IPRs II: How Intellectual Property Rights Can Affect Daily Management of PGRFA

(summary of presentation)

I. Relevance to GR professionals

Intellectual property issues may arise in the acquisition, characterization and distribution of germplasm. One of the inherent characteristics of germplasm is that it is a tangible or real object that can be used consumptively like other natural resources. And as with other natural resources, issues related to ownership and dealing with sharing and access can arise. But germplasm is also used as a source of information: the genetic information found in the chromosomes of the nucleus and associated sub-cellular structures of the plant or animal. This information can be employed to develop useful synthetic compounds or as a source of desirable genetic traits. It is often the latter characteristic that has combined with scientific advances and led to the worldwide expansion of intellectual property (IP) regimes over genetic resources.

Intellectual property issues may involve formal (statutory) IPRs and/or ownership rights arising from contractual obligations.[1] Formal IPRs come about as the result of an assignee or inventor filing an application for protection of IP, such as a patent application for patent rights, or the creation of IP that attracts IPRs automatically, such as copyright (in most jurisdictions). The IP could be something such as an invention or a new plant variety, and filing needs to be done under a national regulation, such as filing for plant variety protection (PVP) under a PVP regulation or rule.[2] A successful application for PVP will lead to IPR, usually referred to as plant breeders' rights (PBR). In addition, it is possible that specific germplasm could have other types of IPR associated with it, such as patent rights or a trademark registration. Having a patent IPR associated with germplasm might occur if a developer of germplasm has used a patented technology—such as a method or a material—in the development of a new germplasm or variety. A trademark may be associated with a particular identification for a variety or a method, for example, that could be valuable as a marketing tool. Genetic resources managers need to know whether there are formal IPRs associated with germplasm that is in their collection—or any contractual obligations that may be attached to germplasm that is in their collection. Such IPRs or obligations may affect or restrict the ability of a genetic resources manager to distribute such germplasm.

Intellectual property 'protection' essentially means that third parties can be prevented from producing or selling goods or services without the right-holder's or title-holder's authorization. Unlike rights associated with physical property, intellectual property rights are temporary, with

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[1] Contractual obligations over germplasm or plant varieties often flow from a material transfer agreement (MTA) that may have covered material provided by another party.

[2] Intellectual property can be protected by a plant variety protection certificate, a patent, a trademark/trade dress, copyright, database right, geographical indication and as a trade secret, for example.

the exception of trade secrets (which are protectable as long as they remain undisclosed) and trademarks (the protection of which can be extended limitlessly).

Depending on national laws, patents (one of the more important forms of intellectual property for the private sector) may be applied to genes, cells, microorganisms and different classifications of plants and animals. In some countries (e.g., the United States, Australia), patent protection may cover biological materials found in nature, to the extent that they have been isolated and purified, as well as those produced with genetic engineering. In other countries (e.g., Brazil), however, protection cannot be granted with respect to biological materials that pre-exist in nature, even if isolated. Plant breeders' rights are a form of protection specifically designed to protect new plant varieties.[3] It is important to note that the availability of the product for further research differs between most patent systems and systems conferring plant breeders' rights. Research exemptions allowing the use of a protected product tend to be quite narrow in patent law. Under UPOV and other systems of PBR, the protected varieties remain available for further breeding (for a fuller discussion, see Session 6). Countries may also develop other effective *sui generis* regimes for that purpose. It is important to understand, however, that in order to receive patent protection, a patent holder must guarantee the availability of the material over which rights have been granted, especially after the patent expires and the invention is in the public domain. There is no such guarantee under most plant variety protection systems as it is thought that others will have used those varieties that are useful, as parental material in the development of new varieties.

Intellectual property rights are originally owned by the inventors, and the inventors are usually under an obligation to assign their rights to their employer, which could be either a public or private entity. The collective rights of indigenous peoples and local communities[4] with respect to traditional knowledge have also been recognized in some jurisdictions. However, the delimitation and enforcement of such rights pose considerable conceptual and operative problems, especially with regard to identification of the inventors. The existence of collective rights on forms of IP that are protected by copyright (for example, a film or video may have many copyright owners) has been a usual practice for many years.

Non-statutory or 'informal' IP protection associated with germplasm often arises from an agreement or contract, often a type called a material transfer agreement (MTA), covering the material to be transferred, given or distributed. The MTA will contain provisions or terms that specify certain obligations about the use and/or distribution of the germplasm. Germplasm does not need to be protected by PVP, or a patent or any other formal protection, in order for its distribution to be made under an MTA. It only needs to be owned or held by a genebank in order for distribution of material to be carried out under an MTA (for a discussion of MTAs under the IT, see Session 5).

Genetic resources managers, especially those involved in acquisition and distribution, need to be aware and have a clear understanding of institutional IP policy and what is expected with regard to implementation of the policy, often in the form of institutional IP guidelines or procedures. If there is no IP policy, an understanding of, first, national laws, and, second, international legal obligations—such as those arising under the IT—relevant to the

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[3] See Session 7 on the UPOV Convention.

[4] See Article 8(j) of the CBD. See also the draft text of a 'Draft Declaration on the Rights of Indigenous Peoples', which states that 'Indigenous peoples have the right to special measures for protection, as intellectual property, of their traditional cultural manifestations, such as literature, designs, visual and performing art, seeds, genetic resources, medicines and knowledge of the useful properties of fauna and flora' (U.N.Doc.E/CN.4/Sub.2/192/33, Annex 1, para. 19).

institution's germplasm, including plans for collecting and distribution, is necessary to assist management in the development of appropriate policies and procedures that fit the institution's mission/mandate. The GR managers responsible for access and distribution are also likely to be responsible for making sure that the necessary procedures—whether a germplasm acquisition agreement (GAA), MTA or another type of agreement—are followed.[5] At a practical level, this means that managers responsible for the access and distribution of genebank material in the genebank need a database of contractual and IPR information relevant to accessions in the genebank. They also need an understanding of the implications of this information for the genebank's ability to distribute particular accessions of germplasm and an awareness of when they should call upon an IP expert (e.g., an IP lawyer, a lawyer who specializes in contracts/transactional issues, a PVP examiner, an IP agent).

II. Main issues with regard to the CBD

The Convention on Biological Diversity (CBD) recognizes national sovereign rights over genetic resources, including establishing the conditions for collection and subsequent use of the collected materials for commercial or research purposes, which must be implemented by national law of those countries that are members of the Convention (see Session 4). Three main issues have been raised in this context: (1) genetic resources as the subject of IPRs, (2) the possible limitations on access to IPR-protected materials, and (3) the recognition and protection of traditional knowledge associated with germplasm. All three of these reflect potential or perceived tensions between private property rights conferred by patents, copyrights, database rights and/or plant breeders' rights and the application of national legislation aimed at achieving the goals of the CBD.

A. Genetic resources and IPRs

As indicated, patent rights, as conferred in some jurisdictions, can be allowed over novel genetic materials by private entities.[6] Patent rights can only be awarded to new or novel inventions. In the context of national patent laws, the legal definition of what constitutes new/novel depends very much upon the interpretation that is given by the national laws and the interpretation of those laws by the attendant national judiciary. For example, in the US an inventor is allowed to file a patent application for a year after the invention is made public. The practical definition of 'novel', is also affected by the ability of patent examiners to find all publicly disclosed, printed material. Patent examiners may only have access to material that has been published in journals or international newspapers.[7] Lack of knowledge of the publication of information has led to a number of patents being granted with respect to the publication of knowledge useful for agriculture or medicine, which is known to and widely used by indigenous and local communities (such as turmeric, Bolivian quinoa and the Amazonian 'ayahuasca')[8]. This has raised concerns in many developing countries about a possible conflict in national law

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5 As the genetic resources manager, you may or may not have the ability to sign an MTA for your institution. Often, only the director general or head of an institution will have 'authorized signatory power' for an institution. However, sometimes such authorization can be formally held by other staff members, such as the genetic resource manager, for specific situations, as in the acquisition and distribution of genetic resources.

6 Please note, that in this context, 'private entities' may include public institutions, such as a public university or research institution.

7 This is just one example of the importance of the publication of *pre-grant* patent applications to a broad audience in order to encourage sending the materials to patent offices, so that patent examiners will be aware of any printed publications that would set the record straight on the state of public knowledge regarding any particular subject.

8 According to US Patent Law, unwritten disclosure *outside the United States* (e.g., by use) does not destroy novelty and, therefore, a patent can be granted if the other patentability requirements are met.

between IPRs, as recognized under the TRIPS Agreement, and the provisions of the CBD[9] on access to and use of genetic resources.

All countries have struggled with the tension between rewarding the individual inventor (who applies conceptual ideas to processes or products that involve germplasm) and society's obligation to share for the benefit of society as a whole. This is especially true when we are concerned with food crops. The need to develop an interface between IPRs and access regulations in order to avoid possible misappropriation of genetic resources has led some countries to impose limitations on the IPR protection of genetic resources and associated knowledge,[10] by establishing special conditions for the application and granting of IPRs relating to biological materials,[11] providing compulsory licences[12] or setting other conditions to encourage competitive practice. However, given the territoriality and independence of patent rights, such limitations and conditions usually only prevent the granting of IPRs or lead to their cancellation in the country where the limitations or conditions were applied, but not in foreign jurisdictions.

B. Limitations to access of material under IPRs

Another issue that has generated concern is the impact, where genetic materials are under IPRs, that such IPRs may have on the access to such materials for further research and development. Those concerns have been fuelled by the expansion of IPRs, particularly patents, to include living organisms (including genes and any sub-cellular components) and the admission in some countries (USA, Australia, Japan) of patents on plant varieties.

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[9] See an analysis of the submissions by developing countries to the Council of TRIPS on this issue (GRAIN May 1999. http://www.grain.org/briefings/?type=2&l=0) and an update on where developing countries stand with the push to patent life at WTO (GRAIN, March 2000. www.grain.org/publications/tripsfeb00-en.cfm).

[10] For instance, the Costa Rica Biodiversity Law recognizes 'the existence and validity of forms of knowledge and innovation and the necessity to protect them by means of the use of legal mechanisms appropriate for each specific case', but it excludes the following from any kind of intellectual property protection (including community intellectual rights):

- sequences of deoxyribonucleic acid *per se*;
- plants and animals;
- non-genetically modified microorganisms;
- essential biological processes for the production of plants and animals;
- natural processes or cycles as such;
- inventions essentially derived from knowledge that is associated with traditional or cultural biological practices in the public domain;
- inventions that, to be commercially exploited through a monopoly, can affect farming or fishing processes or products that are considered basic for the food and health of the inhabitants of the country (Article 78).

[11] For instance, Decision 391 of the Andean Group stipulates that Member countries shall not recognize intellectual property rights over genetic resources or their derivatives or associated intangible components, when access took place in contravention to the access rules provided for by such Decision. The affected Member country can request the cancellation of granted titles. In addition, national offices competent in the area of intellectual property rights shall require proof of the approval and registration of an access contract if they have reason to believe that the products or processes for which protection is sought have been obtained or developed on the basis of genetic resources under the jurisdiction of Member States. The Costa Rica Biodiversity Law provides for a mandatory consultation with the offices in charge of granting patents and PBRs in relation to inventions that 'involve biodiversity elements' and requires the proof—based on a 'Certificate of Origin'—that prior informed consent has been obtained (Article 80).

[12] In the Philippines, in the case of endemic species, research contracts must state that the technology should be made available to a designated Philippine institution and can be used commercially and locally without paying royalties (Section 5.l of the Executive Order No. 247). In Costa Rica IPRs granted on subject matter involving biodiversity are subject to a compulsory licence for the benefit of the State in the case of a declared national emergency, without payment to the title-holder (Article 81, Biodiversity Law).

However, it is also noted that patent rights are only awarded with the agreement that inventions, under IPRs, are dedicated to the public domain at the end of the patent term. In addition, in many countries the invention and the materials/methods needed in order to practice the invention *must be available* (i.e., the invention must be enabled) for 'philosophical pleasure'[13] or for 'research purposes'[14] during the term of patent rights. As a consequence, many countries require that germplasm, such as seeds or transformed/ transgenic plant cells, must be deposited in a 'Budapest Treaty Repository'.[15]

The granting of PBRs under plant variety protection does not limit the use of the protected material as a source for further breeding, owing to the generally accepted 'breeders' exemption'. In addition, *sui generis* types of protection for plant material, such as the Indian Plant Variety and Farmer's Rights Law, or the US Plant Patent,[16] also allow protected material to be used breeding material in the creation of new varieties, without the permission of the holder of the patent rights. In the area of patents, the practice of individual sovereign countries diverges with respect to exemptions to utility patent rights.

C. Traditional knowledge and IPRs

The need to develop some form of protection for the knowledge of communities has gained growing recognition since the 1990s. The adoption of Article 8(j) of the Convention on Biological Diversity gave impetus to this idea (see Session 4). Many approaches have been proposed to deal with communities' knowledge, ranging from the creation of new *sui generis* forms of IPRs to the simple option of legally excluding all forms of statutory rights over such knowledge, be it under patents, breeders' rights or other modalities of IPR.

Many commentators have explored the use of existing forms of IPRs to cover traditional knowledge in a meaningful way, such as the use of copyrights. However, the most recent discussions have centred on requirements in prosecutions under patent law, for stating the origin of the material and/or TK necessary for conceptualizing or practising an invention for which rights are sought. Such a requirement would make it much easier for originators of knowledge or material to receive compensation if the invention is commercialized. A recent case, involving the Hoodia cactus, provides an example of what could be accomplished by such a requirement.[17]

While the World Intellectual Property Organization (WIPO) has been studying this question for many years,[18] only a few countries have so far addressed the complex conceptual and operational

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[13] Under US law, exceptions to infringement are 'purposes of amusement and philosophical gratification' and 'philosophical, amusement, or curiosity purposes' (see 'Roche v. Bolar Pharmaceuticals', USDCA, 572f, Supp 255, 1983), for an interesting and practical treatment of (US) exceptions to infringement, see the article by M. D. Janis (fall 2003) that is available on-line at http://www.card.iastate.edu/research/stp/papers/Janis-seminar-Fall-03.pdf.`

[14] Under European Patent law, for example. According to a recent article, 'Experimenting using the invention is not exempted whilst experimenting on the invention, for example to see if it works, or to improve on it, is' (see http:// www.intellectual-property.gov.uk/ipac/pdf/030204comp.pdf).

[15] For additional information on the Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purposes of Patent Procedure, see http://www.wipo.int/treaties/en/registration/budapest/index.html.

[16] Use of material protected by a U.S. plant patent is not a part of the law; this exemption was provided by a judicial decision.

[17] For a discussion of this case, see R. Chennells (2003): http://law.wustl.edu/centeris/Confpapers/PDFWrdDoc/ChennelFinalApril2003.pdf.

[18] See http://www.wipo.int/tk/en/.

problems involved in the recognition of the rights of indigenous and local communities over their knowledge.[19]

III. Acquisition and use of technology: relevance to GR access and distribution

Genetic resources managers need to acquire new material in such a way as to ensure that problems will not be created if material is to be distributed in accordance with current institutional IP policy.[20] For example, it will be necessary to know if technology has been used to develop the material to be acquired and whether the technology has formal or non-statutory (i.e., contractual) IPR (provisions) associated with it. The need for complete and correct documentation cannot be over-emphasized. If there are proprietary interests[21] in the technology, it is necessary to know in what jurisdictions (countries) IPRs have been awarded, who owns the technology and the status of such ownership (for example, under assignment or licence).

Copies of licence agreements for the technology that was used in the development of the material should be reviewed to understand whether constraints to distribution will be encountered. Sometimes, tracking down all of the technology, the IPRs associated with the technology and the owners of the IPRs can be very complex, will involve the cooperation of many owners, and may require the use of legal assistance, as in the case of *Golden Rice*®.[22] Unless this information is known and assessed, the acquired germplasm cannot be distributed without the possibility of IPR infringement. If there are limitations on the access and distribution of the germplasm that are at odds with institutional IP policy, attempts to clarify the situation might be needed. The need for an exhaustive analysis should be balanced against the risk to your institution. For example, it may be, as in the case of *Golden Rice*®, that in some jurisdictions very few of the innovations are covered by IPRs, especially in countries outside of the industrialized group.

Remember also that IPRs are territorially limited: there is no international patent, for example. This means that if a technology used in the development of a new germplasm is protected only by a patent issued by the United States, then this germplasm is protected only in the United States. In other words, the germplasm cannot be used, sold, exported out of, imported into, or made *in the USA* without proper authority (a licence or licences from the IPR owner/owners). However, this material could be used, made or sold in other countries.

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[19] For instance, the Constitution of Ecuador (1998) recognizes 'collective intellectual property rights' for communities' ancestral knowledge (Article 84). The Costa Rican Biodiversity Law established a legal concept of community intellectual rights and provided for a voluntary registration system. Under this law, any pre-existing community rights shall absolutely prevent any grant of PBR or patents on the same subject matter. In Brazil, Provisional Measure 2.052-6 (21.12.2000) provides that the State recognize the rights of indigenous and local communities to decide on the use of traditional knowledge associated with genetic resources. Said knowledge is protected against 'illicit exploitation' and other unauthorized use [Article 8(1) and (2)]. The Organization of African States (OAU) developed an African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources. The Model law proposes an explicit recognition of communities' intellectual rights through a specific registration system, as well as the right not to allow access to the resources and knowledge under their control when access may threaten the integrity of their natural or cultural heritage.

[20] This discussion does not apply to so-called 'black-box' storage.

[21] 'Proprietary interests' means that the owner of the property has rights (IPRs) that can be exercised in this situation.

[22] The IPR issues associated with the technology used in the development of *Golden Rice*® have only recently been sorted out by the owners, after several years of analysis and compromise. Research was able to continue during this time; however, the required negotiations added transaction costs to this project.

Nevertheless, it is important to remember that there may also be agreements, such as an MTA or other contract that have been signed in order to acquire the material. The terms of the MTA or other contract may specify the terms under which the material may be used, sold, made, etc., regardless of conditions that apply due to formal IPRs associated with the material. These terms may preclude the distribution of such germplasm in a manner consistent a genebank's IP policy.

IV. Lessons from the CGIAR

A. Background

Perhaps some of the most dramatic developments in legal and policy issues affecting the CGIAR's work have taken place in the field of access and intellectual property rights. This has been particularly true with regard to the perception of NGOs regarding the potential application of intellectual property rights to biological materials and processes. It is in this context that the CGIAR has endorsed Guiding Principles on Intellectual Property Rights and Genetic Resources, recognizing that they may need to evolve in response to changing law and technology (Table 3.8.1).

Developments affecting the conservation, exchange and use of genetic resources include, for example, the development of rules of access to germplasm, the use of intellectual property rights, most notably benefit sharing with regard to patenting plant varieties and/or their components. Awareness of these developments has expanded dramatically, creating an uncertain but arguably more restrictive environment for the use and deployment of genetic resources. Methods and technologies of critical importance to the research function of CGIAR centres are also increasingly protected by intellectual property rights, rendering access and use more problematic. However, so far there are no documented cases where IPR owners have refused access to protected technology for research purposes. Distribution of products to poor farmers has rarely been a problem with respect to IPRs[23]; however, wide distribution of results has occasionally been curtailed. The rise of broad, so-called 'blocking' patents raises the possibility that intellectual property rights might be employed in ways that can affect the development, improvement, access to and distribution of genetic resources in genebanks. However, thus far this has not been a problem. And of course, the conclusion of the IT also has IP implications for the CGIAR, some of which remain to be resolved as the treaty moves forward (see Session 5).

The underlying philosophy for the CGIAR Guiding Principles is that the management of intellectual property by centres must be guided by the CGIAR mission to contribute to food security and poverty eradication in developing countries through research, partnerships, capacity building and policy support. Any engagement with intellectual property directly or indirectly would need to be done as the best means of pursuing the CGIAR's mission. The Guiding Principles also reflect the CGIAR's view that the protection of intellectual property should not serve as a mechanism for securing recurring financial returns upon which it (the CGIAR) may depend. To the extent that such returns are generated, they are to be used in support of specific tasks and projects fully compatible with the CGIAR mission and objectives. In addition, the centres are becoming more sophisticated in their ability to negotiate with partners for any collaboration necessary for the development of products that will reach poor farmers.

[23] Considerations of biosafety, food safety and liability have caused delays in product distribution.

B. Specific examples of issues of general relevance

1. IP embedded in the genetic resource

Use of IP that is an integral part of, or has been used in the production of, a genetic resource (often referred to as IP 'embedded' in the genetic resource) can present situations that require a careful understanding of the specifics of the particular situation. For example, if a particular type of breeding scheme, which is protected by patent IPR granted in the United States, has been used to develop a new variety of castor seed, this technology is a part of that particular castor seed germplasm. In other words, if a person grows this variety (or *any* variety of castor seed developed with the protected breeding scheme) *in the United States* without a licence from the owner, then this person will be committing an infringing act. He or she will be infringing on the rights of the IPR owner, and the owner of the IPR can bring a civil suit against (e.g., can 'sue') the person who is growing the castor seeds, *and* anyone *in the United States* who buys, sells or uses the castor seed grown by the non-licensed person.[24] It is easy to see how the use of needed technology could—directly or inadvertently—infringe on the rights of an IPR owner. Genetic resources managers need to know about any technology, especially involving embedded IP, associated with germplasm in their genebank, especially that which is valid within their national jurisdiction.

2. Freedom to operate

In the dissemination or transfer of products that contain proprietary technology, reference may be made to the 'freedom to operate' (FTO) that is associated with a particular product such as seeds or other genetic resources. While not a legally defined term, and thus having a multiplicity of meanings in actual IP management practice, FTO often means that an IP professional (usually a lawyer) has looked at the terms of the IPR and contracts associated with a technology or a product in order to render an opinion as to whether infringement will occur if the technology or product is used, made or sold in a specific situation. In the commercial context, this type of analysis also looks at a firm's own IP with regard to scope of granted rights, to assess the extent to which the firm does not have to be concerned with IP that might arise in the future. This assessment includes terms and provisions—of formal IPRs, of non-statutory (contractual IPR) provisions, of contracts, agreements and licences—associated with the IP involved in the development of the germplasm in question.

The rendering of an FTO involves an understanding of what technology has been used in the development of the germplasm, an interpretation of claims, based on the written description and patent prosecution history, as well as case-derived law and interpretation, a search of IP (e.g., patent) databases to determine the status of statutory IPRs, an investigation of all contracts and agreements associated with the germplasm, and an understanding of the commercial situation regarding the technology used and the germplasm involved. However, sometimes an FTO may be just a quick verbal opinion, rendered by an IP attorney/ professional, based on his or her experience in a particular technology area. Regardless, an FTO is just an *opinion* and does not determine absolute infringement status, only the *risk* of possible infringement if the germplasm is grown, distributed, sold, etc., in a particular sovereign state.

Nowadays, many institutions are considering their risk exposure to the extent of determining if it is necessary for scientists to obtain an FTO opinion before research commences. This might be done in order to prevent a situation where a research product cannot be distributed or

[24] A court of law (a judge or jury) will decide whether any of these parties (the grower, the buyer, the user) are guilty of infringement. A party that is an infringer will have to pay a fine to compensate the IPR owner for revenue lost due to the infringing act. If trade secrets are involved, then criminal charges will also often be brought against the defendant.

used outside of the original laboratory where the research was performed, for fear of an infringement lawsuit. However, a more routine and fruitful approach is to incorporate FTO-risk analysis into a product development and delivery plan (which may also be referred to as a 'technology transfer plan'), as potential partners often have a license that permits distribution of a product, etc.

3. Defensive protection

Another issue that may affect GR managers are IPRs that are sought and obtained in order to provide 'defensive' protection.[25] In this type of situation, a developer may have applied for statutory protection only to prevent others from obtaining a patent or PVP for a new invention or variety. In this way, developers can be assured that no one will be able to prevent them from practising their invention or using their newly developed variety. No country allows statutory protection for an invention or product that is not new.[26] Therefore an invention cannot be patented twice; a defensive patent ensures that inventors will be able to use, sell, make, etc., their patented technology without fear of infringing on someone else's IPRs. An additional reason that inventors (or their home institutions) seek defensive protection is to increase the leverage they have to obtain other technologies from other IPR owners. Defensive protection may be associated with genetic resources and, as the manager, you need to know this. Often the owners of this type of IPR are very willing to give out licences that are royalty-free to anyone who asks.

4. Defensive Publication

Another approach often taken by both public and private institutions is to make a public disclosure that details an innovation or invention in such as way as to preclude someone else from taking out IPRs. Because IPRs are awarded on the basis of new or novel creations, if an innovation or invention is described and published, then it can be successfully argued that this invention is no longer 'new' or non-obvious. However, it must be realized that the 'grace' period of one year that is afforded to published material in the US on the basis of a 'first-to-file' priority system means that this window might allow an inventor to file a patent application (in the US) covering a published innovation. In addition, it is very important to know the rules by which patent examination offices determine the official publication date to ensure that the defensive publication will prevent the allowance of subsequent patent rights.[27]

5. Participatory plant breeding

Participatory plant breeding—the collaboration between traditional users/breeders and agricultural researchers—has been recognized more formally over the last 10 years. Nevertheless, there is still a range of definitions of what exactly it entails and, perhaps more significantly, key aspects of legal and ethical issues are only now being explored. A CGIAR-IDRC project on Participatory Plant Breeding and Property Rights is examining these issues with the goal of establishing 'best practice' or a code of conduct to guide genetic resource

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[25] Some would argue that statutory IP protection such as PVP and patents is always, strictly speaking, of a defensive nature, in that obtaining such rights must be enforced by the owner. An IPR owner must bring a lawsuit against someone that the owner thinks is an infringer. The government of a sovereign state will not bring suit against a potential infringer of a patent or of plant breeders' rights.

[26] There are some types of statutory protection that may not include a search of prior art before protection is awarded. For example, the awarding of some types of short-term patents in certain countries (so-called 'innovation' or 'petty' patents) may not require a search of the literature to determine if the invention is new. There are rare circumstances where legislation may include provisions that are unclear as to the new or novelty requirement, such as the newly enacted Indian PVP and Farmers' Rights Protection law.

[27] For additional information, see 'Defensive Publishing: A Strategy for Maintaining Intellectual Property as Public Goods'. ISNAR Briefing Paper #53, 2002.

professionals in their collaborative efforts with farmers and farming communities. Farmers and scientists are both innovators and inventors; their respective contributions need to be recognized and the benefits need to flow to both. Often such benefits can be non-monetary, such as the development of a new variety that best suits a farmer's needs or the publication of a report that enhances a scientist's professional reputation. Some would say that the heightened awareness of IPR issues has contributed to a better understanding of ethical considerations and the recognition of the contribution that farmers make, for example, when they adapt a variety to their own environmental or growing conditions.

V. Intellectual property management audits

Often an institution will carry out an IP audit to determine the status of IP being used and generated by their staff.

Such an audit might include assembling or making an inventory of relevant documents such as collaborative agreements, material transfer agreements, acquisition agreements and employment contracts. (A relevant document would be one that contains any language or provisions having to do with intellectual property ownership, assignment or any other dispensation; also any intellectual property such as data entered into logbooks or laboratory notebooks, invention disclosures, patents, patent applications, third-party property, etc.)

The auditors will go over each of these documents to assess the terms and conditions of each, how these terms and conditions might affect the ability of the institute to use and distribute (both their own and another's IP) and to (try to) establish ownership of each piece of IP. The audit should also include the establishment of a database of intellectual assets that have been produced by the staff of the organization and the scope of the IP in this inventory. (An audit will often include looking at so-called FTO issues, but likely will not include an FTO opinion, only the identification of the need for an FTO opinion to be made.) The auditors will determine the institution's vulnerability to challenges associated with IP, ranging from infringement to duplication of other's work to the need for defensive protection.

As mentioned previously, the auditors will create an inventory or a database of IP and IP assets.[28] Such a database, created in conjunction with an IP audit, will often, but not exclusively, concentrate on self-generated IP, usually in the form of inventions—or invention-disclosure entries. This will depend upon the terms of reference determined by the institution. It is important to remember that this inventory should include all forms of assets: patents and patent applications, PVP certificates and applications, trademarks, copyrights, databases, trade secrets, traditional knowledge, geographical indications, etc.

Another product of an IP audit should be recommendations with regard to institutional IP management. This might include drafting an IP Policy statement or a comprehensive strategy for dealing with IP issues, or it might just take the form of a limited number of recommendations that can be phased in by management to try to meet more limited expectations. Again, the terms of reference in the contract established with the auditors will determine the extent to which the recommendations are strategic and comprehensive.

[28] In the jargon of the IP professional, *intellectual assets* are those innovations/inventions that are the creation of human endeavour, while *IP* includes those intellectual assets for which formal IPRs have been sought or awarded.

IP audits can strengthen an institution's ability to make sure that it is using 'due diligence' in its use of another's IP, in protecting its own IP in compliance with its own IP policies, and in collaborating with other institutions and assessing the risk associated with the use of another's proprietary property.

The terms of reference for an IP audit of an institution that has a genetic resource should include such items as the following:

a) an inventory of all agreements, such as MTAs that cover individual accessions;
b) an inventory of intellectual assets/IP that is being used and generated by the staff of the institution;
c) an evaluation of all procedures used by the genebank for the acquisition and dissemination of materials;
d) an assessment of employment agreements, including those for temporary visitors, consultants, visiting scientists and scientists who have been seconded from other institutions, especially those persons who are involved with genebank operations;
e) a determination as to the status of embedded technology associated with any accessions, and whether such status suggests that a separate investigation (to determine the risk of exposure for infringement) should be carried out (such an investigation may take the form of an FTO);
f) an assessment of licences, including licences accompanying the procurement and use of laboratory reagents and equipment, to determine whether any IP provisions would affect the acquisition and dissemination of genetic resources;
g) recommendations regarding the management of intellectual assets/IP (both the institution's and other, third-party IP);
h) recommendations regarding legal actions, such as the filing of re-examinations or other types of challenges to the IPRs of others that might affect the institution's ability to distribute genetic resources;
i) evaluation of compliance with national and international agreements and regulations covering genetic resources and IP.

In order for IP auditors to have access to all of the materials and information that they need to carry out a good IP audit, it will be necessary for the auditors to obtain access to information that the institution considers to be confidential. This might be information that the institution has marked as confidential, to protect its IPRs or its ability to apply for formal protection. Or, confidentiality may be stipulated by a third party as part of an agreement or contract. In either case, the IP auditors and the institution will need to enter into a confidentiality or nondisclosure agreement to protect the rights of the institution and other third parties. This confidentiality agreement should follow conventional 'best practices' and include such items as an appendix of specific materials that have been disclosed to the auditors, a statement regarding how the confidential material will be used, a statement regarding ownership of information and reports that result from the audit, the time limitations associated with the access to confidential documents, a statement of whether the documents will be destroyed or returned, a statement regarding the settlement of disputes, an effective date, a termination date, etc. Such an agreement should be written with the help of a qualified attorney or lawyer. The confidentiality agreement needs to be signed by an authorized person and should be put into place before an audit is initiated.

Table 3.8.1. CGIAR guiding principles on IPRs relating to designated germplasm and centre research products

- The centres will not claim legal ownership nor apply intellectual property protection to the germplasm they hold in trust, and will require recipients of the germplasm to observe the same conditions, in accordance with the agreements signed with FAO.
- Materials supplied by the centres, whether designated germplasm or the products of the centres' breeding activities, may be used by recipients for breeding purposes without restriction. Recipients, including the private sector, may protect the products of such breeding through plant variety protection that is consistent with the provisions of UPOV or any other *sui generis* system, and that does not preclude others from using the original materials in their own breeding programmes.
- Based on the conviction that their research will continue to be supported by public funds, the centres shall regard the results of their work as international public goods. Hence, full disclosure of research results and products in the public domain is the preferred strategy for preventing misappropriation by others. Consequently, the centres will not assert intellectual property control over derivatives except in those rare cases when this is needed to facilitate technology transfer or otherwise protect the interests of developing nations. In all such cases, the centres will disclose the reasons for seeking protection.
- The centres do not see the protection of intellectual property as a mechanism for securing financial returns for their germplasm research activities, and will not view potential returns as a source of operating funds. In the event that a centre secures financial returns as a result of the commercialization by others of its protected property, appropriate means will be used to ensure that such funds are used for furthering the mandate of the centre and the objectives of the CGIAR.
- Any intellectual property protection of centres' output will be done on behalf of the centres and not individual scientists. All staff in the centres will be required to disclose innovations and assign all rights on these to the centres.
- Cells, organelles, genes or molecular constructs isolated from materials distributed by centres may be protected by recipients only with the agreement of the supplying centre. Centres will only give such approval after consultation with the country, or countries, of origin of the germplasm where this is known or can be readily identified. This consultation would include consideration of an appropriate sharing of any benefits, whether bilateral or multilateral, flowing from subsequent commercial development of the protected material,* and would require that the original material remains available for the public good.

To promote the availability to developing nations of germplasm and scientific innovations that have been protected by others, the centres may enter into agreements with the holders of such rights. Acceptance of any limitations on the distribution and use of derived and associated materials would have to be consistent with the goals and objectives of the CGIAR, and the benefits of such agreements should outweigh the potential disadvantages.

* It is recognized that this requirement for the granting of permission by a centre before a recipient can take out patent protection represents a significant departure from the current position in which the centres do not require any such permission. While this is not specifically required under the terms of the agreements signed with FAO, nevertheless the CGIAR feels that such a requirement is needed both to protect the interests of countries of origin and to bring CGIAR policy in line with the spirit of the Convention on Biological Diversity (CBD). While the CGIAR centres can not themselves be party to the Convention, it is nevertheless recognized that the majority of CGIAR members and partner countries have signed and ratified the CBD.