

Maintaining Access to Modern Science to Serve the Poor: A Case Study with Rice

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Maintaining Access to Modern Science to Serve the Poor: A Case Study with Rice⁸

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Modern biology is generating revolutionary advances in genetic knowledge and our capacity to change the genetic make up of crops and livestock. Much of this new science is proprietary, owned both by the private sector and increasingly by advanced public sector researchers, leading to a concern by many, and expressed by Serageldin (past chair of the CGIAR):

that the progressive monopolization of knowledge – and the increasing marginalization of most of the world's population – is skewing the new science to the benefits of the rich and excluding the poor.

The poor of the world deserve the best that science has to offer. Consequently, national and international public sectors in the developing world will have to play a key role, in accessing proprietary tools and products (Intellectual property (IP)) from the private sector to serve the poor. Conversely, the owners of the IP have an opportunity and an obligation to see that their technologies are made available to the poor in non-commercial markets. The paper discusses policy and institutional options for accessing IP within a framework of public and private bargaining chips and segmented markets. Four case studies focusing on rice, the food source for most of the world's poor, are discussed. The case studies are the exchange of germplasm to maintain choices

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and diversity in farmers fields, the discovery and ownership of a rice gene from African rice, the freedom to operate (FTO) Vitamin A rice, and an International Consortium on Rice Functional Genomics to provide a public platform for gene discovery in rice.

The challenge is to develop a shared vision for rice research that will provide the public sector access and freedom to use modern tools and sufficient incentives for the private sector (including advanced institutions in developed and developing countries) to innovate, develop, and deliver new rice technologies and more choices to farmers (and consumers).

⁸ This paper draws substantially from other papers published by the author in collaboration with Derek Byerlee including:

- Fischer, K. and Byerlee, D. (2001) Managing intellectual property and income generation in public research organisations. *In*: Byerlee, D. and Echeverria, R.G. (eds) *Agricultural Research Policy in an Era of Privatization; Case Studies of Change*. CABI Press forthcoming, pp. 227-244.
- Byerlee, D. and Fischer K.S. (2001) Accessing modern science: policy and institutional options for agricultural biotechnology in developing countries. *IP Strategy Today* No 1.
- Byerlee, D. and Fischer, K.S. (2002) Accessing modern science: policy and institutional options for agricultural biotechnology in developing countries. *World Development* **30**, 931-948.

Introduction

Crop improvement research, defined to include breeding and other disciplines such as pest science and agronomy that produce new cultivars, has been the major success story of the public agricultural research systems, both national and international, over the past three decades. There has been an unparalleled increase in food at lowered prices, and the benefits have been fairly equally shared among the urban and rural poor.

The base for this success was a culture of sharing genetic resources and the most modern scientific methods without infringing Intellectual Property Rights (IPR). The International Network for Genetic Evaluation of Rice (INGER) is a good example. Over the last 20 years it has safely exchanged over 20 000 breeding lines among 65 countries and from which 525 varieties have been released to farmers. Yale economist Bob Evenson has computed an annual net worth of each released variety to be US\$2.5 million – an enormous help to farmers in non-commercial markets.

However, several trends have contributed to reshaping the environment for public research in the 1990s; these have been outlined by Barton (2000) as:

- *The privatization and globalization of research and development (R&D)* due to the strengthening of IPR to cover biological processes and organisms, leading to consolidation of knowledge of modern science in the hands of a few life-science companies, which largely serve commercial markets.
- *Implementation of plant varietal rights (PVPs) in developing countries* as required under Trade-Related Intellectual Property (TRIPs) agreements. In theory, PVP provides incentives for private investment in research and a mechanism for the public sector to enter into agreements with private seed producers to bring its products to the market and ensure that publicly-funded research has an impact at the farm level (Tripp and Byerlee 2000). PVP, however, may temporarily restrict the flow of germplasm that was so important in the immediate past.

- *Restrictions on the free flow of germplasm* by national rules on export of local germplasm, as allowed under the Convention on Biological Diversity (CBD). Many countries now see these materials as part of their national patrimony that they can use as bargaining chips for gaining access to new tools and technologies from industrialized countries, or as potential sources of income from bio-prospecting. Again, these new laws have reduced the exchange of genetic materials.
- *Funding pressures on public research organizations* due to stagnation and decline of public funding in many countries in the 1990s (Pardey and Beintema 2001). Many governments have responded by asking public research organizations to develop policies to commercialize their products and services, and have set targets for earning a specific share of funding by these means.

Of concern for the public research system will be its ability to access modern science from the private owners on acceptable terms. A complex web of IP ownership is associated with almost all biotechnology innovations. One example in rice is that of Vitamin A rice for which Kryder *et al.* (2000) identified 44 potential patents. There is little experience in developing countries with mechanisms to obtain the FTO for enabling tools and products, and it is still too soon to delineate general patterns of technology transfer agreements that can be used as models for others. However, there are a number of private-public licensing agreements that provide access by the public sector in non-commercial markets at reasonable royalties. These business agreements, including the definition of segregated commercial and non-commercial markets, needs to be encouraged.

Centre stage in modern biological science is *genomics* – the science of deciphering the structure and function of a genome in totality. It is fortuitous that rice, the world's most important food crop, has a small genome, which has been sequenced. To fully exploit the wealth of structural information about the rice genome, scientists must now understand the specific biological functions encoded by a DNA sequence through detailed genetic and phenotypic analyses. Only then will the new science of genomics lead

to trait discovery and help solve intractable problems for sustainable rice systems.

The public sector is asset rich in the biological stocks and technical knowledge (phenotyping) needed to describe the function of genes. It is important that the public sector collectively manages these assets in order to have access to modern science and this can best be achieved through a public platform for functional genomics in rice that provides benefits to both private and public members.

This emerging environment for the application of modern science raises the question about the principles and strategies the public sector can take towards IP to:

- Maintain a flow of germplasm to provide diversity and choices to farmers.
- Access IP and obtain the FTO at reasonable royalties.
- Use public assets for gene discovery through functional genomics and ensure use of the products.

This paper uses a few case studies in rice to outline the effects of the modern era of science on public goods research and then proposes some principles and strategies for public organizations to gain access to modern science in the new environment..

The era of modern science: some case studies in rice

1. The privatization and globalization of research and development

The strengthening of IPR to cover biological processes, along with modern biotechnology, has increased investment by the private sector in agriculture. At the same time public organizations in developed countries are increasingly asserting ownership as a means to generate income. These changes are increasing the interest by the private sector to invest in agriculture in developing countries (provided that there is adequate protection of their IP) and this adds choices to farmers (provided that there is a well-funded public research system as well).

These changes are, however, affecting the public research system, particularly in the exchange of plant genetic resources. Two examples in rice

have focussed the attention of policy-makers in developing countries.

- a) US Patent No. 56,663,4811 was lodged on the 2 September 1997 seeking protection of 'basmati rice lines and grains' in the USA. The patent describes the plant breeding process using basmati lines to develop varieties in the USA. The names of Texmati, Kasmati and Jasmati have also been trademarked in the USA. These lines have been developed from Basmati collections that were freely exchanged in the past among all public researchers.
- b) US Patent No. 5,859,339 grants the Regents of the University of California a gene that enhances resistance of plants to *Xanthomonas*. The basic biological assets used to discover the gene (Xa 21) were the original germplasm collection from Mali and the near isogenic lines developed at the International Rice Research Institute (IRRI). These were freely shared with research partners and used to further innovate, leading to the cloning of the Xa21 gene and the proprietary ownership of it by the University of California.

Both cases highlight how genetic assets of developing countries have been used, in the past era of free exchange of materials among all scientists, to develop proprietary products, some of which may be restricted in their use to help the poor. The issue for today is to ensure that such materials are shared under material transfer agreements(MTA) that would provide benefits to the public goods research system.

2. Implementation of plant varietal protection (PVP) in developing countries

Intellectual Property Rights to cover biological inventions is a requirement by the TRIPS agreement for developing countries to enter the World Trade Organisation. In theory, IPR in the form of PVP provides a strong incentive for private investment in research leading to superior varieties. Also, because PVP provides protection to the owner or breeder of a particular variety, it provides a mechanism for the public sector to enter into agreements with the private sector to bring its products to the market. PVP can therefore increase the efficiency of the seed delivery system and in that way ensures that

publicly-funded research has an impact at the farm level. Most countries are implementing relatively weak PVP systems that provide breeders' rights to use protected varieties for research and farmers' privileges to maintain seeds.

Prior to the introduction of PVP, most countries exchanged their materials freely, usually through an international or regional network supported by one of the international centres. An example is the INGER which has worldwide membership and has resulted in the release of over 1700 varieties in farmers fields.

This free flow of germplasm has not only increased the diversity of varieties in farmers fields; it has also increased the genetic diversity in modern cultivars through more complex pedigrees. For example, in rice, only three varieties released before 1965 had more than four ancestors; 222 varieties released through INGER after 1976 can be traced to five or more ancestors, and 75 varieties have more than 15 ancestors. The origin of the 1700 modern rice varieties developed in Asia can be traced to 11 592 cultivars (Evenson and Gollin 1997). Evenson estimates the value of each released variety linked to INGER at US\$2.5 million annually. Member countries are both a donor and receiver of these benefits.

Changes in IPR, however, are affecting the very basis for past successes of public sector research in developing countries. In the case of INGER, many participants have stopped sharing their rice cultivars even though they have in place PVP laws that in theory would protect their genetic resources. The number of varieties in the INGER network has fallen from 1454 in the years 1985-1989 to 208 in the years 1998-2001.

Maintaining this culture of exchange of varieties in order for breeders to continue to use the material of others directly, or as material to intercross locally, is critical for the long-term sustainability and resilience of rice systems. The issues for the NARS are:

- To ensure that PVP and bioprospecting laws do not reduce the flow of genetic diversity.
- To ensure that privatization and globalization do not reduce the diversity of varieties deployed in farmers fields.

- To encourage public-private collaboration to deliver more choices to farmers.

3. Accessing the freedom to operate IP technology

All research organisations generate IP in the form of their research products and services, and they have the option to develop exclusionary mechanisms on their use through a variety of forms of IPR. In order to use IP products, it is increasingly necessary to gain the FTO from the owners. Arrangements for access will differ widely depending on the technologies, their use in commercial or non-commercial markets and the business interests of their owners.

For example, the enabling technology of transformation is basic to the use of the technology for gene transfer. It is a radical innovation owned by a few. This can create strong barriers to the use of this technology. Thus, even in many developing countries with weak patents laws, the owners have taken out IPR on enabling technology, thereby requiring users to seek licensing agreements..

In another example, that of Vitamin A rice, there are many components to the technology all with IPR and diffuse ownership. Kryder *et al.* (2000) identified 44 potential patents related to the FTO Vitamin A rice in the USA, while the number of relevant patents in developing countries varies from 0 to 11. Thus many developing countries face patent restrictions on the use of Vitamin A rice, although there is no clear pattern related to the size of the rice market (Table 1).

Even those countries with no relevant patents (i.e. Thailand, Pakistan) face difficulties with FTO if used on products exported to countries where patents are held. Thus, although it is strictly legal to unilaterally access (without FTO from the owner) the technology in those countries that do not grant a patent (or no patent is lodged), there are a number of limitations; the complexity of many tools often needs the associated know how and training; and the rapid advances in science will likely leave the public sector working with outdated tools.

Table 1. Number of patents on Vitamin A rice, level of rice production and fraction exported, by country

Country	Rice production 1998 (Mt)	Fraction exported 1998 (%)	Number of patents
China	200.6	2	19
India	127.5	4	5
Indonesia	49.2	4	6
Bangladesh	28.3	0	0
Vietnam	29.1	13	9
Thailand	22.8	28	0
Myanmar	16.7	1	0
Japan	11.2	0	21
Philippines	10.2	0	1
USA	8.5	37	44
Brazil	7.7	0	10
Pakistan	7.0	27	0
Egypt	4.5	10	0
Nepal	3.6	0	0
Nigeria	3.3	0	0
Cote d'Ivoire	1.4	0	10
Uruguay	0.9	76	0
Senegal	0.1	0	0

Source: Byerlee and Fischer (2002) with original source Kryder *et al.* (2000) and FAO statistics (www.fao.org)

Most countries need to develop a strategy and business plan to access IP products and gain the FTO, preferably at reasonable royalties in the non-commercial markets.

4. The new science of genomics for gene discovery

Rice has one of the smallest genomes among food crops and is the first to be completely sequenced by a public consortium coordinated by the Japan Rice Genome Program (www.staff.or.jp/rgp/rgpintro.html). The number of participants is large and includes, in addition to Japan, the rice-growing countries China, India, Korea and Thailand as well as France, the UK and the USA. Recently China has completed sequencing of Indica rice and both Monsanto and Syngenta have released a working draft and a complete sequence respectively of the rice genome.

A completely sequenced rice genome promises an enormous pool of genetic markers and genes for rice and for other cereal improvement through marker-assisted selection (MAS) using conventional breeding or through gene transfer within and between species. There is concern by some (Serageldin and Persley 2000) that the poor will not be adequately served by the new science. Many of the products with high potential for alleviating poverty will not be those that attract the necessary private sector investment. Yet these national systems are asset rich in the resources now needed to add function to the gene sequence, viz. genetic stocks and phenotyping capacity. The main issue is for the public sector to become an equal partner to the suppliers of the genomic tools to access the new products. To do so requires the public sector to develop new guiding principles and strategies for the use of their assets.

Principles and strategies for managing IP by the public sector

In the broadest definition almost all products of applied research can be classified as IP that has potential to generate income or be used as a bargaining chip to trade for the IP of others. The development of an institutional policy on management of this IP must have as its major objective to maximise benefits of public investment to society and ensure equity in the distribution of those benefits. The policy must consider a number of issues including:

1. Maintaining the flow of germplasm

In most crops, the public sector has access to, or is custodian of, large sets of genetic resources. These genetic resources can be grouped into three distinct classes based on their use and application (Table 2).

Of these, the IP management of the original germplasm, either in banks or *in situ*, is a complex issue, the principles of which are covered under the Convention on Biological Diversity (CBD) and for which the International Treaty of Plant Genetic Resources for Food and Agriculture has developed implementation guidelines.

The introduction of PVP and bio-prospecting laws has reduced the flow of the other two categories: the genetic stocks and developed varieties.

Table 2. Genetic resources of the public sector categorized by their application to agricultural research and the policies for their exchange

Germplasm category	Application and policy for exchange ^a
Germplasm collection	Material discovered, collected, and documented; the CBD covers its exchange and use; <i>ex situ</i> collections held in trust by the CGIAR system are exchanged under a FAO-CGIAR accord that prevents patenting of these materials. Each nation has sovereign rights to materials.
Genetic stocks as research tools	Various materials derived from germplasm collections and developed materials that provide insights into gene function. Includes near-isogenic lines, mutants, mapping populations, cDNA libraries, and insertion lines. Genetic stocks are important assets for genomics and gene discovery. IP managed by MTA and patents.
Developed varieties	Products that are genetically uniform and distinct. Includes varieties, inbred lines (fixed), hybrids, and transgenic lines. IP managed by PVP and MTA.

^aCBD = Convention on Biological Diversity, IP = intellectual property, PVP = plant variety protection MTA- material transfer agreement

At this early stage in the implementation of the new laws, there may be a growing temptation for public-sector programs to restrict access or charge unrealistically for materials. The public sector needs to be realistic about the potential for income generation and consider the following policy options:

- View public-private agreements as a means of effectively carrying out its broader societal mandate by using the private sector to ensure wide distribution of its products.
- View membership in international genetic resource networks as both a donor and a receiver; there is good evidence to suggest that the benefits to society of the free exchange of germplasm out weigh financial gains (Evenson and Gollin 1997).
- Introduce regional rules and guidelines as proposed by the ASEAN Framework

Agreement on Access to Biological and Genetic Resources (www.grain.org/brl/asean-acces-2000.cfm) to govern the exchange of materials.

- Explore the use of the IP associated with Geographical Indication (i.e. regional trademarks and appellations) (Blakeney pers. comm.) to protect valuable resources and markets. For example the geographic trademarking of Basmati or jasmine rice that is produced by unique varietal and environmental conditions and which has well-established consumer markets.

2. Public-private collaboration, market segmentation, and the use of bargaining chips

As seen in the vitamin A patent profile, patents on the important enabling tools have been lodged in most countries, requiring public systems to develop IP and business strategies to access the modern science in order to best serve their clients.

One approach to negotiating successful partnerships is to identify complementary assets for use as bargaining chips. Another is to clearly define the market and target research of the public sector to the non-commercial segment, thereby increasing the opportunity for collaboration with the private sector.

One of the major bargaining chips available to the public sector is access to, and especially its knowledge of, germplasm and associated evaluation networks in developing countries. In the past, the public systems shared these assets freely as in the case of Xa21gene and Basmati lines. Clearly public systems must develop new strategies to balance the gains from the free flow of germplasm against the potential to use the assets as bargaining chips for effective licensing agreements.

Recently Fischer *et al.* (2000) have proposed that genetic resources (with the exception of those materials held in trust in the germplasm banks) required for functional genomics in rice be made available to the public and private sectors under a MTA that:

- Permits recipients to obtain patents on genes discovered through the use of the material.
- Requires the owners of the IP to make available those rights for research purposes in

all public sector research in the developing countries.

- Requires the owners to make available the rights for use at reasonable royalties in commercial markets (in the developing countries) and at zero royalties for subsistence markets.
- Prevents recipients taking out IPR on the genetic stock *per se*.
- Makes the genetic information gained from the study using these stocks publicly available.

There is recent evidence that the pattern of rights envisioned in this MTA can be implemented through licensing agreements that agree on a segmented market as seen in the agreement for the use of Vitamin A. The acquisition of the pro-vitamin A transgenic seed and of the genes for beta carotene was made possible by the donation of IP by Syngenta Seeds AG, Syngenta Ltd, Bayer AG, Monsanto Co, Orynova BV and Zeneca Mogan BV to IRRI and selected NARS. The agreement allows IRRI to sub-license the materials to its research partners to facilitate the development of the golden rice. The final product will be made freely available to subsistence farmers, defined as those earning less than US\$1000 per annum. This includes most rice farmers in Asia and Africa. This is a good example of the partnership between the private and the public to address technology for the poor. There is a clear commitment for the free use of the technology in the non-commercial markets, while the private sector can pursue profits in the commercial sectors in developing countries with farmer incomes of less than US\$1000 annually. Segmented markets must be decided on a case-by-case basis and, although appealing, the concept has practical hurdles to overcome. In practice market segmentation often requires intense negotiations, the development of trust between partners, and the capacity to enforce agreements on markets.

In addition to these approaches, the public sector has various options such as joint ventures, confidential agreements, licensing, purchasing and 'design around' to gain access to the use of the modern science (Erbisch and Fischer 1998), which are described in detail by Byerlee and Fischer (2001) and Fischer and Byerlee (2001).

3. A public platform for functional genomics in rice

Rice a unique model crop – not only is it the most important food source for the world's poor, it also has the smallest genome which is now fully sequenced. If managed properly rice can be a model to take advantage of the evolutionary relationship between plants and translate the knowledge across other species. The IRGSP has provided the first building block by collectively making the genome sequences available in the public domain. On 4 April 2000, Monsanto released the first 'working draft' of the rice genome and has provided the draft and some clones to the IRGSP for research purposes. In January 2001, Syngenta announced the complete sequencing of the rice genome, making this information available on a restricted basis. And more recently China has announced the sequencing of the rice genome based on *Indica* rice.

This combined effort by the private and public research system leads to the possibility of a assigning function to the approximately 50,000 genes of the rice genome.

There are three main pillars of functional genomics as indicated in Figure 1, which are:

- Genetic resources
- Phenotyping
- Genomic tools

and the integration of them by bioinformatics.

In rice, the developing countries are richly endowed in the first two of these pillars. They can be used as bargaining chips with owners of the other components in a public-private collaboration for gene discovery in rice.

Fischer *et al.* (2000) have called for a set of principles to collectively guide the use of these assets in order to improve the most important food crops of the world.

The Guiding Principles (suggested) would include:

- Full adherence to the Biological Convention on Genetic Resources.
- Open access to genetic stocks, phenotyping information and genomic tools for research to enhance our fundamental knowledge of the world's most important crop.

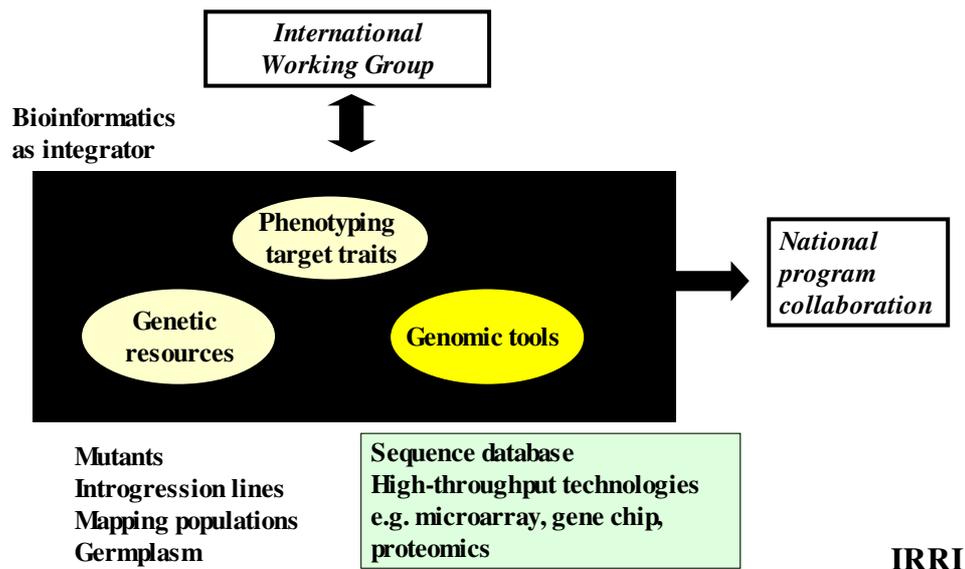


Figure 1. Functional genomics: public resources platform and collaborative framework (from H. Leung, IRRI pers. comm.)

- Encourage and reward innovation through patenting of products.
- Respect the need for IPR to capture profits in the commercial markets.
- The inventor is required to make rights under those patents available at a reasonable royalty for application in the developing world, and at zero royalty for subsistence agriculture.
- All information (including sequence information) gained from research using public goods genetics must be posted on a website, after an appropriate delay to allow publication or patenting.

To begin such collaboration, an International Rice Functional Genomics Working Group (FGW) (www.cgiar.org/irri/genomics/index.htm) has been formed and, through a series of consultations, IRRI, which hosts the FGW, identified three activities of high priority in the rice research community:

1. Create an information node to communicate information related to functional genomics. This information node is largely being constructed as a part of the International Rice Information System (IRIS; <http://www.iris.irri.org>).
2. Promote the sharing of genetic stocks.

3. Facilitate access and sharing of genomics tools and related resources (e.g. microarrays and proteomics).

As of now, over 15 institutions and research laboratories from developing and developed institutions are members. What is now necessary is the commitment and public announcement by all members to a set of guiding principles that ensures that the collaboration will provide innovations for the poor. Such a statement requires vision and social commitment by both parties.

Conclusions

In the past decade the privatization of research and growing assertion of IPR by both private and public R&D organizations over biological inventions and germplasm assets are radically reshaping research in the public systems in developing countries.

An early change has been in the free exchange of genetic material and varieties that have served all countries well in adding diversity and choices for farmers. As countries implement their PVP and bio-prospecting laws, there is also a need for sensible rules and regulations to be developed at the regional level to guide the flow of germplasm in regional networks. The ASEAN community has begun such a process. Without such changes

farmers will be denied choice in the diversity of varieties for sustainable development.

The public research systems must develop strategies to gain access to proprietary tools and technology. One way is the better use of their own assets as bargaining chips for cross licensing at reasonable royalties. The IPR profiles of modern technology are often complex and the private sector has shown some willingness to assist in gaining FTO among the various IP owners at zero royalties in non-commercial markets.

The concept of 'market segmentation' provides a way forward for access IP to serve the poor, and needs to be strengthened through more good-will from the private sector, more trust between the private and public sectors, more clarity in the goals of the public sector to serve the non-commercial markets, and enhanced capacity by the developing countries in IP and business negotiations.

A healthy, well supported public research system is essential in order to leverage public-private collaboration.. The IRGSP is a good example. It accelerated the sequencing effort and the public release of the data by the public and the private sectors.

Finally, a public platform for rice functional genomics is the logical sequence to the IRGSP and is necessary to ensure that genetic knowledge of the most important food crop remains freely accessible for use in future plant breeding. The next steps are to gain public-private confidence and trust through a 'community contract' so that a truly collaborative agenda can be developed. The proposed collaborative agenda is not unique in most aspects. What we advocate in rice that is unique, however, are the arrangements for specific rights in new inventions derived from biological and 'know how' assets held by the public sector. We seek, in exchange for the use of these assets, the use of the products in developing countries at reasonable royalties. If fully embraced by the private and the public sectors, such collaboration can bring the benefits of innovation and modern science to solve intractable problems for both commercial and subsistence farmers, most of whom rely on rice.

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