

Institutional Policies and Strategies

The boundaries of any property must be clear. As a farmer needs to know where his or her field begins and ends, an innovator must know exactly the definition of his or her invention. But it is more difficult by far to delineate where rights to something intangible begin and end. In addition, intangible assets can be difficult to keep track of, to share, and to use. Yet in a research-and-development environment, intangible assets are often the most valuable and important ones. How then, can they be leveraged to reinforce the mission of an institution? How can the specific objectives be achieved more effectively and efficiently through the incorporation of best practices in IP (intellectual property) management? What are these principles and practices? And how does an IP policy relate to an operational IP strategy?

This section offers insights into achieving and maintaining **clarity about the ownership of intellectual property in public sector institutions** and stresses the value of IP strategies and IP policies. These are important for achieving success and have been increasingly encouraged—or required—by certain donors as a strategy to **ensure global access**. Global access, especially by the poor, and ownership of intellectual property go hand in hand. Indeed, the most important aspect of IP protection is that it bestows *control* over intellectual assets. If an organization—especially a public institution—fails to obtain IP rights for its inventions, it risks losing control over them. Failure to maintain rights may

result in private entities appropriating elements of the value without major regard to the mission of public institutions, or it could lead to the intellectual assets becoming useless due to lack of further investment and development. This is the most important reason why the public sector should take IP management more seriously than it traditionally has. IP management is a fundamental element in the public sector's strategy of putting intellectual property to work for the public good.

Appropriately, the first chapter in this section of the *Handbook* is a comprehensive discussion on IP strategy by Pitkethly.¹ His definition of strategy relevant to IP management is:

- the formulation and adoption of courses of action enabling the reaching of long-term goals and objectives of an institution
- the allocation of resources (financial and human) necessary for carrying out these actions

By extension, **IP strategy is an integral part of an overall business strategy that uses IP rights to manage technology**.

Pitkethly begins by mapping out how IP rights systems fulfill four purposes:

- providing incentives for innovation
- allowing for the packaging of intellectual assets into innovative processes
- encouraging the diffusion of technical information

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 5: Institutional Policies and Strategies. 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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- enabling the capturing of added value (economic and/or humanitarian) through the control of intellectual assets

Viewed in this way, IP rights systems can be instrumental in enabling the diffusion of technological information. For example, patent specifications provide detailed embodiments of inventions, which are available for all to see. Using the Internet, these records can be accessed for free anywhere in the world. This availability of and access to information greatly facilitates innovation, since others will be able to work to improve or invent around the disclosed patented invention. Patents can also be useful sources of information for scientists, since the patent application may be the first and only publication about a competing innovation.

Organizations should have both **external and internal IP strategies**. Broadly speaking, this is referred to as litigation, licensing, and learning.

An external IP strategy involves exploiting inventions (by developing them in-house, selling them, or licensing them). Litigation denies IP rights to others; licensing allows rights to others. Learning can be a part of technology out-licensing, since it not only gives others access to these technologies but also provides learning opportunities for the organization. This strategy is especially effective if an institution's aim is to diffuse technology as widely as possible and ensure global access.

As a result, **donors are increasingly requiring grantees to take IP management seriously**. Ballantyne and Nelki² of the Wellcome Trust (the Trust) in the United Kingdom, a major charitable funder of biomedical research, is one such pioneering funding entity. The Trust requires institutions that have produced intellectual property using the Trust grants to determine whether the public will benefit from the protection of that property and whether all participants in the process receive proceeds proportional to the amount of money, equipment, knowledge, or labor they contributed. But above all, the Trust insists that intellectual property arising from its grant awards be adequately exploited; the Trust does not shy away from taking over activities if grantees fail to

adequately exploit the intellectual property. The chapter ends with a series of case studies that illustrate the practical aspects of IP strategies.³

Grantees more and more frequently will need to present IP management strategies as part of their proposals. In the case of the Bill and Melinda Gates Foundation, certain grantees are required **global access strategies**⁴ that outline how recipients will manage new and existing intellectual property. Certain minimum standards may also be required, such as:

- keeping the research field open by prohibiting any licensee from enforcing intellectual property against universities and research institutions that carry out noncommercial activities
- retaining licensable research rights to any invention developed with donor funding
- obtaining freedom to operate for all background intellectual property owned by collaborating institutions
- ensuring good IP management, which includes exploitation of intellectual property, with the goal of ensuring its use in developing countries

Some granting agencies also require prospective grantees to explicitly state their **IP policies**. Kowalski⁵ reviews and discusses several institutions' policies and concludes that, at a minimum, an IP policy should define IP ownership, outline the patenting policy, describe the manner in which an institution will handle confidential information, set out the principles of its IP licensing and marketing approaches, explain how income arising from intellectual property will be distributed, and delineate the rights and obligations of inventors and the institution, as well as any rights the institution will retain (such as for research and for humanitarian uses).

Any new or revised IP policy (and IP strategy) will have to be "sold" to people both inside and outside an institution. It is important to explain *what* the policy contains and *why* the policy is designed the way it is. And perhaps staff at multiple levels should be involved in developing and revising, as needed, the IP policy. This group will be able to have extensive discussions

about the role and function of intellectual property in the organization. These discussions will be an effective mechanism for building capacity and staff support of the policy. Some of the most controversial issues can be resolved before they become an obstacle, such as: Who owns what? Who benefits and how?

These sometimes-troublesome questions are discussed by Weidemier,⁶ who reviews how universities in the United States are handling these aspects. Her chapter examines eight possible cases that illustrate and clarify the somewhat abstract principles of **ownership of university inventions** and are followed by a series of hypothetical scenarios. Weidemier, among others, concludes that universities should require all employees and visitors to sign **invention assignment agreements** on their date of arrival. Neither an employee handbook that discusses patent assignment nor a published university patent policy may be enough to ensure that the university is assigned ownership.

With the assignment of ownership rights to an employer comes the duty to disclose that an invention has been made. Indeed, an inventor is responsible for and has much to gain by making timely disclosures of his or her invention to the technology transfer office (TTO), the first step in enabling technology transfer. Di Sante⁷ points out that successful commercialization is built on a foundation of good relations between inventors and technology transfer professionals. Such relationships should be established long before the transfer services of the technology transfer office are required, since this will enable technology managers to negotiate both faculty and business concerns about licensing agreements whenever the opportunity arises. **The role of the inventor in the entire IP protection and IP licensing/transfer process cannot be overstated** and should continue throughout the life of the technology.⁸ For example, years after a patent has been licensed, the inventor may be the best-placed person to alert a TTO that a certain product being sold may infringe the patent.

But dealing with inventors is not always easy.⁹ Inventors are prone to fall in love with their own creations, and, perhaps unreasonably, anticipate that theirs is the next great thing. It is

the technology transfer professional's responsibility to tactfully ensure that the inventors' expectations are kept in line with reality.

Establishing good relationships with inventors is an important way to identify the intellectual property being generated in the research institution. But from an institutional point of view, a more comprehensive perspective on intellectual property is often warranted. This applies particularly to times when an organization develops a strategic plan or IP management strategy. In this context, IP audits can be essential and often form the basis for an internal review and a revision of IP strategy. Blakeney¹⁰ provides a comprehensive overview of IP audits. Indeed, the **importance of IP audits** is becoming more and more apparent, in the private sector as well as in the public sector, as public entities increasingly deal with other parties' intellectual property.

An IP audit seeks to accomplish three broad objectives for an institution. First, it seeks to identify the intellectual property generated by its researchers. This intellectual property is an asset, with value that an institution ought to identify, assess, and manage. Second, an audit seeks to identify and review the management of third-party intellectual property as a way of avoiding liability for misuse. The IP audit is thus a systematic, methodical identification of the intellectual property within the institute.¹¹ As the chapter shows, the audit follows a procedure, from start to finish, so that at the audit's conclusion senior managers are able to frame and implement good IP management practices. This is the third broad objective of an IP audit: to contribute to the formulation and execution of the IP policy and IP strategy.

From a practical point of view, an IP audit reviews a number of existing practices and establishes the context in which intellectual property is being handled. For example, a research institute's ownership and control over any intellectual property will depend on its legal status as an entity. An IP auditor will review the incorporation documents to identify what powers the institute has to own and to deal with intellectual property. For universities and government institutions, such a review will also include the prevailing government policies.

The IP auditors will also scrutinize the IP policy of the institute, if indeed there is a policy. It should ask questions, such as: Where is it posted? What does it say? Are new employees required to read it? IP audits may also uncover potential conflicts of interest. Bennett¹² offers a primer on issues related to the management of conflict of interest and conflict of commitment. **Conflict of interest** occurs when the financial interests of an institution's researchers are incompatible with the institution's mission, policy, or goals. **Conflict of commitment** may arise when the time a researcher spends in external activities related to, for example, downstream technology development, interferes with his or her attention to duties to the institution (for example, teaching or extension responsibilities).

While **conflicts of interest should not be seen in a negative light**, making exceptions to the rules is both dangerous and potentially harmful. Someone with a potential conflict of interest is not guilty of anything; rather, he or she may actually be a more valuable "asset" *because* of the potential conflict. This applies most strikingly when a professor has an interest in forming a spinout company based on university research. Potentially, larger issues will arise due to undisclosed conflicts of interest. What a university needs is to define a clear chain of command and in rare circumstances to establish oversight committees. Committees tend to slow the process with significant delays in time, which typically makes the process unmanageable and useless.

Most conflicts arise when *potential* conflicts are not disclosed. Conversely, a major tactic in managing conflict of interest is to disclose *potential* conflicts. And most conflicts of interest can be managed fairly easily provided the policy is clear and precise. M.I.T., for example, manages an unusually large number of spinouts and, therefore, has a very strict conflict of interest policy (this is discussed by Nelsen¹³). A technology transfer officer's role is to creatively craft arrangements within the rules, not to use these rules as deterrents. Put differently, Nelsen describes M.I.T.'s operating motto: "A firm wall between university and industry—but a wall with many doors... In sum, **technology transfer inevitably brings conflicts of interest. The challenge is to manage them.**"¹⁴ ■

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 5.1 by R Pitkethly titled IP Strategy, p. 459.
- 2 Chapter 5.2 by Z Ballantyne and D Nelki titled Management Policy: A Donor's Perspective, p. 475.
- 3 The following are reviewed in detail: the development of a typhoid vaccine, malaria drugs, the single nucleotide polymorphisms (SNP) consortium, and the International HapMap Project.
- 4 For an example of how global access strategies can be incorporated into product development partnerships and vaccine development, see Mahoney RT, A Krattiger, JD Clemens and R Curtiss III. 2007. The Introduction of New Vaccines into Developing Countries IV: Global Access Strategies. *Vaccine* 25(2007): 4003–4011.
- 5 Chapter 5.3 by SP Kowalski titled Making the Most of Intellectual Property: Developing an Institutional IP Policy, p. 485.
- 6 Chapter 5.4 by BJ Weidemier titled Ownership of University Inventions: Practical Considerations, p. 495.
- 7 Chapter 5.5 by AC Di Sante titled The Role of the Inventor in the Technology Transfer Process, p. 507.
- 8 An important exception to this is licensing. A TTO officer typically would not have the inventor participate during negotiations with potential licensees, although rare exceptions may apply.
- 9 See also Section 8 dealing more exhaustively with inventions and inventors.
- 10 Chapter 5.6 by M Blakeney titled Conducting IP Audits, p. 515.
- 11 This may include: patentable biological assets, such as germplasm resources, DNA libraries and enabling technologies (marker genes, probes); technological know-how; confidential information; patents, utility models and industrial design rights in equipment; copyrighted information (database rights, computer programs, and databases); publications; CD-ROMs; video materials; online materials; trademarks; and more.
- 12 Chapter 5.7 by AB Bennett titled Conflict of Interest and Conflict of Commitment Management in Technology Transfer, p. 527.
- 13 See Box 1 for M.I.T.'s policy (Chapter 3.13 by L Nelsen titled The Activities and Roles of M.I.T. in Forming Clusters and Strengthening Entrepreneurship, p. 309).
- 14 Chapter 6.1 by L Nelsen titled Ten Things Heads of Institutions Should Know about Setting Up a Technology Transfer Office, p. 537.



FOR GOVERNMENT POLICYMAKERS

- ✓ There is an ongoing debate over how IP systems can achieve the optimal **balance between private rights and public benefits**. However, experience suggests that IP rights systems, if soundly applied and used by the public sector as well as by the private sector, are better than any of the proposed alternatives in achieving public-goods objectives. Government policies can be instrumental in helping public sector institutions find the right balance.
- ✓ As a specific requirement, public sector institutions should be required to develop and publish their **institute-specific IP policies** that adapt broader principles to the specific context of the institution's mission and strategy. Such policies should include clear conflict-of-interest policies.
- ✓ Incorporating the goals of dissemination of public-sector-generated R&D to benefit primarily the poorer segments of the population are goals that **do not run counter to benefiting economically** from inventions. Much will depend on the specific context and how these seemingly contradictory goals are managed.
- ✓ Public sector institutions can achieve little with their intellectual property in the absence of an enforceable **system for protecting and promoting local innovation** that includes clear assignment rules regarding ownership of inventions.
- ✓ A government may wish to analyze the interface between its **laws governing charitable organizations** and how the laws may impact the freedom of nonprofit institutions in owning and licensing both their own and third-party intellectual property.
- ✓ Policymakers should consider the promotion of legislation that clarifies under what circumstances employees in the public sector, including those at universities, shall **assign patent rights to their employers**. This aspect has ramifications for statutory laws in many countries with respect to “hired to invent,” “shop-right,” and other matters.
- ✓ Technology transfer and IP management are complex, requiring the creative input and participation of different professionals from varying fields of expertise. Therefore, it is important to recognize that **investments in public sector education and training programs** need to consider many aspects, including scientific, business and entrepreneurial, legal, judicial, and policy.

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.)

- ✓ A sound **IP policy** should address, among others issues, clear ownership of intellectual property generated, conflicts of interest and conflicts of commitment, the manner in which an institution will handle confidential information, the principles of the institution's IP licensing approaches, how income arising from intellectual property will be distributed, and any rights the institution will retain (such as for research and for humanitarian uses).
- ✓ An **IP strategy**, on the other hand, describes the courses of action enabling the reaching of long-term goals of the institutions and the allocation of resources necessary to carry out these actions. Public sector institutions may wish to specifically address in their IP strategies how their research endeavors, in general, and IP management strategies, in particular, will achieve global access of their products and how the endeavors will benefit humanitarian objectives.
- ✓ Components of such an IP strategy may include how the institution deals with **incoming** third-party intellectual property, how it deals with **internally generated** intellectual property (patenting and other protection strategies that should include how the institution balances the public sector component of its mission with economic imperatives), and how it will **out-license** its intellectual property to third parties.
- ✓ Particular emphasis should be placed on **global access strategies**, not only because philanthropic funding agencies increasingly require grantees to address them, but because this approach is especially effective if an institution's aim is to diffuse technology as widely as possible.
- ✓ The **process by which an IP policy and IP strategy are developed** may be valuable in bringing about internal culture change and create strong support from staff.
- ✓ Successful IP commercialization is built on a foundation of good **relations between inventors and technology transfer professionals**. Such relationships should be established long before the transfer services of the technology transfer office.
- ✓ The **importance of IP audits** is becoming more and more apparent, in the private and in the public sector, as public entities increasingly deal with third-party intellectual property. IP audits can be useful mechanisms that form the basis for an internal review and revision of an institution's IP strategy and IP policy.
- ✓ Technology transfer invariably brings **conflicts of interest**. The challenge is to manage them in a transparent and consistent manner. Importantly, potential conflicts of interest should not be viewed in a negative light. Most real conflicts arise when **potential** conflicts are not disclosed.



FOR SCIENTISTS

- ✓ As the creator of inventions and technologies, **your role in technology transfer** is critical. So please read on!
- ✓ Your role can best be carried out if you have good relations with the technology transfer office and officers. But fulfilling your role also requires a good knowledge of and understanding of your institution's **IP policy**. The policy will likely articulate ownership of intellectual property, conflict of interest, the handling of confidential information, and more. Become familiar with the content and the meaning of the various provisions and how they may affect you.
- ✓ The purpose of such a policy, and more importantly of your institution's **IP strategy**, is not just to protect your inventions, but also to control technologies and IP assets in such a way as to allow you and the TTO to determine how your inventions can—and should—be used to spur economic growth and contribute to the greater public good.
- ✓ Remember, few inventions will lead to blockbuster products, make millions of dollars, or save billions of people. Have realistic expectations, especially regarding what it will take for your invention to make a difference. It is not bad to love your own creations as long as you have **realistic expectations**.
- ✓ More and more philanthropic donors expect to find IP management components in **grant applications** and to understand how intellectual property will be used to achieve global access and humanitarian benefits. This is just one reason why a close relationship with your TTO is important, and becoming even more so.
- ✓ When your institution conducts or commissions an **IP audit**, view this as an opportunity to better identify the intellectual property generated in your research program, to improve and streamline the management of third-party intellectual property (allowing you to concentrate more on research), and to contribute to the formulation and execution of an IP strategy that benefits your program and its (global) impact.
- ✓ One of the most important responsibilities you have is to disclose any **potential conflict of interest**. You are not guilty of anything if you have a potential, perceived, or even real conflict of interest. Most problems arise when conflicts are not disclosed. Clear conflict of interest policies that are followed and implemented in a transparent manner is all that is required to manage them.



FOR TECHNOLOGY TRANSFER OFFICERS

- ✓ An **IP policy** should address, at a minimum, ownership of intellectual property, conflicts of interest and conflicts of commitment, the handling of confidential information, the principles of IP licensing approaches, the sharing of income derived from intellectual property, and any rights the institution will retain (such as for research and for humanitarian uses).
- ✓ Public sector institutions will increasingly be expected to define an institutional **IP strategy** that specifically addresses how IP management will be used to achieve global access/humanitarian benefits of the inventions and products developed at your institution. It should include how the institution deals with **incoming** third-party intellectual property, how it deals with internally generated intellectual property, and how it will **out-license** its intellectual property to third parties.
- ✓ The **process by which an IP policy and IP strategy are developed** may be valuable in bringing about internal culture change and create strong support from staff.
- ✓ Successful IP commercialization is built on a foundation of good **relations between inventors and technology transfer professionals**. Such relationships should be established long before the establishment of transfer services of the technology transfer office.
- ✓ The **importance of IP audits** is becoming more and more apparent, in the private sector and even in the public sector, as public entities increasingly deal with third-party intellectual property. IP audits can be useful mechanisms that form the basis for an internal review and revision of an institution's IP strategy and IP policy.
- ✓ Technology transfer invariably brings **conflicts of interest**. The challenge is to manage them in a transparent and consistent manner without granting any exceptions, irrespective of the prestige of the scientist or the amount of funding they attract. Importantly, potential conflicts of interest should not be viewed in a negative light, provided they are disclosed (and managed). Most problems arise when **potential** conflicts are not disclosed. Few conflicts of interest are well managed by committees.
- ✓ All employees (and visitors in some cases) should be required to sign an **invention assignment agreement** on their date of arrival. Neither an employee handbook that discusses patent assignment nor a published university patent policy may be enough to ensure that the university is assigned ownership.

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.