

Innovation and IP Management: A Contextual Overview

The pressures on innovative organizations and countries are many and varied—economic, technological, organizational, environmental, political, and societal. Leaders of public sector institutions and private companies have limited control in most of these areas. But a leader of any entity, public or private, can exercise a high degree of control over the entity's own intellectual property (IP) through sound IP management and critical tools to accelerate innovation. Section 1 of the *Handbook*¹ presents an overview of innovation and IP management, which are the focal points of the entire *Handbook*, and logically, the *Executive Guide*.

IP rights are a critical tool for fostering innovation. Managed judiciously, they balance private rights and public necessity in a manner that, overall, encourages innovation. The first chapter of the *Handbook*, by Mahoney and Krattiger,² directly addresses the paradox that underlies the *Handbook*: **the pursuit of the public interest through private rights**. Focusing on the life sciences, the chapter asks how IP rights can best be managed to promote public welfare. It finds an answer, not in the system of IP rights, but in the judicious and skillful *use* of proprietary science. In short, the authors argue that creative management of IP rights, especially by public sector institutions, is essential for achieving public benefits.

Understanding how intellectual property fits into the much broader context of innovation and product development is important for any

public sector entity, whether in a developing or developed country, for addressing neglected diseases, for alleviating poverty, for development in agriculture, and for eliminating chronic malnutrition. Mahoney and Krattiger discuss how, within the rapidly evolving global IP landscape, public sector institutions can better mobilize resources in order to accelerate products through the innovation pipeline through best practices in IP management. **These best practices include creative licensing practices that ensure global access and affordability, improved institutional IP management capabilities, the formulation of comprehensive national IP policies, and the strengthening of IP court systems and patent offices.**

Recent national and international changes in IP treaties, legislation, and frameworks are having profound effects on innovation systems and on how public and private research and development institutions implement their missions and how health and agricultural innovations reach the poor. Seen within this broader context, **intellectual property is one of six interrelated components of innovation management**³ that focuses on developing a variety of issues:

- R&D capability by the public and private sectors
- safe and effective regulatory system that covers drugs, vaccines, and agricultural products
- manufacturing capability for health products and for the inputs into and outputs of agricultural production

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 1: Innovation and IP Management: A Contextual Overview. 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 bioDevelopments-International Institute (Ithaca, USA). Available online at www.ipHandbook.org.

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- expansion of national health or agricultural delivery systems, including an attractive, private sector domestic market for health or agricultural products and services
- international trade systems for health products (including global procurement funds) and agricultural inputs and outputs; and an IP system (legal framework, judiciary to enforce it)
- institutional management capabilities

The authors raise important questions and make significant proposals, framing IP management within a global context. This global approach is inexorably spreading and expanding at an accelerating pace. Because of the increasing interaction between developed and developing economies and the increased number and complexity of relationships between the public and private sectors, understanding the best ways to forge and maximize partnerships has a high priority. Such **partnerships will be the engines that drive global innovation.**

The chapter further reviews recent dramatic developments in the institutional aspects of intellectual property, as well as global policy shifts and international case studies. In the field of health, changes have been particularly pronounced with the founding of a novel form of institution for innovation: product-development partnerships (PDPs). Mahoney and Krattiger make the case for a fundamental shift in the way IP management in health and agricultural innovation is viewed and conducted: **the public sector can employ new ways to achieve its goals within the evolving IP framework.** In response to rapid global evolution, nongovernmental organizations (NGOs) and PDPs will have important roles to play in the global IP environment, particularly for developing countries.

It is well established that intellectual property advances product development because **intellectual property provides incentives for R&D, commercialization, and product distribution.** Investors in biotechnological R&D naturally want to protect their investments, and must, therefore, secure IP rights for their inventions. Before the creation of IP rights protection, the

private sector had little incentive to develop safe and efficacious pharmaceuticals. Historically, the public sector had neither the funds nor the capability to develop products. Yet, the world is changing. As the public sector devotes more of its efforts to humanitarian missions, and engages in more development partnerships (such as PDPs) in the fields of health and agriculture, it will also have to consider the critical role of intellectual property in a broader innovation context.

The permanence of intellectual property is evident. **If the public sector does not effectively utilize the IP system, it will neither be serving its own interests nor the interests of those it has promised to serve.** Without effective IP management skills, the public sector risks squandering the rights, powers, and opportunities that the IP system provides. Intellectual property is a tool, and, like all tools, its impact depends on how it is used, who uses it, and for what purpose. IP strategies can serve to either restrict or expand access to innovations; it's all a matter of *capacity, management, and context.* These three aspects are addressed in the creation of a best practices document.

For IP management to efficiently function within a larger framework of innovation, **best practices need to be documented.** That is what the *Handbook* and this *Executive Guide* seek to do: to provide a teaching and capacity building resource for IP management, with a focus on health and agricultural biotechnologies. When it comes to increasing developing countries' access to fundamental innovations in health and agriculture, success requires knowledge, capacity and active engagement. This is what best practices in IP management strive to bring about and what the *Handbook* promotes.

To illustrate how best practices may be used, Mahoney⁴ reviews the **impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the development of the pharmaceutical industry** in Korea. Korea was able to implement a wide range of initiatives—including an upgrade of its IP regulatory systems—that benefited its pharmaceutical industries. It is likely that Korea's success was largely achieved because its IP systems aligned with those of developed

countries. The empirical data gleaned from the experience of Korea is promising, suggesting that TRIPS compliance will improve biotechnological capabilities in developing countries.

Building innovation capabilities in developing countries often relies less on the creation of IP systems and more on the creation of markets and support for R&D. Broadly speaking, the evolution of IP rights in developing countries involves three basic stages (before reaching stage 4):

- **Stage 1:** In the early stage of development, little intellectual property is generated domestically and few foreign companies are interested in introducing their technologies to these countries due to inadequate IP rights protection.
- **Stage 2:** At a later stage of development, the country's innovative capabilities improve, but due to the same inadequate IP rights protection, there is limited foreign investment in technology.
- **Stage 3:** Eventually, when domestic companies are able to generate their own intellectual property, they demand more-effective IP protection. With more-effective protection, foreign investment in technology increases along with the presence of foreign technologies.

Within the pharmaceutical industry (and many parallels exist with the agri-biotechnology industry), companies in developing countries tend to move through four stages described in Table 1. This shows that technological and IP capacities tend to develop in tandem. However, such a measured-pace “natural coevolution” is no longer likely with TRIPS requirements in effect. These state that signatory countries' pharmaceutical industries *must* rapidly progress from either Stage 1 or Stage 2 on to Stage 3. It remains to be seen whether this mandatory accelerated development will hinder or help developing-country pharmaceutical industries in the longer term and to what extent TRIPS will facilitate the transfer of technology to and within developing countries.

However, elsewhere, especially in the United States, Europe, Japan, and parts of Australasia, **technology transfer from universities works and**

works well. Examples of this are when we get into a car and buckle up, when we sweeten our coffee with saccharin, when we search the Internet using Google™, or when we take advantage of the innumerable medical and agricultural advances of the last quarter-century. In essence, we are reaping the benefits of technology transfer. Universities do not only educate the next generation and create new knowledge, but also create knowledge that enhances the quality of life, increases economic productivity, and even saves lives.

Fraser⁶ points out that university–industry collaborations and licensing have soared, for example, in the United States, ever since the Bayh-Dole Act of 1980, which forces the moving of inventions from laboratories to store shelves more quickly. The law allowed U.S. universities and public research institutions to patent inventions that were based on federally funded research, then to license those inventions to the private sector.

Some people continue to question the fairness of the global IP system, but others are using new opportunities created by this system to improve lives in the developing world. Technology transfer is thus changing rapidly. Traditionally, the mission of technology transfer offices has been to make university-generated innovation available to the public as rapidly as possible. However, **technology transfer offices now have a broader purpose: to enhance the reputation of academic institutions and to help them to achieve their missions of education and outreach by assisting in forming relationships with the private sector.** Technology transfer has the potential to benefit the entire world. As technology transfer develops, it will undoubtedly evolve again, in response to new conditions.

University technology transfer professionals are already becoming increasingly aware of their obligation to ensure that the underserved communities of the world have access to medicines and agricultural biotechnology that have been developed from basic research conducted in their universities. But certain conditions need to be remediated, for example: many university administrators, technology transfer officers, and businesspeople are unaware of the need for new health technologies in developing countries; few

TABLE 1: THE FOUR STAGES IN THE DEVELOPMENT OF BIOTECHNOLOGY

	DEVELOPMENT OF DISTRIBUTION SYSTEMS		DEVELOPMENT OF R&D CAPABILITY		IP SYSTEMS	DRUG AND VACCINE REGULATION
	DEVELOPMENT OF NATIONAL	INTERNATIONAL	PRIVATE SECTOR	PUBLIC SECTOR		
STAGE 1. ESTABLISHING THE FOUNDATION	Importation of finished goods or assembly of parts into finished products	Small domestic market	Very little, except as toll manufacturer	Very little	Initial development allowing patents for local inventors; no interest from foreign inventors	Very limited
STAGE 2. CAPACITY BUILDING	Production on license or by copy	Growing local market of increasing interest to foreign companies; import substitution	Growing companies learning how to establish export markets	R&D to understand technology either to produce on license or to copy	Interest growing among foreign inventors; local inventors starting to file more patents	Limited services but without enforcement capabilities
STAGE 3. MATURATION IDCs	Manufacture of domestically developed, high technology products	Rapidly growing domestic market of interest to foreign companies	Increasing exports that account for a growing share of GNP	Small-scale, advanced R&D effort capable of creating new products for domestic and export market	Advanced IP system but with certain limitations such as lack of enforcement	Advanced capabilities but not at highest level because of lack of enforcement capabilities
STAGE 4. THE MOST-DEVELOPED COUNTRIES, WITH A DRUG OR VACCINE INDUSTRY	Highest capabilities to produce high technology drugs and vaccines	Highly profitable market in both the public and private sectors, generating profits to support, in part, advanced research	Global companies	Generous support for health research from basic to applied; large research investment by private companies, including large pharmaceutical manufacturers and biotechnology companies	Sophisticated system of IP management operating according to the requirements of the TRIPS Agreement	Sophisticated agency overseeing regulatory approvals of drugs and vaccines; government oversees clinical trials and production facilities and enforces regulations

Source: Mahoney⁵

people know how to incorporate patenting and licensing practices into global access strategies; and best practices for global access strategies have not yet been defined.

Nelsen and Krattiger⁷ describe **several possible strategies for ensuring both that everyone has access to technologies and that for-profit companies have incentives to develop those technologies**. The Association of University Technology Managers (AUTM) has formed Technology Managers for Global Health (TMGH), the purpose of which is to draw attention to global health issues and compile and promote a collection of best practices, policies, and licensing terms. The National Institutes of Health (NIH) issued guidelines on the patenting and licensing of research tools as a way to increase global access to health innovations. And this *Executive Guide* serves similar and perhaps broader purpose.

Careful **patent-filing strategies** can help ensure that developing countries have access to the technologies they need. One example of this is when using a *prohibition of filing strategy*, one does not file for patent protection in developing countries if there is a very large market for the product in developed countries. In fact, it may be a good idea to file a patent in developing countries if those countries create a substantial demand for the drug or vaccine in question. These patents can provide incentives for private sector development, and also provide powerful tools for the consolidation of resources via aggregation of developing-world markets (in addition to enabling or at least strengthening technology transfer through the licensing of know-how associated with patents).

Questions to consider include: whether it is better to prohibit or to require filing patents in developing countries, whether patents encourage private sector investment by aggregating the developing world market, what kinds of licenses should be granted, and what requirements for development milestones, product delivery in developing countries, pricing, or sublicensing options work best for a particular situation.

There are a number of **licensing strategies**:

- Licenses can be exclusive, nonexclusive, or a combination thereof.
- Licenses can specify milestones, such a requirement that the licensee has to contribute a minimum toward the development of a product earmarked for developing countries.
- Establish pricing controls in developing countries.
- Insist upon sublicensing, which ensures that the licensee finds partners who can move the product to developing countries.

However, as the chapter points out, there are no clear answers as to how best to increase global access to necessary technologies. Each of the above strategies has been tried, but they are all relatively new, besides which each situation will require a tailored solution. There is no one-size-fits-all approach nor are there boilerplate strategies that can be applied in a suite of different contexts. For this reason, everyone has to build upon his or her own experiences and find creative solutions. Universities can take the lead. Indeed, their public sector missions compel them to do so. When universities implement consistent and effective licensing strategies, they not only stimulate investment in R&D but also ensure that the products of that research are affordable and widely available in developing countries. **Where there is a will, there is a way.**

Some individuals and organizations have denounced, on ethical grounds, any patents for biotechnological applications, genes, or living organisms, especially patents on pharmaceuticals. However, there is neither a single articulation of such concerns nor is there a branch of any government that can address the concerns. For example, patent offices are ill-equipped to address ethical questions. In addition, any blanket prohibition on patenting genes or other biological materials would *generally* be inconsistent with TRIPS, which requires countries to allow IP protection for *most* biotechnology products. Still, under TRIPS, there are exceptions to this general prohibition. TRIPS also contains a provision that certain unethical inventions or innovations may be denied patents; a similar provision is found in the European Union's *ordre public* clause. U.S. patent law, however, does not have this kind of morality provision.

But are some or all patents for genes and cells unethical per se? How should tissue samples be collected? And how exactly are patents used to restrict access to medical and ag-biotech inventions? These are **some of the fundamental ethical questions** addressed by Marchant.⁸

With respect to obtaining biological samples, the ethical norm is that people who donate tissue for research purposes relinquish property rights to the donated cells, genes, and other biological material. Problems can arise, however, when human, animal, and plant materials and specimens are collected in developing countries and subsequently used to create biotechnological inventions that are patented in developed countries; some people have questioned the ethics of what they call biopiracy. Marchant explains that ethically questionable situations can usually be avoided if the following principles are followed:

- **Prior informed consent** should be obtained from the relevant entities before taking any samples.
- An organization agrees to share with a developing country any economic benefits that result from patented inventions based on biological materials collected in that country, called **benefit sharing**.

The above methods help to minimize, but do not eliminate, the ethical quandaries related to the collection of biological materials. Many questions remain: Who is authorized to give prior consent? Should more than one authority give consent (for example, both tribal and government officials)? How much must be disclosed about the proposed research to ensure that the authorities are adequately informed?

Benefit sharing can also be difficult to implement. First, many scientific researchers do not have funding to properly compensate indigenous peoples for their assistance. Second, who decides how benefits will be allocated? Third, if benefits are offered to people who assist researchers, some individuals may “assist” researchers purely for the money they will receive, not unlike some blood donors.

There are few laws that address the ethics of patenting. In the absence of any clear consensus, **ethical decisions concerning biotechnological patents will need to be made on a case-by-case basis**. The ethics of patenting is an evolving field that currently is more gray than black-and-white.

This is just one reason why it is hoped that this *Executive Guide* and *Handbook* will encourage all parties to take greater advantage of the unprecedented opportunity to benefit from the strategic management of intellectual property aimed at promoting the public welfare—especially those people who have, until now, been unable to benefit from today’s technology—and that this will contribute to building a healthier and more equitable world. ■

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 Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez, and SP Kowalski. (eds.). 2007. *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.
- 2 Chapter 1.1 by RT Mahoney and A Krattiger titled The Role of IP Management in Health and Agricultural Innovation, p. 3.
- 3 Chapter 1.2 by RT Mahoney titled Building Product Innovation Capability in Health, p. 13.
- 4 Ibid.
- 5 Ibid.
- 6 Chapter 1.3 by J Fraser titled IP Management and Deal Making for Global Health Outcomes: The New “Return on Imagination” (ROI), p. 19.
- 7 Chapter 1.4 by L Nelsen and A Krattiger titled Ensuring Developing Country Access to New Inventions: The Role of Patents and the Power of Public Sector Research Institutions, p. 23.
- 8 Chapter 1.5 by GE Marchant titled Genomics, Ethics, and Intellectual Property, p. 29.



FOR GOVERNMENT POLICYMAKERS

- ✓ **Intellectual property (IP) is a tool to foster innovation.** Whether viewed as a legal concept, a social construct, a business asset, or an instrument to achieve humanitarian objectives, the value of intellectual property cannot be disputed.
- ✓ **IP rights are a compromise and an imperfect solution,** representing the search for balance between making all knowledge available within the *public domain* and granting *ownership* of valuable discoveries to the inventors. Reaching an appropriate balance requires continuous, sound IP management.
- ✓ The use of the existing IP system, especially coupled with sound patenting and licensing strategies, resolves the **apparent paradox: the pursuit of the public interest through private rights.**
- ✓ **The emerging global systems of innovation in health and agriculture open up new prospects for innovation everywhere.** This notion, that the public interest can be served through private rights, has profound implications for the management of innovation, technology transfer, market competition, and economic development in every country, regardless of its economic status.
- ✓ **Innovation is a complex process.** It is stimulated by coordinated and structured policies and programs. The IP management system is an important factor, but it is only one of six factors that determine a country's or institution's ability to innovate.
- ✓ **Intellectual property is integral to all six components of innovation** that are, in addition to IP management: R&D in the public and private sectors; safe and effective regulatory systems; the ability to produce new products to high standards of quality; a national distribution system in both the public and private sectors; and international distribution systems and trade in technologies.
- ✓ Policies to promote the creation and management of intellectual property by public sector institutions should give first priority to **advancing the missions of those institutions.**
- ✓ There are few laws that address the ethics of patenting. In the absence of a clear consensus, **ethical decisions concerning biotechnology patents will need to be made on a case-by-case basis.**
- ✓ **Protection and licensing go hand in hand.** Public research institutions have much to gain if they are permitted to protect their inventions. A system that allows technologies to be patented and that encourages institutions to license them will both help countries to reach their economic goals and better serve the poor.
- ✓ Policymakers should encourage and fund **national technology transfer managers' associations** to the extent that doing so is feasible. Such associations are working to determine best practices in technology transfer and licensing.

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.)

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- ✓ Public sector institutions that **optimize their IP management capacity** and those that have capacity in any of the additional areas, such as regulatory systems, will be better equipped to actively participate in innovation.
- ✓ Often the most innovative organizations are those with the most **dynamic networks**, and those that reach out to other entities and potential partners.
- ✓ The case studies in the insert of the *Executive Guide* demonstrate how **public sector technology transfer can make a difference** in the developing world and elsewhere.
- ✓ Technology transfer officers should have ample **opportunities for professional development and networking.** Technology transfer is a field in which much information is shared informally.
- ✓ **Technology transfer and licensing are heavily context-specific.** A one-size-fits-all patenting and licensing policy and strategy is rarely effective for an institution.
- ✓ Public sector institutions ought to have **ethical guidelines** for IP management that are consistent with national laws and an institution's mission.

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FOR SCIENTISTS

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- ✓ **Innovation is a complex process.** It is stimulated by coordinated and structured policies and programs. The IP management system is an important factor, but it is only one of six factors that determine a country's or institution's ability to innovate.
- ✓ Your work is part of a larger **innovation process** that spans R&D across the public and private sectors, using regulatory systems, enabling the ability to produce new products to high standards of quality, allowing for the national distribution of new products through the public and private sectors, accessing foreign technologies, and managing intellectual property in a way that fosters partnerships.
- ✓ **Research is the very foundation of innovation.** Research leads to discovery; discovery fosters invention; inventions nourish innovation.
- ✓ **Your sustained interest in your invention is important** if it is to reach the marketplace, especially if it is to benefit those who most need it.
- ✓ It will be wise to consider the **ethical implications of your research.**
- ✓ You should **always obtain prior informed consent** when you access other people's materials or samples irrespective where they originate.



FOR TECHNOLOGY TRANSFER OFFICERS

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- ✓ **Intellectual property is integral to all six components of innovation** which are, in addition to IP management: R&D in the public and private sectors; safe and effective regulatory systems; the ability to produce new products to high standards of quality; a national distribution system in both the public and private sectors; and international distribution systems and trade in technologies.
- ✓ An IP manager should **consider the entire innovation process** when making patenting and licensing decisions.
- ✓ The traditional mission of technology transfer offices (to bring university-generated intellectual property to the public as rapidly as possible) is broadening. **Technology transfer enhances the reputation of academic institutions and helps them achieve their missions,** both at home and abroad.
- ✓ IP managers should join **professional national and international licensing and technology transfer societies** whenever possible.
- ✓ **Creative licensing strategies** will help your institution gain the greatest benefits from the research it conducts. Such strategies include, at a minimum, the balancing of exclusive and nonexclusive rights, defining field of use, setting appropriate milestones, requiring the delivery of products to developing country markets, and exercising control over pricing.
- ✓ In **benefit sharing,** an organization agrees to share with a developing country any economic benefits that result from patented inventions based on biological materials collected in that country. Make sure the individuals in your organization who collect biological resources are aware of this and obtain **prior informed consent.**

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.