Conducting IP Audits

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ABSTRACT

This chapter explains how important it is for a research institute to audit both the intellectual property (IP) that it generates and the third party IP that its researchers utilize. Such an audit will have the practical consequence of enabling the research institute (when appropriate) to secure ownership, maintain, and manage the IP for which it is responsible.

1. INTRODUCTION

For a number of years, intellectual property (IP) rights were considered private rights and not of concern to the public research community. A number of developments have changed this perception. First, genetic materials have been privatized, limiting the genetic materials available for public research. Second, IP rights have been asserted over enabling biotechnologies, which has the potential to thwart the ability of public research institutions to pursue modern biotechnological research. Third, funding for public research institutes has been reduced, making them aware of their need to take an active role in IP management. Indeed, because of the above developments, public research institutes are now using their IP assets to bargain for access to private proprietary rights.

The first step in IP management is to conduct an IP audit. This will identify the IP that the institution's researchers generate, allowing it to be used as an asset and aiding in the identification of the IP of third parties. The latter is particularly important for the institution's ability to avoid liability for the misuse of third-party IP.

2. METHODOLOGY

The usual objectives of an IP audit are to identify relevant IP, establish the ownership of that IP, put in place procedures to manage the IP, and assist in the formulation and execution of the research institute's IP policy.

Of course, before any of these processes can begin, the scope of the audit must be determined. In some cases, an audit might be done to satisfy donor institutions or for external accreditation. On the other hand, it might be prefatory to the research institution's collaboration with the private sector. In each case, those commissioning the audit must determine the objectives. A decision will have to be made about who gets the results of the audit. It may be confined to the board, to donors, to management, or be made available to the public.

The audit may be conducted through:

- online surveys of senior administrative and research staff
- follow-up interviews, by phone or in person, with those staff

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- analysis of contracts, material transfer agreements (MTAs) and other documents held at the central administration
- analysis of relevant documents identified through interviews

Before the audit, it is often useful to sensitize staff about the relevance of IP to the research institution's operations. This can be achieved through workshops or distributing explanatory material, both of which can be done online. Surveys to identify agreements and activities with potential IP implications can also be administered online. Follow-up interviews will explore this information and identify documents that need analysis. Of course, all of the institution's contracts should be scrutinized for their IP implications.

Keeping the results of the audit confidential will be essential for securing the full cooperation of the institute. After all, the audit might disclose matters that the institute may find damaging to its reputation. More positively, areas of education and training for staff may be identified and the results of the audit translated into best management practices.

3. OWNERSHIP AND CONTROL OF IP

3.1 *Introduction*

A key goal for any IP audit is helping to establish the research institute's ownership and control of the audited IP. This requires examining all documents relevant to: (1) the legal status of the institute; (2) the obligations of personnel under their service agreements and employment contracts, together with their obligations under the institute's IP policy; (3) agreements with research collaborators; (4) agreements with funding bodies and donors; and (5) documents relevant to the research institute's status within any research network.

The ability of a research institute to assert ownership and control over any IP depends upon its legal capacity. In the case of an incorporated institute, this will be set out in its constitution and bylaws (memorandum and articles of association). The laws governing the place of incorporation will usually govern these documents. But if the research institute has international status, its powers may be derived from a headquarters agreement between the host state, donor bodies, and the institute.

Once it has the legal power to exercise dominion over property, including IP, the institute will also have the power to contract with its employees. Typically, IP clauses will be inserted in contracts of employment or in an institute IP policy or code referred to in the employment contract. The simplest of these clauses will oblige an employee to comply with the institute's IP policy, which will typically be available in printed form or on the institute's Web site.

For example, Washington State University's IP policy states:

All employees accept the terms of these policies as conditions of employment or gratis association. Employees shall agree to execute an assignment of their future patentable works and discoveries to the University. These policies may be modified by the administration with approval from the Board of Regents after consulting with faculty and staff of the University.[1]

As indicated below, this policy obliges employees to notify their employers of any innovations that might generate IP rights. For example, Texas A & M's IP policy applies to:

(i) *all persons employed by the System; and*

(ii) *any persons using the System facilities under the supervision of System personnel, including but not limited to visiting faculty and adjunct faculty, unless special terms for management of the work of such individuals are negotiated by the System or the applicable System component. System employees should not enter into intellectual property agreements related to outside employment, such as consulting or summer employment agreements, without affirmative notice to the prospective employer that the intellectual property rights of the System cannot be subordinated to a third party consulting or employment agreement*.[2]

It will be up to the institution to decide what to do with such IP. In some cases, IP rights might be waived. More usually, there is a procedure to

share the benefits of any exploitation of IP. The IP policy of Texas State University is typical:

In those instances where the System licenses rights in intellectual property to third parties, the costs of licensing, including the costs to operate and support a technology transfer office and departmental or institutional intellectual property advisory committees, and the costs of obtaining a patent or other protection for the property on behalf of the Board shall first be recaptured from any royalties or other license payments received by the System, and the remainder of such income (including, but not limited to, license fees, prepaid royalties, minimum royalties, running royalties, milestone payments, and sublicense payments) shall be divided as follows:

- *50% to creator*
- *50% to System*

With the prior approval of the Board … component institution may include provisions in its Handbook of Operating Procedures to adjust the allocation of royalties set forth herein, but in no event shall the creator receive more than 50% or less than 25% of such proceeds.

A similar situation will apply in research institutes operated by government departments. In each case the government department will have to decide whether any IP generated by its employees will be made available to the employee, whether it will be secured by the relevant department for exploitation or, alternatively, made available to the wider research community.

3.2 *Headquarters agreements*

For international research institutes, the agreement between donors and host governments will usually delineate the institute's legal personality. It will usually be designated as "*an autonomous, philanthropic, tax-free, nonprofit, nonstock, benevolent corporation*."[4] There will usually be a term for which the institute is to exist, such as 50 years from the date of incorporation, with a possibility for renewal. It will usually be indicated who owns the assets of the institute at the end of the term. Should an institute establish a collection of biological resources from other countries, biopiracy objections may arise if their ownership is lost at the end of the term.

The headquarters agreement will usually indicate the power of the institute to "*receive and acquire by donation, grant, exchange, devise, bequest, purchase, or lease, either absolutely or in trust, contributions of such properties, real and personal as may be necessary to carry out the objects and purposes*" of the institute. This provision will have no operative effect, as the power will be conferred by incorporation.[5]

3.3 *Incorporation*

Typically, a research institute will be incorporated under the law of the host country. This law will contain provisions about the types of corporations and their powers. Companies are usually divided into nonprofit and profit-making enterprises, and the ownership and assets structure of each may differ. Invariably, the voting rights of the company will be allocated by reference to shares. Management will consist of a board under a panel of directors and a chief executive officer. The powers of the company are usually set out in a constitution or a memorandum of association and detailed in its bylaws or articles of association. These documents should be scrutinized to see what powers the institute has to own and to deal with IP. The documents will also explain the powers of the corporation's officers to enter into transactions on behalf of the corporation. The procedures for terminating the existence of the institute and the disposal of its assets on termination should also be described.

The constitutive documents of a corporation are commonly silent about the fate of intangible property, such as IP, that is generated by the corporation during its life. This is because IP has only relatively recently become a corporate concern. However, where the tangible property is specifically disposed of, it is likely that the intangibles will follow the same route.

3.4 *Charter of the institute*

Public research institutes commonly indicate their public service function in a governing charter. The board, under the corporation's bylaws, will usually promulgate such a charter. As such, the charter will be subordinate to the general operation of the articles of incorporation and confer no powers

that are greater than those defined by the articles of incorporation.

3.5 *Personnel documents*

Typically, the personnel at a public research institute include national staff, internationally recruited staff, visiting scientists, consultants, affiliate scientists, project scientists, collaborative research fellows, and doctoral and postdoctoral students. Asserting ownership and control over the IP that personnel may generate will depend upon the terms of their engagement. For convenience, we can categorize these persons as staff and nonstaff.

3.5.1 *Staff*

The ownership and control of IP generated or held by staff will be handled by a combination of personnel contracts and the institute's personnel policies and procedures. These will usually be gathered in a personnel manual. Given the growing concern about IP staff, some institutes have been requested to sign an IP rights statement or a nondisclosure agreement. At the International Rice Research Institute (IRRI), for example, the statement is an *IPR Agreement* in which staff agree that "*all inventions, improvements, data, processes, technologies, discoveries and other intellectual properties*" generated by them, while employed by IRRI, "*that relate to the research and development programs of IRRI or result from tasks*" assigned to them "*are the sole property of IRRI*."[6]

Publication is a significant issue if a partner desires nondisclosure and the ethos of the institute is to publish its research. Premature publication in articles, research papers, and at conferences and meetings may destroy the novelty of a patentable invention. This is in tension with the desire of researchers to place their scholarship into the public arena. The IP audit can be an opportunity to introduce staff to the impact of IP upon their research. When proprietary technologies are licensed from the private sector, the license agreement may sometimes restrict publication until the commercial opportunities generated by the research have been evaluated. Nonresearch staff and board members should also be bound by a confidentiality obligation.

This list of IP categories embraced by the agreement is presumably intended to be informative and exhaustive for the staff members who sign it:

- The IRRI *IPR agreement* obliges staff to disclose the listed categories of IP "*promptly to IRRI*." A procedure for such disclosure should be established, identifying the person or office to whom/which disclosure should be made.
- The IRRI *IPR agreement* requires that employees assign relevant IP to IRRI and "*do all things necessary, including executing documents*" to assist IRRI in obtaining legal protection for its IP. This is a fairly effective means for IRRI to secure title to the IP generated by its staff.
- The *IPR agreement* also obliges staff to use confidential information only in the performance of duties for IRRI and not to disclose information to unauthorized persons both during employment with IRRI and for a five-year period after the termination of their employment. This provision appears to effectively impose confidentiality obligations.

Staff includes those employed outside the institution, such as those working in the field or attached to other institutions. They are bound by their employment contracts and potentially by the IP policies of the external institutions for which they work. The legislation of the countries where they work may also apply. For example, a number of countries have enacted legislation to regulate access to biological materials that might become the subject of patent applications. A research institute would be in breach of that law if it filed IP applications related to biological material that was obtained without consent.

Usefully supplementing the IPR agreement could be a reference to any institute policy on IP rights and a definition of those rights. Box 1 sets out a comprehensive definition of IP.

3.5.2 *Non-staff*

Research institutes frequently host various categories of nonstaff, such as visiting scientists, consultants, project scientists, collaborative research fellows, and students. Maintaining ownership

and control of the institute's IP can be a particular problem where non-staff are concerned. Without an agreement with them, the institute will be unable to assert control over IP that these visitors might generate or use. Indeed, problems have arisen from the uncertain status of visiting researchers, who in some instances have acquired patent rights over the subject of their research while a visitor. Accommodating researchers funded by outside donors has also been an issue. Uncertainty about the ownership of the research of such donors can be clarified in the institute's IP policy. Accordingly, a number of countries commonly require nonstaff to execute an IP and confidentiality agreement.

3.6 *Policy on IP*

Currently, public research institutes commonly formulate policies to deal with IP ownership and control. The policy is usually agreed to and approved at the board level. As a general principle, the institutes emphasize the free availability of the information, inventions, and biological material that they develop. Institutes are obliged, however, to seek IP protection to ensure the availability of advanced biological technologies or biological materials for developing countries. Some institutes declare that they may seek to protect technologies or materials that they develop for their client communities. Protection may also be pursued to prevent third parties from obtaining IP rights over their innovations. For example, by filing a provisional patent application, knowledge about an institute's innovations will be placed in the public domain. This is intended to destroy the novelty—and hence the patentability—of innovations that are required for the benefit of developing countries. This will prevent such inventions from being appropriated by the private sector.

Box 1: Intellectual Property

Intellectual property means information, ideas, inventions, innovations, art work, designs, literary texts and any other matter or thing whatsoever as may be capable of legal protection or the subject of legal rights and includes the following protections:

- patents
- confidentiality (for information which is of a kind and which has been communicated in such a way as to give rise to a duty of confidentiality)
- copyright vesting in literary works (including computer programs), dramatic works, musical works, artistic works, films, sound recordings, multimedia works, broadcasts, published editions, and certain types of performances
- registered trademarks
- unregistered trademarks used or intended for use in business
- registered designs and designs capable of being registered
- rights of breeders for new plant varieties
- rights associated with designs
- rights related to databases
- other rights resulting from intellectual activity in the industrial, commercial, scientific, literary, and artistic fields

A number of public research institutes include their IP policy within a policy on partnership with the private sector. These research institutes will often concede that to ensure that developing countries have access to biotechnology-derived products and advanced biotechnologies, it may be necessary to enter into special agreements that stipulate some limitations on distributing derived and associated materials. Within the context of this policy, the institute may assemble a list of IP that it is willing to share with the private sector in exchange for access to its IP, under mutually acceptable terms.

4. IDENTIFICATION OF IP GENERATED BY A RESEARCH INSTITUTE

4.1 *Background*

An IP audit obviously has to identify all the IP generated by the research institute, whether existing in a registered or unregistered form. This requires analyzing questionnaires completed by management and research staff, as well as the examination of contracts, MTAs, licenses, collaboration agreements, memorandums of understanding, collaborative work plans, employment contracts and other legal arrangements. This will allow the auditor to: (1) clarify the terms under which IP is being accessed; (2) determine whether the terms of access impose restrictions on the institute's ability to distribute products and services produced with the help of this IP; (3) identify ownership of relevant IP; (4) identify the source of IP in order to identify areas in which IP access and ownership issues may have to be reexamined to ensure compliance with the institute's current IP policy; (5) assess the importance of the IP to the institute's activities; and (6) identify all new IP being developed at the institute (specifically, the IP opportunities perceived by the institute, for its own and third-party IP).

Typically, an audit will identify the following main types of IP:

- patents and know-how associated with the biological assets of the institute
- patents and industrial design rights
- IP associated with agricultural equipment developed by the institute
- copyright, database rights, and know-how associated with publications, computer programs, and databases generated by the institute
- copyright databases and know-how developed from the functional genomics research undertaken at the institute
- trademarks
- industrial designs

4.2 *Patentable biological assets*

The principal biological assets located at a scientific research institute will include:

- germplasm collection
- DNA collection
- biological tools for gene discovery
- enabling technologies (for example, marker genes and probes)
- advanced mapping populations
- near isogenic lines
- introgression lines: mutants (characterized/uncharacterized); BAC library
- introgression lines
- gene pyramids
- advanced lines from conventional breeding: conventional lines; new plant types
- inbred lines for hybrids: a, b, and restorer lines
- varieties/cultivars
- hybrids
- transgenic lines

These biological assets represent a considerable investment by the institute, its partners, and collaborators. Insofar as they contain potentially patentable or licensable information, they also represent various levels of added value, utility, and inventiveness.

4.3 *Patents, utility models, and industrial design rights*

A medical or agricultural research institute is likely to develop equipment and tools that need IP protection.

4.4 *Technological know-how*

Not all IP is protected through a system of registration. An important unregistered category of IP

in medical research is confidential information. It is often an adjunct to registered IP rights. For example, patent protection is conferred in exchange for the disclosure of enough information in a patent application to permit the invention, which is the subject of the application, to be used. To protect its competitive advantage, the applicant inevitably will withhold information about how to effectively commercialize an invention. This information, or know-how, may include plant design and setup, training, marketing plans, customer lists, and accounting and survey methods. Similarly, a protected trademark is of limited commercial utility without an associated scheme for advertising, licensing, franchising, and marketing the goods or services under that mark. Ensuring the quality control of the licensed goods will usually entail the application of trade secrets.

At the center of the attempt to protect confidential information are efforts to restrain the disclosure of trade secrets by former employees or researchers. A particular difficulty in these cases is distinguishing between information that can be regarded as the skilled employee's or researcher's own expertise and other information gained during employment, such as secret industrial formulae or processes, which may properly be regarded as the employer's. Generally speaking, if the information in question can fairly be regarded as a separate part of the employee or researcher's stock of knowledge that a person of ordinary honesty and intelligence would recognize, the information would be considered to be the property of the employee. In applying this objective test, the courts have tended to look, among other things, at the nature of the employment, the nature of the information, and whether the information was capable of being isolated from other unprotected information. Chemical formulas and recipes and engineering drawings and designs are usually considered to be discrete categories of undisclosed information that fall within the category of protectable confidential information.

National laws protecting confidential information differ. Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO) deals with the preservation of confidential test data submitted to government approval agencies. Given the long approval process, particularly for pharmaceutical products, the opportunities for wrongful appropriation of such data by competitors was self-evident. Accordingly, Article 39 (3) provides that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

4.5 *Biological assets protectable as plant varieties*

New plant varieties developed by agricultural research institutes may be protectable under plant breeders' rights legislation. Such varieties can also be patented in the United States but not in Europe.

4.6 *Rights associated with publications, computer programs, and databases*

Copyright arises in relation to publications, CD-ROMs, databases, online displays, and software. Governing the protection of works created within a country, copyright laws are territorial. But through international agreements a particular country's laws can be respected outside its territory. Most countries are signatories to the TRIPS Agreement, which affirms the Berne Copyright Convention and adds some additional protection.

Most copyright laws provide protection for printed works, such as books, conference proceedings, research reports, and journals. Copyright protection is also available for research notes, provided that these are in written form. Copyright protection is also available for films, photographs, sound recordings, and CDs. Under the Berne Convention and TRIPS Agreement, computer programs are treated as if they were literary works. Finally, copyright protection is available for online materials and

screen displays. The period of copyright protection is conventionally 50 years from the date of a work's publication.

4.6.1 *Publications*

Copyright will exist in the textual material, photographs, graphic designs, diagrams, charts, and the compilation or arrangement of a publication. A research institute will publish scientific books (including monographs, conference proceedings, manuals, and field guides); discussion papers; proceedings of conferences, meetings and workshops; technical bulletins; and scientific posters.

4.6.2 *CD-ROMs*

A number of different copyright interests may arise for material on a CD-ROM. Copyright may arise with respect to text, artistic works (such as photographs, drawings, diagrams), musical works, sound recordings, and films, as well as in relation to the compilation of material contained in the CD. An institute may produce CD-ROMS as part of its training materials. For example, the asynchronous Internet-based courses in Experimental Design and Data Analysis and in Agricultural English, created and administered by IRRI, are available on CD-ROM. When materials have not been generated at the institute, the audit should ascertain whether permission or clearance has been obtained from the author or original source prior to publication. The audit should also determine whether the author or original source is acknowledged. When material appearing on CD-ROM is generated at the institute, the CD-ROM should carry a copyright notification with respect to the compilation and the individual elements of the CD.

4.6.3 *Video materials*

Video materials produced for the purpose of training are copyright protectable. Thus video materials produced at the institute should acknowledge it as the source and carry a copyright notice. If desired, this could be accompanied by a notice authorizing reproduction or copying of the material provided the institute is acknowledged as the source. If videos are produced involving material generated from outside the institute, then procedures have to be put in place to obtain copyright authorization and copyright indemnities.

4.6.4 *Copyright databases and know-how*

The various research projects undertaken or underwritten by an institute generate considerable bodies of data. Under current copyright law, raw data or information is not protectable. But legislation is being considered in a number of countries that would allow databases and possibly raw data itself to become the subject of sui generis, or special, IP protection. However, while raw data contained in databases may not be copyright protected, the way in which information is expressed can offer some protection. For example, a passage of text, a diagram, or chart contained in a database may be protected by copyright. It is also possible that in certain circumstances, where sufficient originality or creativity in the arrangement of data is present, the database as a whole may be protected by copyright on the basis that it is a compilation. Because individual components of the database may be protected by copyright, there must be mechanisms and procedures to ensure that the database does not contain material that infringes the copyrights of others. IP rights are of particular concern when the creation of a database is collaborative. In this case, when copyright exists in individual entries it may be unclear whether the copyright belongs to one collaborator or to all the collaborators jointly. Moreover, when material is contributed from diverse sources, each collaborator may become liable as an infringer—even if only one of the collaborator infringes the copyright of a third party.

To deal with some of these copyright issues, the Document by Bioversity International recommends that the copyright notification page contain a general notification hyperlinked to a page of specific copyright notifications. These would identify which part, or center, of the institute owns copyright in the relevant material. The document suggests the following general notification:

This site is protected by international copyrights in the design of the site including the layout, typography, and graphics reproduced herein, and in the expression of the information contained herein,

whether as a compilation, literary or artistic work or otherwise.

The form of the specific copyright notifications recommended in the Bioversity International document is:

Copyright [*full name of copyright owner*] [*year of creation of work*] in [*describe*] as [*compilation/published edition/literary work/artistic work*] or otherwise.

4.6.5 *Online materials*

The copyright principles that apply to printed works and CD-ROMs apply equally to online materials. Thus an institute would have to secure permission and indemnities to use copyrighted material that it displays on its Web site.

IP approval for hypertext links to other World Wide Web sites has recently raised some copyright concerns. If the institute's home page links to a large number of Internet resources, it should be ensured that the proprietors of those online resources have no objections to those linkages.

Copyright issues are also raised by mirroring and framing. Mirroring occurs when a site is duplicated on another server. Framing occurs when one Web site imports material from another site and makes it part of its own site. When such framing or mirroring occurs, it is essential that copyright clearances and indemnities are obtained.

4.6.6 *Computer programs*

Copyright subsists in both source and object codes of computer programs. Where commercially available programs are used or are incorporated in larger programs developed by the institute, licenses are available from the suppliers of those programs. It should be noted that a license to use commercially available software will not necessarily authorize the development or improvement of that software. The development or improvement of commercially available software for the purposes of, for example, facilitating or improving the accessibility of information stored on a database will infringe the copyright unless a license to develop the program has been obtained. Where programs are written in-house by institute employees, copyright problems do not arise.

In order to provide evidence that computer programs have been generated in-house, it is recommended that when institute personnel generate such material they complete a declaration of originality. Such a declaration could be made in electronic form in order to facilitate and centralize collection and storage.

4.7 *Trademarks*

Research institutes commonly seek trademark protection for their names and key research products. The acronym and name of a research institute, for example, could be registered in Class 16 of the Nice Trademark Classification in relation to "research and educational materials." Registrations can be obtained in each country in which research is undertaken. When an institute makes products such as seeds, these could be registered in Class 30, in relation to "[plant] variety/breeding lines." Trademarks can also be sought for equipment and tools, for example in Class 7, which covers agricultural equipment.

4.8 *Confidential information*

Research data compiled in institute projects by institute researchers may be protectable as confidential information. To be protected, the institute has to impose confidentiality through confidentiality agreements with employees and researchers. These will inform them that the institute attaches the quality of confidence to its research data and to its research methods. For the most part, a public research institute will waive its rights to the confidential information that it generates in its research findings. However, for agreements according to which the institute undertakes to share unpublished research findings and data with its collaborators, some enforcement of confidentiality agreements will be necessary to ensure that the research findings are shared and not dissipated. As awareness of IP protocols becomes more widespread, research collaborators will begin to insist upon an enforceable confidentiality regime. It will be increasingly important, therefore, to put in place mechanisms and procedures that ensure that confidential material is not publicly disclosed.

4.9 *Biodiversity rights*

The Convention on Biological Diversity (CBD) seeks to establish an international program for the conservation and utilization of the world's biological resources, as well as for the "*fair and equitable sharing of the benefits arising from the utilization of genetic resources*." A similar policy animates the International Treaty on Plant Genetic Resources for Food and Agriculture. For example, the CBD contains provisions dealing with access to genetic resources. Article 15 requires contracting parties to "*endeavour to create conditions to facilitate access to genetic resources for environmentally sound purposes*" by other contracting parties according to mutually agreed terms and conditions on the basis of "*prior informed consent*." A detailed code of access to biotechnology is prescribed in Article 16. Access and transfer are to be "*provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights*." The Article provides that developing countries that provide genetic resources shall be granted "*access to and transfer of technology which makes use of those resources*." In addition, Article 19.2 provides for the grant of access on a fair and equitable basis and on mutually agreed terms to contracting parties, "*particularly developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those contracting parties*." Additionally, Article 8(j) of the CBD envisages that where the knowledge, innovations, and practices of indigenous and local communities are utilized, the benefits arising from their utilization should be shared equitably.

A number of developing countries have introduced legislation that seeks to enact the benefit sharing provisions of the CBD. Thus, when a patentable invention results from institute germplasm that is contributed by indigenous persons or local communities, or that is collected as a result of the utilization of the knowledge of those persons or communities, a compensation liability may arise. Indigenous groups and local communities have begun to insist upon the collection of samples under the terms of bioprospecting agreements, which invariably define the distribution of benefits from any royalties that may result from patents. In a number of developing countries, the use of bioprospecting agreements is becoming mandatory.

5. THIRD-PARTY IP

5.1 *Patents and know-how associated with biological technologies*

Most research institutes will have third-party proprietary technology licenses. The basis of the proprietary claims made by most of the licensors will be the confidentiality of the biological materials or know-how that is licensed to the research institute. Additionally, patented research technologies may be licensed.

The salient features of these licenses are:

- permissible use of the licensed material confined to scientific research
- confidentiality of licensed material to be preserved
- all information concerning improvements in the material or inventions associated with the material to be reported to the licensor
- research progress to be reported periodically
- use of material only by identified institute scientists
- advance copies of manuscripts of publications to be provided to licensor

The various obligations these agreements with third parties impose emphasize the importance of an IP management facility at a research institute.

5.2 *Genetic material*

Medical and agricultural research increasingly utilizes genetic material provided to an institute under an MTA or confidentiality agreement. The terms of that MTA may restrict how that material can be used. For example, it may be on the condition that IP rights are not sought in relation to that material, or that it is not used for commercial purposes. Sometimes the MTA will require that material derived from the supplied material should also be supplied under those conditions. In each of these cases, the responsibility

to observe those conditions will be imposed on the institute; it will be the purpose of the audit to identify these obligations and document how they are being managed.

On occasion, genetic material is made available informally by a scientist from a third party, acting without the authority of that third party. In this case, the unauthorized use could involve the research institute in liability. Consequently, the audit should identify the terms of all accessions of third-party genetic material.

5.3 *IP rights associated with equipment utilized by a research institute*

A number of items of research equipment obtained from commercial suppliers may generate IP obligations. For example the Bio-Rad Biolistic PDS-1000/He apparatus is often supplied to researchers at IRRI subject to an agreement that it be used "*for research purposes only*." The Hybaid PCR Express Thermal Cycler is also subject to a license "*to practise the PCR process for internal research and development*."

6. IP MANAGEMENT STRUCTURES

An IP audit should analyze the management of IP at a research institute from the perspective of the adequacy of the management structures and procedures. It should also consider IP management in terms of the staff's awareness of IP obligations. Finally, the institutional mechanisms for dealing with institute and third-party IP should be examined.

6.1 *IP management culture*

A critical feature of effective IP management is the existence of a research culture in which IP awareness is communicated to researchers. In order to ascertain the extent of IP knowledge and of IP management practices within an institute, questionnaires could be administered to administrative and research staff. To supplement the general IP consciousness-raising activities mentioned above, it would be very useful for staff to be provided with an IP handbook, containing a general primer on IP, as well as all relevant IP documents and procedures. This IP handbook could also be made available online and accessed from the institute's Web site.

6.2 *Office of IP coordination*

As IP becomes increasingly significant for scientific research, establishing an IP coordination office or officer for an institute becomes more important. This office, which may be within the research institute or located within the offices of a third-party subcontractor, would be responsible for coordinating both IP administration and procedures within the institute. The IP office would also be responsible for external IP liaison. The coordination of IP procedures would include securing the IP compliance of staff and visitors; ensuring the inclusion of IP provisions in relevant third-party agreements; ensuring the utilization of appropriate MTAs by the institute, both as a recipient and distributor of germplasm and biological tools; maintenance of a central repository of IP documents; maintenance of the institute's IP database; and raising awareness of about IP issues. Externally, an IP coordinator could provide an IP dimension to negotiations with research collaborators and act as a liaison with IP officials of other institutes.

The IP coordination office would ensure that:

- staff and visitors sign and adhere to IP and confidentiality agreements
- copyright permissions and indemnities are secured for various publications
- Copies of MTAs and other IP agreements are filed centrally and provided to appropriate staff members
- Proper research records are made, maintained, and filed
- the MTA granting procedure is coordinated
- the IP provisions of other agreements are supervised
- the institute's legal advisers are updated on IP matters

6.3 *Research records*

Establishing provenance for research is central to any policy of securing and exploiting the IP rights that might be generated from an institution's research. The practice of maintaining laboratory notebooks with consecutively numbered pages

that are signed at the end of each day by the supervising scientist is normal in private enterprise, but may be alien to the research culture at a public research institute. However, without this sort of management practice, it would be difficult to contest a *first to invent* dispute under patent law. Similarly, it would be difficult to identify the technological know-how brought by a scientist to the institute and to distinguish it from that which has been developed at the institute. This is important in delineating the respective confidential information of a staff member and the institute.

6.4 *Material transfer agreements (MTAs)*

Guidelines and procedures for the approval of material transfer agreements could efficiently direct the management of IP in a scientific research institute. For germplasm designated under the International Treaty on Plant Genetic Resources for Food and Agriculture, an established procedure already exists. Some of the Consultative Group on International Agricultural Research (CGIAR) genebanks distinguish between designated germplasm and germplasm that they themselves have developed, which is accordingly regarded as non-designated. Separate MTAs are being developed by research centers to deal with the distribution of this material.

7. CONCLUSIONS

Modern scientific research often requires expenditures to enable the generation of protectable IP. The institute will have to decide whether this IP will be placed into the public domain or registered, either to pursue commercial exploitation or to prevent its privatization by unauthorized third parties. Before any of these actions can be taken, however, the research institute must identify the IP that its researchers generate or utilize. An effective IP audit is therefore an important tool for supporting the research objectives of the institute. ■

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1 www.wsu.edu/~oipa/FacIP.html.

2 www.tamut.edu/SACS/3-2-1417-02-01.pdf.

3 www.utsystem.edu/OGC/Intellectualproperty/2xii.htm.

4 See, for example: www.irri.org/publications/chandler/pdfs/Appendices.pdf.

5 See, for example: www.irri.org/about/images/Memorandum%20of%20Understanding.pdf.

6 For an example of a standard research agreement along these lines, see Oklahoma State's template for a sponsored research agreement at: www.vpr.okstate.edu/Forms/Forms%202003/Spon%20Res%20Agmt.doc.