and geographically), the better the likelihood of achieving private sector support and cooperation. The African Agriculture Technology Foundation (AATF, www.aatf-africa.org) would appear to be one such example, with its focus on public-private partnerships aiming to help African agriculture with specific, managed projects.

Beyond the question of IP/technology access - which is the focus of this survey - there are arguments to look elsewhere for other factors that are possibly more important in impeding the uptake of biotechnology for humanitarian agricultural applications, and these should certainly be considered. Adrian Dubock of Syngenta (9th ICABR Conference, Ravello, Italy July 2005) lists the Convention on Biodiversity, varying interpretations of "precautionary principle" to assessing risk (and benefit), as well as NGO opposition to GM agriculture, as major negative influences in technology adoption.

Several of the major agbiotechnology companies have more or less well publicized involvements in sharing technology with not for profit and public organizations, including with CGIAR system, although this report does not intend to examine these in individual detail. Examples include the "Golden Rice" program (www.goldenrice.org), CIMMYT's access to maize and wheat molecular markers from Pioneer/Dupont (see later), the Insect Resistant Maize for Africa program (IRMA) and the CIMMYT Apomixis Consortium. The latter has just completed its first five years brings together CIMMYT with three private sector contributors – Pioneer HiBred, Limagrain and Syngenta. At least one of these companies regards the Apomixis Consortium as a model for how the CGIAR system can work together with not just one private sector party but several. Despite these experiences (or because of others?) the access of CGIAR to private sector technology has, apparently, not become any more routine.

Overall there is a common view among the private sector parties surveyed that the CGIAR capacity in a broad range of product development skills – particularly for biotech products – is very weak or non-existent. This is currently a sensitive area for the private sector, which has been dealing with its own challenges in this respect.

In providing proprietary IP/technology to CGIAR researchers, the headline issues and concerns for the private sector are:

- There must be clear and real benefits to resource-poor farmers.
- Impact of CGIAR activity/outputs on the company's own products and markets.
 - How can CGIAR, via disparate, and dispersed downstream national systems, prevent the export to and use of a company's IP in markets where that company actively participates?
- Becoming blocked from future developments.
 - If further IP is developed as a result of CGIAR's use of company technology, that could not have been developed otherwise, the company would not want to be locked out such an area of research or technology.
- Inadvertently assisting their commercial competitors.
- Research and development stewardship in CGIAR.
- Protection of confidential information by CGIAR.
 - Apart from the more routine confidentiality issues associated with intellectual property and commercial information, companies will be very unlikely to contribute any trade-secret property to a CGIAR project.
- Product stewardship by CGIAR including regulatory concerns.
- Liability concerns arising from CGIAR and NARS activity.
- Costs to the company whether planned or unplanned.
- Resources committed or diverted by the company whether technical, legal, regulatory or otherwise.

Risks to the company's reputation both technically and in public opinion.

As well as addressing these types of concerns in detail, any agreement to provide IP/technology to a CGIAR program will likely be required to include a grant-back to the company of exclusive or non-exclusive royalty-bearing rights to exploit inventions derived by CGIAR from its use of the provided technology.

A recurring concern amongst private sector respondents is in connection to bioregulations and cross border movement of materials to territories with no regulatory system, or different regulations with different requirements. Under many national and international regulations a company could still ultimately be held liable as a consequence of CGIAR use of its technology and this is seen as an unacceptable risk.

Also identified as a concern for the private sector, is that in some of the countries where companies anticipate that CGIAR would want to utilize the relevant technology/IP, the prevailing judicial system could not be relied upon to uphold agreements rigorously and the company could not be certain of vigorous enforcement/restitution.

More than one company highlighted the requirement that if they would agree to provide a particular technology there would need to be a high level of confidence that the project would deliver a technically successful outcome – for many reasons including public perception. This could require a significant technical input from the company, bringing resource issues into play. Moreover, technologies in which they would have a high level of confidence would most likely those in which they have most internal experience and in turn these are more likely to be "core business" projects – which would be more sensitive with regards to availability to outside parties, such as CGIAR. As well as the company's level of confidence in the technology that it would provide, there would need to be a high level of confidence in the technical capability of the CGIAR recipient, requiring a certain amount of due diligence to be carried out by the company.

Assuming, though, that agreement to provide a technology would be reached and terms consolidated in an agreement, companies see a considerable open-ended resource implication for contributing technology to third party programs such as CGIAR, particularly for GM biotech crop applications, covering the research and product development stewardship issues, regulatory, legal and public perception issues. For some companies, contributing this internal resource commitment may be as much a barrier to engaging with CGIAR research as IP or contractual issues.

The Private Sector Committee (PSC) of the CGIAR, which includes representatives from several major agbiotech companies, is involved in stimulating a range of interactions between CGIAR and the private sector (see Appendix 3 - 2004 PSC Report to CGIAR AGM). Of particular relevance to the present survey, is the implementation of the "Scientific and Know-How Exchange Program" of "SKEP". This will, according to the 2004 PSC report, be implemented in 2005 with a ten year perspective to "transfer [to CGIAR] technology, know-how, knowledge, information in designing, controlling and managing R&D and developing a higher level of trust". SKEP may also facilitate interactions between CGIAR and private sector technology providers where the latter do not have or wish to contribute project monitoring and management from its own resources.

There are other private sector organizations and initiatives established to communicate agricultural industry issues to a wider audience and to promote stewardship and responsible practices in the plant science industry, chemical crop protection, pesticides and agricultural biotechnology. One of these, Crop Life International (www.croplife.org) provides a downloadable "field trial compliance manual" containing detailed guidelines for conducting field trials of genetically modified crops. CGIAR centers may find these of benefit in meeting the expectations of private sector technology providers.

Most or all of the above concerns will likely have to be addressed <u>before</u> a company will commit to provide IP/technology, at least under anything more than a limited research-use-only agreement. As many of these are "downstream issues" beyond initial "basic" research, settling them *ab initio* will introduce significant delay (and frustration on both sides), as is evidently already the case judging from experiences of, for example, dealing with MTA's to date.

At least one major agbiotech company has stated that it is intending to move away from implementing MTA's towards instead adopting a policy of applying "non-assert" licenses, which do not involve any transfer of materials. On the basis that, particularly for molecular biological materials and biotechnological methods, the physical provision of materials is not always necessary and can be produced locally by the CGIAR researcher, a non-assert license under company IP/patents allows the CGIAR research to go ahead without complications of a MTA. However, as mentioned earlier in this report, IP providers do expect their property rights (which goes beyond patents) to be respected and CGIAR should consider very carefully before proceeding without any agreement in respect of a recognized piece of third party IP/technology.

Specific examples of private sector MTA terms do exist, and vary according to circumstances. Pioneer HiBred International has made herbicide (imidazolinone) resistant maize germplasm available to CGIAR researchers with permission to use, sell or distribute maize containing the "IR" trait so long as the germplasm released by CGIAR contains no more than 12.5% (by pedigree) of the contributed Pioneer background material. This gives CGIAR access to the IR trait without use of extensive components of proprietary Pioneer background germplasm. Pioneer is also providing a lycopene epsilon cyclase maize mutant line for high beta-carotene levels, and associated genetic information, under a letter agreement where the recipient accepts sole responsibility for any claims and liabilities that arise out of the use of the materials. CIMMYT's access to Pioneer/Dupont maize and wheat molecular marker probes was on the conditions, under a Material Transfer Agreement format, that:

- Use by CIMMYT is only for research in maize, wheat and related species.
- Text of intended publications reviewable for 60-day period by Pioneer, and right for Pioneer to withdraw commercial sensitive information.
- Acknowledgement of Pioneer in publications.
- Worldwide, royalty-free, non-exclusive license to Pioneer under any inventions developed as a result of CIMMYT's use of Pioneer materials.
- Option for Pioneer to secure legal (patent) protection of inventions on behalf of CIMMYT (at Pioneer's cost).

Another agbiotech "major" differentiates between "enabling" technologies (e.g. selectable markers for plant transformation) and "trait" technologies. While pointing out

that the company does not file for patent protection in least developed countries, the company will license enabling technologies to public sector programs for humanitarian applications, but not "trait" technologies as for these it is perceived to be "too difficult to reconcile commercial and humanitarian interests".

Conclusions

Both private and public sector technology providers are willing to provide technology to CGIAR researchers both to carry out research more successfully and to deliver new outcomes to CGIAR target agricultural systems.

CGIAR researchers should be encouraged/assisted to access information about externally available IP/technology and may benefit from (local?) help to do so, both directly and through CGIAR policies, management and cultural approaches.

The CGIAR system needs to engender a culture that respects and understands international IP issues as part of routine research project management activity, and encourages participation with private and public sector technology providers, as an opportunity for the CGIAR system – both to access important technology and to recognize the value of its own - and not as a defensive necessity.

Progress is most likely to be made by focusing attention to projects on a case-by-case basis with specific requests for technology, for specific purposes. In the future, success with these may form the basis for more routine general practices to provide technology to the CGIAR system.

CGIAR needs to convince technology suppliers that its system is capable of meeting the technical demands of such research and development as well as the research and product stewardship requirements.

It is possible to envisage that private sector confidence can be built in CGIAR institutions' ability in (bio)technology and product stewardship issues, through experience and demonstration by successful examples (which need to be shared and publicized both internally and externally), as well as through initiatives such as AATF or SKEP. What is harder to see a near term solution to, is the issue of where subsistence/non-profit agriculture stops and commercial competition starts.

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CGIAR System: Jonathan Crouch of CIMMYT; Dave Hoisington of ICRISAT; Marianne Banziger of CIMMYT Kenya; Gerard Barry of IRRI.

Private Sector: Judith Rylott of Bayer Crop Science; Rob Horsch of Monsanto; Tom West of Pioneer HiBred / Dupont; Adrian Dubock of Syngenta; Mike Murray of Dow Agrosciences; Johan Cardoen of Crop Design.

Appendix 1

Questions posed in the Survey

- How could CGIAR researchers find out what agbiotech technologies exist and are available from your [organization/company] that could be used by CGIAR research?
- Is your [organization/company] willing (in principle) to make such IP available to CGIAR researchers? this would be in the knowledge that that the CGIAR's intention is to use the IP/technology in creating/breeding new varieties or breeders lines and to subsequently transfer these varieties/breeders lines to specific National Programs in developing countries for use directly as a variety (including distribution through local seed merchants) and/or used to breed further specific locally-adapted lines.
- If so, then what sort of headline terms and conditions would you wish to apply to such use by CGIAR? (E.g. royalties and other terms/conditions/requirements)
- If not, then what would be your reasons/concerns?
- Have you already been approached by CGIAR Institutes for IP/technology?
- Have you already made IP/technology available to CGIAR? And if so on what general terms and conditions has this been done? (And under what contractual format? E.g. license, MTA etc)

Appendix 2

PIPRA (Public Intellectual Property Resource for Agriculture)

Draft Definition of Humanitarian Use

Definitions:

"Humanitarian Purposes" means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a Developing Country.

"Commercial Purposes" means to make, have made, propagate, have propagated, use, have used, import, or export a product, good or service for the purpose of selling or offering to sell such product, good or service.

"Developing Country" means any one of those countries identified as low-income or lower-middle-income economies by the World Bank Group* at the time of the effective date of this agreement and all other countries mutually agreed to by Licensor and Licensee.

Reservation of rights

"Notwithstanding other provision of rights granted under this agreement, University hereby reserves an irrevocable, non-exclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.

* World Bank Low-Income and Lower-Middle-Income Countries (2005)

Afghanistan Indonesia Sri Lanka Albania Iran, Islamic Rep. Sudan Algeria Iraq Suriname Angola Jamaica Swaziland

Armenia Jordan Syrian Arab Republic

Azerbaijan Kazakhstan Tajikistan
Bangladesh Kenya Tanzania
Belarus Kiribati Thailand
Benin Korea, Dem Rep. Timor-Leste
Bhutan Kyrgyz Republic Togo

BhutanKyrgyz RepublicTogoBoliviaLao PDRTongaBosnia and HerzegovinaLesothoTunisiaBrazilLiberiaTurkeyBulgariaMacedonia, FYRTurkmenistanBurkina FasoMadagascarUganda

Burkina Faso Madagascar Uganda
Burundi Malawi Ukraine
Cambodia Maldives Uzbekistan
Cameroon Mali Vanuatu
Cape Verde Marshall Islands Vietnam

Nigeria

Pakistan

Central African Republic Mauritania West Bank and Gaza Chad Micronesia, Fed. Sts. Yemen, Rep.

Zambia

Zimbabwe

Micronesia, Fed. Sts. Chad China Moldova Colombia Mongolia Comoros Morocco Congo, Dem. Rep Mozambique Congo, Rep. Myanmar Cote d'Ivoire Namibia Cuba Nepal Djibouti Nicaragua Dominican Republic Niger

El Salvador Papua New Guinea

Equatorial Guinea Paraguay
Eritrea Peru
Ethiopia Philippines
Fiji Romania

Ecuador

Egypt, Arab Rep.

Gambia, The Russian Federation

Georgia Rwanda Ghana Samoa

Guatemala Sao Tome and Principe

Guinea Senegal

Guinea-Bissau Serbia and Montenegro

Guyana Sierra Leone Haiti Solomon Islands

Honduras Somalia
India South Africa

Appendix 3

CGIAR Private Sector Committee: Science and Know-How Exchange Program (SKEP)

Extract from Report to the CGIAR AGM 2004 of the CGIAR Private Sector Committee

Center Interface Program: Bernward Garthoff presented the draft outline of the "The Scientific Exchange and Training Program". A new name was suggested for this program – 'the Scientific and Know-how Exchange Program' (SKEP), to indicate the comprehensiveness of the proposed activities. The years 2005 to 2008 would be the Phase I/ramp up of the program, starting with 1 or 2 exchanges, and the years 2008 to 2015 would be the full program, each with defined milestones. The full program would envisage up to 20 scientists per year.

The program mission and targets are: the transfer of technology, know-how, knowledge, information in designing, controlling, managing R&D and developing a higher level of trust. Inputs of the CGIAR are to be incorporated as we go forward. We need a shared vision to achieve deliverables. Two IP ownership options were also presented.

Bernward Garthoff offered, on behalf of Bayer CropScience, to provide to the program, the position of the head of the program for the start-up phase. Members welcomed this kind gesture.

It was agreed that the program was about commitment to:

- relationship building, underlying trust
- competency development, which is workforce development
- · reach and complete projects more effectively and
- about public relations and corporate responsibility,

...which the members further agreed, could be the key output of the program.

Kanayo Nwanze welcomed the proposal and indicated that it had a high chance for success because it was addressing a real need in a win-win fashion. There would have to be preconditions, e.g. conditions to be observed for protection of IP. He thought that the time frame was realistic. Selcuk Ozgediz felt that it could be thrown open to all the centers who are interested and that those interested could form a "pilot group" to test the idea. Others could join depending on the results being obtained. Kanayo Nwanze also felt that they need to look for 'champions', to build alliances between PS and CG.

The following were among the main points made during the ensuing discussion:

- SKEP should be planned with a long-term perspective (10 year proposal).
- Members should review the 2 IP options (or a hybrid that could be developed) and express their views to Bernward Garthoff.
- Discussions should take place directly with the Centers.
- The Centers need to be convinced that there is a space for Global Public Goods to be produced with this framework (of SKEP).
- Financing to be finalized in the coming months, with Bayer Crop Science already offering to provide the Head of the program for the start-up phase and CGIAR willing to support with funds.

THE ROLE OF INTERMEDIARIES IN MAINTAINING THE PUBLIC SECTOR'S ESSENTIAL ROLE IN CROP VARIETAL IMPROVEMENT

Gary Toenniessen and Deborah Delmer The Rockefeller Foundation, New York, USA

Introduction

Seeds form the foundation of agriculture. Without seeds there is no next season's crop. The prevailing methods of developing, accessing and exchanging improved seeds and other planting materials determine in large measure that benefits from advances in the plant sciences, crop breeding and biotechnology.

As opposed to the health sector, where science now primarily leads to only high-priced end products, we in the agricultural sector are fortunate to still have BOTH a strong public sector international research system (Figure 1) that can "prime the pump" of crop varietal improvement, and if necessary, deliver affordable end products to poor farmers, AND a private sector seed system that can add value to crop varieties and increase the efficiency and sustainability of seed deliver systems.

Fundamental Research Institutions

Agricultural Universities,
Biotechnology Research Institutes

International Agricultural
Research Centers

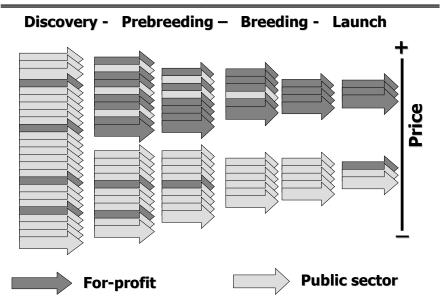
National Agricultural Research Sys.
NGOs. Local Seed Companies

Developing Country
Farmers

Figure 1. The International Agricultural Research System

For many years, the public sector and private sector seed systems have functioned in parallel, and sometimes in partnership – often strengthening and seldom impeding each other (Figure 2).

Figure 2. Crop Variety Development Pipeline



Publicly funded agricultural research has traditionally played and continues to play an essential role in developing and disseminating improved crop varieties: 1) for poor farmers who have limited purchasing power, and 2) when and where seed sales are thought to be unprofitable by the private sector. In many regions of the world such "public sector" crop varieties have led to significant increases in farm productivity and profitability.

From 1960 to 2000, over 400 public breeding programs in over 100 countries released over 8,000 modern varieties of staple crops derived in part through this international network (Evenson and Gollin, 2003). Roughly three-quarters of the cultivated land in Asia is now planted to such modern varieties and the vast majority of all improved crop seeds used by farmers in developing countries are still produced by this public sector system.

Through resulting increases in crop productivity small scale farming became the engine of national economic development in many countries. And, as the purchasing power of farmers increase, they are able to afford even better crop varieties marketed by the private sector. This process has benefited literally billions of poor people and is one of science's greatest accomplishments.

The advent of biotechnology now presents a number of challenges (proprietary property, regulations, public acceptance) to these established seed systems, particularly to the public sector's ability to deliver seeds of inexpensive improved crop varieties. Increasingly, enabling technologies and information used to produce improved varieties are protected as proprietary property by both the private and public sectors. Industrial countries have made IPR an important component of international trade negotiations, using them to exploit their competitive advantage in research and development. Countries joining the World Trade Organization, for example, must have IPR systems that include protection of crop varieties, according to the Trade Related Aspects of Intellectual Property Rights (TRIPS) provisions. Many developing countries had only until January 1, 2006, to implement such IPR systems. In the USA and Europe IPR systems have

contributed to the oligopolization of the seed industry leaving only a handful of major international seed companies serving farmers.

Because poor farmers cannot afford to purchase new seed for each planting, it is important that developing-country IPR laws are modelled on plant variety protection systems that include provisions allowing farmers to save and replant seed, and plant breeders to use varieties for further breeding. This is in contrast to the utility patent system that extends protection to the seed and progeny of patented plants so breeders cannot legally use protected varieties as breeding material.

Ironically, a major IPR change that is threatening the operations of the international agricultural research system comes from public, not private sector research institutions. To promote technology transfer and product development in the United States, the 1980 Bayh-Dole Act gave universities and other public funded research institutions the right to obtain patents on and commercialize inventions made under government research grants. Similar arrangements have emerged in most other industrialized countries. The result is that while many biotechnology discoveries (e.g. knowledge of gene function and gene regulation) and enabling technologies (e.g. Agrobacterium and biolistic transformation methods) are generated with public funding in research institutions and agricultural universities, these discoveries are no longer being treated as "public goods". Rather, they are being patented and licensed, often exclusively, to the for-profit sector (Graff, et al., 2003). Such discoveries now primarily flow from the public sector to the for-profit sector. If they flow back out, it is usually under material transfer agreements (MTAs) that significantly restrict their use (usually for research purposes only), limit further sharing and often include reach-through provisions to capture results of future research.

Since crop genetic improvement is a derivative process, each incremental improvement made through biotechnology now comes with a number of IP constraints, with new IP added with each transfer or further improvement (Barton and Berger, 2001). IP is used to protect biotechnology tools and reagents; genes and gene sequences; regulatory sequences; processes of transformation, regeneration and diagnosis; and, the resulting modified plants. It is in part to deal with this thicket of patents, and to gain "freedom to operate" (FTO), that the private sector is becoming greatly centralized through a large number of mergers, acquisitions and cross licensing agreements.

The publicly-funded agricultural research community, for the most part, lacks FTO. Leading academic researchers are primarily interested in research competitiveness. They readily sign research-use-only MTAs to gain access to the latest research tools but are then restricted from further transferring their research products. Many universities have "technology transfer offices" where maximizing licensing and royalty income is just as important as technology transfer, and thought to be best achieved by granting exclusive licenses. The net result is that most improved plant materials produced by academics are highly IP encumbered. Academics often have no, or at best only partial, rights to the products they produce because they have used someone else's enabling technologies. If they share such products, a research-use-only MTA is usually used to protect the university from infringement suits. Commercializing such products is only feasible when done by companies having an IP portfolio covering most of the technologies used.

The international agricultural research system does not have a significant IP portfolio and, as a consequence, the traditional flow of materials through the system is breaking down, particularly where useful new technologies and improved plant materials had flowed from public sector

researchers in developed countries to international Centers and national crop improvement programs in developing countries. Even when academics and other public sector researchers in developed countries do share technologies and plant materials, they seldom can offer any rights to commercialization. Thus, Africa in particular is being short changed of the benefits of biotechnology because, unlike Asia and Latin America, its public sector has little capacity to use biotechnology for the benefit of poor farmers, even in countries where the IP is not protected. Africa is much more dependent on partnering with others, but publicly funded researchers in industrial countries are no longer partners who can freely and usefully share their most important discoveries and products.

New mechanisms are needed to re-establish and re-invigorate the linkages between universities and the international agricultural research system, and to build new linkages to the expertise and resources of the private sector.

Intermediaries

Over the past few years a number of intermediary organizations have been established to facilitate the transfer of new crop improvement technologies to developing countries. Three that the Rockefeller Foundation has helped to establish are described below.

Public Intellectual Property Resource for Agriculture (PIPRA)

PIPRA is a consortium of leading agricultural universities and plant research institutes located primarily in the USA and committed to strategically managing intellectual property on behalf of its members, to enable the broadest commercial and humanitarian applications of existing and emerging agricultural technologies. Currently PIPRA has 23 members with 16 more in discussions to join. The University of California Davis has been chosen as host institution and one of its faculties, Prof. Alan Bennett is serving as Executive Director. The universities and institutes associated with PIPRA have generated much of the IP in crop biotechnology, but they have also entered into exclusive licensing agreements for this IP with the private sector. These agreements often eliminate their ability to share their technologies with each other or with other public-sector institutions such as national and international research Centers that are working on new crop varieties for poor framers in developing countries.

For many public universities, the practice of exclusive licensing has also constrained their ability to generate specialty crops for farmers of their own states and countries – a mission that is often part of their charters. There are dozens of new transgenic varieties of crops like strawberries, apples and lettuce in university greenhouses; plants that can grow without pesticides, that would benefit both local farmers and the environment, and that were paid for with taxpayer dollars, but are not being brought to market (Gianessi, et al., 2002). Neither the universities nor small companies have sufficient IP rights to commercialize them, and the companies that hold the rights are only interested in major crops like corn, soybean and cotton.

The irony is that, collectively, the universities originally held most of the necessary IP rights but have exclusively licensed away rights to the enabling technologies they themselves now need. To correct this problem, the universities involved in PIPRA will promote licensing strategies that favor retention of some of the rights to their own technologies, while still realizing a return on licensing the major market rights to the private sector. The licenses they grant will therefore no longer be exclusive. The universities will retain and share rights to use their technologies for humanitarian purposes, and also for the development of specialty crops for which markets are

small and which do not compete with the large private companies. By maintaining a public database, PIPRA will also provide information about technologies that are now available to the public sector without IP constraints. It will also explore IP pooling mechanisms designed to help scientists develop new crops that can truly reach those that are most in need.

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 IPR, to 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 has established a series of near-term objectives aimed at demonstrating the feasibility of this initiative and laying the groundwork for collective public sector IPR 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. PIPRA will seek to enhance IP expertise and management practices among researchers, administrators, technology transfer staff, sponsors, policymakers, industry, and farmers, to facilitate publicprivate R&D partnerships and promote technology transfer to developing countries. For these endeavors, PIPRA has recently developed a working relationship with another RF-supported intermediary called MIHR (Center for the Management of IP in Health R&D; see www.mihr.org). Through a special grant from RF, MIHR and PIPRA will collaborate to expand MIHR's Handbook of Best Practices for Management of Intellectual Property to include case studies and experience from agriculture; and to develop educational materials and outreach programs for technology managers in Northern research institutions to promote licensing practices that benefit both global health and poor farmers in developing countries. They also hope to adapt MIHR's capacity building program so that PIPRA can accelerate its own work schedule -- by joining MIHR's ongoing effort -- to raise the stature and capacity of technology managers in publicly-funded research institutions in developing countries.

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. PIPRA will work to increase the transparency and reduce uncertainty about FTO in agricultural biotechnologies. It 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 and availability, information not usually available in other databases. PIPRA will provide preliminary FTO analyses and patent landscapes displaying the patents neighboring technologies. It has partnered with M-CAM, a patent analysis firm, to provide on-line public access to PIPRA's portfolio database and to offer members the benefit of state-of-the-art IP management tools. PIPRA will also work with MIHR to explore whether it will be possible to expand PIPRA's patent and licensing database to incorporate health technologies that are of interest to MIHR.

Facilitate Access to Public Sector IP PIPRA will develop and promote use of common licensing formats and languages with specific "fields of use" designations that encourage licensing of

technologies to the private sector for specific crops and territories while maintaining rights for the development of subsistence and specialty crops. It has also developed its own working definition of "humanitarian use", and interacts with other groups interested in IP issues to help craft more general licensing strategies that protect IP for humanitarian uses. It hopes to bundle complementary technologies from member institutions under single sub-licenses to increase usefulness and availability while decreasing transaction costs. PIPRA will assist its members and its clients in negotiating legal access to the tools they need for commercial crop improvement applications. PIPRA will also facilitate important patent donations and assure their stewardship.

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. PIPRA is also identifying technologies that can substitute for those with legal restrictions and is now engaged in the process of creation of new plant transformation vectors with components such as promoters that are drawn from the IP of its member institutions or from the public domain. These are intended to be licensed broadly and to provide optimal FTO.

PIPRA has begun to expand its membership beyond the USA with the International Maize and Wheat Improvement Center (CIMMYT) and the Fundacion Chile recently joining and is in dialog with other institutions. Other international research Centers may also want to explore membership as one option for dealing with IP constraints and management issues. See www.pipra.org for further information.

Biological Innovation for Open Society (BIOS)

BIOS is the creation of CAMBIA (Center for the Application of Molecular Biology in Agriculture) based in Canberra, Australia. At its on-line website (www.bios.net) the "Patent Lens" component of BIOS provides an extensive patent database, IP tutorials, guides to IP policies and practices, and information on the countries in which patents have been filed. The database has over 1.6 million life science patents from the US and European-based databases in a fully text searchable and downloadable format. It includes INPADOC patent family information provided by the patent offices of over 70 countries as well as information on the status of the patent in most of those countries. These tools assist the user in determining the IP boundaries of what is free to use in what countries and what is not.

A second component of BIOS is termed BioForge. It is a new internet-based platform for cooperative invention, improvement and delivery of biological technologies within a dynamic protected commons. BioForge hopes to provide a portfolio of key enabling technologies for biological innovation that are available through an "open-source" license designed to encourage further innovation. This is accomplished through covenants in the license which require that: 1) all improvements in the technology be shared and licensed without charge to all other licensees; and, 2) all regulatory information generated concerning the technology be shared with all other licensees. The BioForge website (www.bioforge.net) is a modification of the software developed by CollabNet for sharing innovations in software.

CAMBIA recently developed two new tools for plant transformation that will be made available for use and further improvement through BioForge (Broothaerts, et al., 2005). These tools should provide an excellent test case for applying open source concepts in the life sciences.

African Agricultural Technology Foundation (AATF)

The AATF (www.aatf-africa.org) is a new institution designed to promote public-private partnerships that benefit African agriculture. The AATF is an African-based and African-led facilitative organization that will operate by creating partnerships with existing organizations. The AATF has offices in Nairobi, a staff of about 15 and is led by the prominent African food scientist, Dr. Mpoko Bokanga. The AATF will not be aimed primarily at distributing finished products. Rather, it will be a focal point where Africans can access new materials and information on which technologies and products can be built. It is a way of giving very poor nations the tools to determine what new technologies exist in the public and private sectors, which ones are most relevant to their needs, how to obtain and manage them, and how to develop nationally appropriate regulatory and safety regimes within which to introduce these technologies.

In a series of discussions over the past few years, representatives from the large private sector companies with large IP portfolios in 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 real 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 protection against use of the technologies in ways that interfere in the company's own commercial spheres of interest.

The AATF will transfer materials and knowledge, offering its partners access to advanced agricultural technologies that are privately owned by companies and other research institutions, usually on a royalty-free basis. In exchange for access to these technologies, the AATF will identify and often support partner institutions that can: use them to develop new crop varieties that are needed by resource-poor farmers; conduct appropriate biosafety testing; distribute seed to resource-poor farmers; and, help create local markets for excess production. Most of the major international seed companies and the US Department of Agriculture have expressed serious interest in working with the AATF to accomplish its goals. The AATF will provide the organizational stimulus to bring together the elements of the public-private partnerships. The existence of new technologies with great potential, not only for food security but also for income generation by resource-poor producers, and the willingness of companies to collaborate make this the right time to bring these elements together.

The AATF has engaged 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 are identified, and the AATF 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 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 may 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 provide the matchmaking, stewardship, and guidance at all levels to ensure the development of 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 critical, and the size of current markets makes it unlikely that the private sector alone will enter into R&D and commercialization 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 partnership in other parts of the developing world.

Conclusions

PIPRA, BIOS and AATF are all relatively new entities that face many challenges. One major challenge will be to remain steadfast in their goals. For PIPRA this means sticking with its policies that will keep its IP broadly available even when temptations to engage in exclusive licensing persist. For AATF, the challenges relate more to its persistence and skill in finding mechanisms to keep the private sector engaged and willing to find solutions for transfer of its valuable technologies for use in Africa. For BIOS, the newest of the entities, the challenge will be to find strong partners willing to take the risk of working within the framework of a creative commons. All three entities will also need to find means to become self-sustaining. But one hopes that new organizations like PIPRA, BIOS and the AATF will prove their worth and ultimately make long-lasting contributions that can help millions of the world's farmers with limited purchasing power access affordable improved crop varieties that can help make their farms more profitable and build their purchasing power. Over time they too can then become important customers of private seed companies. The key to such success is for the public sector and private sector to work together to maintain and strengthen the parallel crop variety development system depicted in Figures 1 & 2.

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