The IP Toolbox

Best practices in the management of intellectual property require a basic understanding of the various forms of IP protection that are available. The **forms of IP rights** in most countries include patents, trademarks, geographical indications, copyrights, and trade secrets. Special provisions for plants are also offered in many countries in the form of plant variety protection, or plant breeders' rights. A further emerging type of protection is that related to regulatory data, which can be protected from disclosure or acquisition for a certain period of time and offer data exclusivity. Although each of these statutory mechanisms of IP rights protect different forms of intellectual property, thus conferring different IP rights, when used alone or in combination, they provide a set of options for organizing and then making the most out of an organization's IP assets.

All of the above are reviewed in detail by Dodds and Krattiger[1] in Chapter 4.1, which includes short sections on institutional aspects including employee agreements, how to integrate the various rights, and how to identify infringement. Importantly, the form of protection chosen for a given invention should be guided by the mission of the institution (whether public or private), the purpose of the work it conducts, and the nature of the invention, or other intellectual property that will be subject to IP rights protections.

A **utility patent** is a type of statutory IP protection covering inventions, that is, a grant by the government to an inventor for any invention that is a new and useful process, machine, article, manufacture, or composition of matter or any new and useful improvement thereof. The invention, that is the intellectual property itself, is a product of the inventor's mind. The patent, then, confers certain rights to this property; it is the right to *exclude* others from making, using, selling, or importing the invention in the country where the patent is granted, normally for a period of 20 years from the date of the patent application.

In patents, many aspects of inventions are disclosed. Patents should thus not be seen as the exclusive domain of lawyers. Scientists in particular are well advised to be up-to-date on patents issued in their field of endeavor, and Nottenburg[2] in Chapter 4.2 provides a comprehensive guide to patents, using biotechnology patents as an example, that instructs scientists and others how to read utility patents.

Trademarks are a form of IP protection that serves to distinguish the products or services of one individual, company, or organization from the products or services of others. A trademark can be a word, phrase, symbol, design, or a combination thereof. Trademarks can even be sounds or colors, if they are in some way distinctive, that create an immediate association in the mind of the consumer between the trademark and the good. IP protection for a trademark confers an exclusive right to use the mark in commerce.

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 4: The IP Toolbox. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Krattiger A, RT Mahoney, L Nelsen et al.). MIHR (Oxford, UK), PIPRA (Davis, USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil), and *bio*Developments-International Institute (Ithaca, USA). Available online at www.ipHandbook.org.

Trademarks are an often overlooked and undervalued form of intellectual property by the public sector and this is well argued by Needle[3] in Chapter 4.3 on the basis of many colorful examples. Trademarks should be a valuable component of any IP management strategy, complementing the protection afforded by other forms of statutory IP protection. Trademarks can complement other forms of IP protection, and, as in the case of many pharmaceuticals, serve to strengthen the period of proprietary rights to a product.

Geographical indications are signs used on goods that have specific geographic origin and possess qualities or a reputation that are derived from their place of origin. Geographical indications are another type of intellectual property, similar to trademarks in that they are source indicators. Most commonly, a geographic indication consists of the name of the place of origin of the particular goods (for example, Roquefort cheese or champagne).

Copyright is a type of statutory IP protection for the original works of authors, such as the chapters in the *Handbook*. Such works include literary, musical, dramatic, and architectural works. The copyright protects the work immediately after it is fixed in a tangible medium, for example, words on a page (what you are reading at this very moment) are copyrighted. The owner of the copyright, for example, we, the authors of this chapter, have certain rights to the work. Typically, these rights include moral rights (that is, having our names associated with the work) as well as the right to reproduce the work, to prepare adaptations of the work, and to distribute the work to the public. However, these rights can be either licensed or assigned to others. In the case of this chapter, we agreed to make it freely available to all through the Internet.

Trade secrets (in certain circumstances and jurisdictions called **know-how**) are an important form of intellectual property. Trade secrets protect know-how and any confidential information so designated. To be protected as a trade secret, the inrellectual property must, of course, be kept secret, and must also confer some sort of commercial advantage to the holder. Enforcement of IP rights for trade secrets is possible when a competitor has misappropriated and/or stolen the trade secret.

A point often raised is when one should file for a patent or maintain the information as a trade secret. What is important to note is that patents and trade secrets are not in conflict with each other but are complementary IP assets. Depending on the nature of the know-how, or the invention, the organization may choose to either file a patent or to continue to hold as a trade secret. Dodds and Krattiger in Chapter 4.1 discuss trade secrets briefly, but they are fully discussed in the context of licensing in another section of the *Handbook*.[4]

The protection of intellectual property related to **plants, germplasm, and varieties** is covered in several chapters because there are many dimensions to the topic. Kesan[5] in Chapter 4.4 describes the various forms of intellectual property applicable to plants. These are utility patents (available in a few countries only), plant variety protection (or plant breeders' rights), plant patents, trade secrets, geographic indications, and trademarks. The strengths and weaknesses and pros and cons of each are discussed. It is worth noting that the use of one form of protection is not necessarily exclusive, in that a single plant may be simultaneously covered by several forms of IP protection.

Plant variety protection (PVP) is the most common tool for protecting varieties, and many countries have legislated and implemented a PVP system. Lesser[6] describes the PVP system in Chapter 4.5. PVP regimes are implemented in order to:

- provide breeders (both public and private sectors) with an opportunity to receive a reasonable return on past investments
- provide an incentive for continued or increased investment in future breeding research
- recognize the legal right of the innovator to be recognized as such
- acknowledge the economic right to remuneration for his or her efforts

In general, there are two exemptions to the protection provided: 1) a research exemption and 2) a farmer's exemption (this is not to be confused

with farmers' rights). A research exemption allows for breeders to develop a new variety by using a protected variety; a farmer's exemption allows for the saving of seed for the sole use of replanting the farmer's land.

Given the advantages of a PVP system in attracting private investments and offering farmers a broader range of improved varieties, countries may gain substantially in internationally harmonizing their PVP regimes, as it lowers costs for users, simplifies the introduction of new varieties, and thus leads to the availability of more varieties and choices for farmers.

Lesser also points out that those countries that are members of the Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**) agreed to implement special protection for plants (the so called *sui generis* protection). Many elect to follow the principles of the International Convention for the Protection of New Varieties of Plants (**UPOV**), an international treaty that provides an effective framework for PVP.

Plants can also be protected through trade secrets, trademarks, and geographical indications. Geographical indications might be used to communicate to consumers the association between a plant's special characteristics and the territory from which it originates. Trademarks can have particular value if the variety has market potential, and consumers come to specifically associate the trademark with desirable characteristics and qualities of the variety. Such value has important implications for developing countries that are exporters of agricultural commodities and products, as it can add significant additional value to their exports.

The management of intellectual property related to crops and germplasm is an essential function of a technology transfer office (TTO) and is the focus of Chapter 4.6 by Dodds and colleagues.[7] They also discuss specific issues related to IP management involving genebanks and practical aspects on the establishment of a PVP office. Blakeney[8] in Chapter 4.7 reviews international aspects, including the international exchange of germplasm. A working knowledge of the relevant **international treaties related to genetic resources** is important for anyone dealing with genetic resources as they increasingly affect the international exchange and use of germplasm.

One such treaty is UPOV. Significantly, the latest revisions of 1991 expanded the scope of protections that could be granted to include *essentially derived* varieties. This has important implications for genetically modified organisms. These revisions also allow countries to limit farmers' rights, allowing them only to save seeds for use on their own land.

Another agreement is the **Convention on Biological Diversity**, particularly the provisions concerned with informed consent to use of biological materials and equitable benefit sharing following access. Some people argue that these requirements may be in conflict with this requirement of TRIPS. In practice, however, whereas UPOV and related *sui generis* systems focus on plant varieties, the Convention on Biological Diversity essentially deals with wild genetic resources. Exceptions include the reach of the Convention into genetically modified crops through the Cartagena Protocol on Biosafety, but this is not related to intellectual property.

The International Treaty on Plant Genetic Resources for Food and Agriculture (the Treaty) is a recent addition to international agreements. The Treaty establishes a multilateral system that embodies a sort of genetic commons within which the exchange of germplasm in major crop varieties between member states is facilitated. Conditions limit the rights of recipients to seek IP rights in material obtained and support the rights of donors to share in some form of benefit. The Treaty further recognizes the contribution of farmers and indigenous peoples' **traditional knowledge** to agricultural biodiversity. This is accomplished through the development and conservation of landraces, in primitive varieties developed to deal with local climate and diseases and to appeal to local tastes, by interbreeding locally occurring undomesticated plants with cultivated plants, as well as by exchanging different genotypes among farmers and farms. Again, some argue that certain terms of the Treaty may not be compatible with UPOV standards but overall this assessment seems unlikely.

A distinct but closely related topic is that of **information resources.** These include **computer software** and systems, **databases**, **geographic information systems** (GIS), **remote sensing** (RS) information, and **library** resources. The integration of these is increasingly prevalent in advanced agricultural systems such as the forecasting of disease and harvests. Dodds and colleagues[9] in Chapter 4.8 discuss the various IP elements related to information resources and how they can be managed effectively. The chapter also addresses licensing elements.

A very different topic is that of **data protection** and **data exclusivity**. These systems of protection are especially important in pharmaceuticals and agricultural chemicals. Two chapters review these complex topics, Chapter 4.9 by Clift[10] and Chapter 4.10 by Cook.[11] In short, regulatory data are the data that the researcher or manufacturer of a product must provide to the appropriate regulatory agency in order to prove that the product is safe and efficacious. Regulatory data are protected from disclosure or acquisition for a certain period of time, usually five to ten years from the product's first authorization to market, during which time no other applicants are allowed to use it to obtain marketing authorization for the same product.

Regulatory data protections are substantively different from other sorts of intellectual protection, including confidential information protection and patents. The provisions in Article 39.3 of TRIPS, concerning the protection of regulatory data, are broad and subject to interpretation. Both the United States and the European Union have interpreted and implemented the obligations in different ways (as explained in Chapter 4.10).

The chapters by Clift and Cook also examine data exclusivity from the perspective of specific TRIPS requirements (Article 39) which essentially include three obligations on governments:

- protect data on new chemical entities, the collection of which involved considerable effort, against unfair commercial use
- protect such data against disclosure, except where necessary to protect the public
- protect such data against disclosure, unless steps are taken to ensure that the data are protected against unfair commercial use

It is important to note that these requirements do not create new IP rights (other than defining the reach of trade secrets). Article 39.3 only articulates widely accepted trade secret and unfair competition law and is not an invitation to create new IP rights per se for test data. ■

All chapters refer to: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. 2007. A Krattiger, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski (eds.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org. The online version contains for each chapter a detailed Editor's Summary, Implications, and Best Practices.

1 Chapter 4.1 by J Dodds and A Krattiger titled The Statutory Toolbox: An Introduction, p. 337.

2 Chapter 4.2 by C Nottenburg titled How to Read a Biotech Patent, p. 351.

3 Chapter 4.3 by W Needle titled Trademark Primer, p. 361. Trademarks and trademark licensing are further discussed in detail in Chapter 11.6 by WT Tucker and GS Ross titled Use of Trademarks in a Plant-Licensing Program, p. 1059.

4 Chapter 11.5 by KF Jorda titled Trade Secrets and Trade-Secret Licensing, p. 1043.

5 Chapter 4.4 by JP Kesan titled The Statutory Toolbox: Plants, p. 371.

6 Chapter 4.5 by WH Lesser titled Plant Breeders' Rights: An Introduction, p. 381.

7 Chapter 4.6 by J Dodds, A Krattiger, and SP Kowalski titled Plants, Germplasm, Genebanks, and Intellectual Property: Principles, Options, and Management, p. 389.

8 Chapter 4.7 by M Blakeney titled Plant Variety Protection, International Agricultural Research, and Exchange of Germplasm Legal Aspects of *Sui Generis* and Patent Regimes, p. 401.

9 Chapter 4.8 by J Dodds, S Somersalo, SP Kowalski, and A Krattiger titled IP and Information Management: Libraries, Databases, Geographic Information Systems, and Software, p. 419.

10 Chapter 4.9 by C Clift titled Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals, p. 431.

11 Chapter 4.10 by T Cook titled Regulatory Data Protection in Pharmaceuticals and Other Sectors, p. 437.

FOR GOVERNMENT POLICYMAKERS

- ✔ The statutory **tools of IP**, such as patents, copyright, trademarks, trade secrets, geographic indications, and plant variety protection, are tools that can be used to achieve a goal. The tool in itself is neutral; what matters is how the tool is used.

- ✔ When setting up a **patent office**, notwithstanding considerable latitude provided under TRIPS, there are advantages in implementing practices that are consistent and compatible with the practices of other countries. Doing so will facilitate greater opportunities for international collaboration in R&D and technology transfer. Particularly important is making patent applications and issued patents available online. This furthers innovation and licensing.

- ✔ **Copyright** is also an important form of IP that can be used to encourage innovation. The recent trend, at least in the United States, to provide for ever-increasing duration of protection (now exceeding four generations) should be avoided as this approach prevents the availability of important commercially but insignificant works.

- ✔ The use of **trademarks** is important for building integrity and stability in commerce and for offering new opportunities for national innovations. Trademarks can also be highly valuable for public sector entities.

- ✔ Judicious **plant variety protection** of new varieties will encourage investments in the development of crops that are essential for food security, a better environment, and economic development. As with patents, domestic innovation, the transfer of foreign varieties for increased production and productivity, and spurring national investments in crop breeding can be enhanced significantly through membership in international bodies, such as UPOV. This can lead to the earlier availability of improved varieties.

- ✔ Notwithstanding the above, countries can exercise significant latitude in regulating access to certain categories of plant genetic resources they consider strategically important. Plant breeding, however, and the enhancement of crops, is based on the stepwise improvement of existing varieties, and this requires **broad access to genetic material**. Related to this are geographic information systems and corresponding **data protections** that can add substantial value to biodiversity resources and **traditional knowledge**.

- ✔ Introducing stringent confidentiality of data and exclusivity laws can prevent **early introduction of generics and promote competition critical for improving access to life saving drugs.** There is a need to balance the various competing interests.

- ✔ IP protection mechanisms, however, depend upon effective and **equitable enforcement** by national governments. This requires effective, transparent, and enforceable **contract law** that can be implemented to protect natural, cultural, and economic resources, all by furthering useful interactions with the global community. This balance is critical.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR SENIOR MANAGEMENT

(UNIVERSITY PRESIDENT, R&D MANAGER, ETC.)

- ✔ The implementation of a **broad institutional IP policy**, consistent with the institution's mission, can foster the integration of the various forms of IP protection in furtherance of an institution's mission and goals.

- ✔ For public sector institutions, **trademarks** can be a valuable element in an institutional strategy that aims at fostering a positive image (or brand) and generating value. Because of the broad value of trademarks, they assist institutions in maintaining a good image and brand, thus serving as a tool for senior management in maintaining and enhancing the institution's reputation, standing, and value.

- ✔ Scientists can gain a lot from regularly reviewing newly issued **patents** from around the world. Patents often disclose much more than scientific publications but are generally overlooked as valuable sources of scientific and technical know-how. Such an information-gathering approach requires appropriate staff training and the availability of good Internet connections, which make it possible for patents to be downloaded. All patent office Web sites provide patents free of charge as does the Worldwide Intellectual Property Organization (WIPO).

- ✔ A sound **patenting strategy** is an extremely useful tool to bring inventions to fruition that make an impact on economic development and meeting public sector goals.

- ✔ Although many public sector institutions have for years provided their improved germplasm free of charge or at nominal costs to breeders and farmers, the **protection of improved varieties** can be a critical tool in furthering broad access and simultaneously meeting commercial and humanitarian objectives through appropriate "market segmentation."

- ✔ In many countries, but not in the United States, patent law includes a broad **research exemption**. This should not be confused with possible restrictions on materials obtained through material transfer agreements. Although extremely useful, material transfer agreements should be used judiciously, particularly when intellectual property is also embedded in material. This aspect also requires well-trained licensing/technology-transfer personnel and good management systems.

- ✔ The delivery of innovation for the greater **public good** by public sector institutions is not necessarily inconsistent with appropriate patent and other forms of IP protection. **Trade secret protection** in particular may be a valuable—and cost effective—means of achieving greater accessibility by disadvantaged members or groups of society. Whereas academic institutions in particular may regard such protection as inappropriate, it should be remembered that their mission is gradually shifting and increasingly include the delivery of products. This requires adjustments in the way information and know-how are managed. In turn, the changes require much internal discussion and sometimes culture change.

- ✔ Senior management's backing of the **technology transfer office** is important as is its support in the implementation of rigorous IP-related policies and procedures (such as those related to confidentiality).

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR SCIENTISTS

- ✔ Research endeavors can go much further, in certain circumstances, if **appropriate IP protection** is sought. If appropriately managed, this is not in conflict with the broad dissemination of research results but encourages that your inventions serve humanity.

- ✔ **Patents** often disclose much more technical and scientific information than do academic publications. Make it a habit of regularly reading up on newly published patent applications or issued patents in your field. You can access this information for free on the Internet (such as on www.uspto.gov).

- ✔ Your institution's good reputation and standing can be used as a valuable **trademark or brand**. Maintaining the high reputation requires strict adherence to your institution's policy and best practices.

- ✔ Good **data management**, especially accurate record keeping through comprehensive notebooks, is the foundation for building a portfolio of IP assets. Essentially, best practices in scientific record keeping should be precisely the same as best practices in record keeping for purposes of IP management.

- ✔ Conversely, you should always know the origin and possible restrictions of **data and information** you use, no matter how insignificant they might seem. Make sure you document the source of important data and information in your laboratory notebook. If you have questions, never hesitate to contact your technology transfer office for help or clarifications.

- ✔ Particularly if your research is related to product development, the **confidentiality of your data** may be critical in ensuring global access. Data is a valuable form of intellectual property that can be used to obtain certain price or access terms in licensing negotiations. Whereas, as a researcher in an academic environment you may regard such protection as inappropriate, remember that it is the goals of your research that should drive the IP tools applied to your inventions. If you are engaged in the delivery of products, adjustments in the way your information and know-how are managed may be necessary to speed-up the translation of your research findings into innovative products or services.

- ✔ If a given invention cannot be patented in your own country (for example, a **biological invention**, including gene sequences), the invention may still be patentable in another country. The United States and Canada tend to have the broadest interpretations with respect to the patenting of organisms and biological materials. In pursuing patenting elsewhere, under certain circumstances, your research endeavors may leverage additional investments required to bring the fruits of your research to benefit your country and society at large and may also lead to additional research grants.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.

FOR TECHNOLOGY TRANSFER OFFICERS

- ✔ Intellectual property is often perceived as constraining research, particularly in public sector institutions. **Your role in communicating** the importance of judiciously using patents, trademarks, trade secrets, and so forth, and the benefits of good IP management, is critical. Such communication should be tailor-made to senior management, and even to your institution's board, as well as to scientists. Each responds to a different language. (And different colleagues will require different degrees of understanding. For example, your discussions on patents will necessarily differ with scientists and patent counsel. Choose your words and the level of detail you provide judiciously.)

- ✔ In many institutional settings, making better use of **patents** and other forms of intellectual property requires a culture change to a greater or lesser degree. This may include establishing an expectation for scientists in your institution to regularly review patents. Encouraging scientists to share a **broader IP awareness and culture** will be potentially powerful and valuable.

- ✔ **Trademarks** are a critical, and often overlooked, option for IP protection. They can be used as stand-alone IP protection, or they can be integrated into an overall strategy for integrated IP protection, for example, a strong trademark for a patented product or process.

- ✔ Your job requires a judicious balance of work that relates directly to your benchmarks and targets, and of **contributing to the overall IP culture** of an organization. The latter is often not spelled out in your job description but it is important nonetheless. The greater the general level of awareness related to intellectual property, the more likely it is that the value of IP assets can be captured and utilized. And your job also becomes easier when you gain a broader understanding of intellectual property.

- ✔ Genebank management and that of **genetic resources**, in general, is increasingly becoming a sensitive issue. An organized, stepwise approach is vital for effectively managing a genebank and for avoiding difficulties. Ownership of genetic resources can be tricky, so rigorous documentation and clear procedures on incoming and outgoing genetic resources may be critical.

- ✔ The above point applies equally to **data**, both incoming and outgoing. Particularly if your institution conducts research related to product development (especially clinical trials), the **confidentiality of data** may be critical in ensuring global access. Specific data are a valuable form of intellectual property that can be used to obtain a certain price or access terms in licensing negotiations.

Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.