Specific Strategies and Mechanisms for Facilitating Access to Innovation

Innovation is a wonderful thing. Innovation occurs when any new knowledge is introduced into and utilized in an economic and/or social setting. People and institutions (agents) orchestrate this process. Simple economic theory states that such agents act in a rational way, responding to price signals as a way of maximizing investments. But modern innovation research indicates that this is not so, particularly when noncommercial or humanitarian goals are being pursued. Agents, both public (governments, universities, extension services) and private (small, medium, and large companies, as well as farmers, individual consumers, and communities) are essentially strategists who respond to other agents' behaviors. For example, a governmental "behavior" in this context would be changing a range of policies, such as research, regulatory, trade, and IP (intellectual property) policies. Each of these agents directly or indirectly engages in the production, processing, marketing, or distribution of products and services. Simultaneously, agents engage in the processes of knowledge creation or dissemination and the application of knowledge through both market and nonmarket relationships.

Using this definition of innovation, public research institutions and universities may be invention creators. They are not necessarily innovators per se but are important actors in the innovation process. Their roles are strengthened if they are well connected. That is, they are stronger if they function in partnerships that extend beyond their primary missions and include others who can turn inventions and knowledge into products and services that become economically successful or that have major social and humanitarian impacts. This impact can be measured through three key conditions that jointly determine whether an innovation is adopted. These are:

- availability
- affordability
- acceptability[1]

In addressing the needs of developing countries, achieving these three conditions concurrently can conveniently constitute **global access**. But translating the three into an effective innovation management plan or operational strategy is more challenging. To manage these goals, a strategy that consists of six thrusts should be considered:[2]

1. Development of R&D capability by the public and private sectors
2. Development of a safe and effective regulatory system that covers drugs, vaccines, and agricultural inputs and outputs
3. Development of manufacturing capability for health products, seed production systems, and value-added processing
4. Development of an IP system (legal framework, judiciary to enforce it, and institutional management capabilities)

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 2: Specific Strategies and Mechanisms for Facilitating Access to Innovation. 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.

5. Development and expansion of national health or agricultural delivery systems, including an attractive, private-sector domestic market for health or agricultural products and services
6. Development of international trade systems for health products (including global procurement funds) and agricultural inputs and outputs

Although IP management is but one of six components, it can be viewed as the thread that runs through the innovation process or as the glue that holds partnerships together. Partnerships are based on the mutual interests of two or more parties and agreed upon in contracts. The terms and provisions of a contract can be almost limitless (provided they are both legal and agreed to by the parties) and are discussed elsewhere in great detail.[3] The present section focuses on the components that are most specific to global access. And one of the first and foremost sets of licensing terms, at least for universities and other public sector research institutions in the licensing of invention, is **the reservation of certain rights**. Indeed, Bennett[4] urges universities and public sector institutions to ensure that they preserve the right to use licensed technologies for educational, research, and humanitarian goals—including distribution rights in developing countries.

In essence, the terms of a license can subdivide the rights with respect to a technology. **Rights can be segmented** and apportioned across:

- *technological fields, markets,* or *economic contexts* in which the technology is used (such as farm size, farm income, or income derived from a particular crop, in the case of agriculture; or certain drugs to combat neglected diseases in the case of health)
- *income levels* (for example, per capita gross domestic product)
- *geographic regions* (by country, or by lowland or highland agricultural systems) or by customer (public procurement or private hospitals and pharmacies)[5]

This practice can be used by any technology owner to maximize the application of its inventions. Most importantly, subdividing and field-of-use licensing can allow both commercial and noncommercial uses of the technology to proceed in parallel and, thus, constitutes a central element in a global access strategy. Bennett provides suggestions for creating explicit reservation of rights in a commercial technology license. This will ensure that institutional objectives to support humanitarian applications of technologies that have applications to the needs of the poor are not inadvertently compromised.

The global **importance of humanitarian licensing** is also discussed in detail by Brewster, Hansen, and Chapman[6] with pragmatic answers about the why, who, and how of the process. The authors encourage IP managers, in both private and public sectors, to adopt such strategies, noting in particular that they are not incompatible with commercially driven businesses. The *why* for humanitarian-use licensing is obvious, with the vast unmet health and agricultural needs of developing countries. The *who* is increasing as more and more organizations have been using IP management practices to promote the health and food security of poor people (and the chapter offers many recent examples). The *how* is discussed through a number of case studies[7] on humanitarian licensing. The authors conclude, with others, that much can be achieved using best practices, many of which are enumerated at the end of the chapter.

Eiss, Hanna, and Mahoney[8] look at the same topic but on the basis of how various **product-development partnerships (PDPs)** seized upon public and private sector strengths and how they are **leveraging existing infrastructure and research** in developed and developing countries. Although each of the PDPs reviewed are very different, they nonetheless share some common strategies for maximizing IP management for global health. These include:

- defining a discrete territorial market
- establishing different structural incentives in public sector and private sector markets
- extending field of use to make the product applicable to diseases in developed countries
- using royalties to benefit the party that needs the most incentive

- providing access to the developed technology, should the private sector not follow through on the project

The authors conclude that whereas these issues can be complex, they should be addressed as early as possible in the formation of partnerships. But most importantly, the chapter concludes with the observation—grounded in much experience—that an approach that takes into account the six components of innovation discussed at the beginning of this chapter will have a much better chance of success than those efforts that take a piecemeal approach to product development and distribution. Such a comprehensive effort should not be considered daunting, but rather an opportunity for creativity.

It is widely acknowledged that IP rights are important drivers of innovation, and this applies equally to the private sector and the public sector. This is especially the case for product patents. However, for **research tools[9] in both medical and agricultural innovation**, Clift[10] demonstrates that patents related to research tools can have negative implications and, hence, should be balanced carefully with disclosure to place inventions in the public domain. Developing countries need to think about how to implement patent legislation (that is consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, best known by its acronym TRIPS) while meeting their own objectives, particularly those related to genetic discoveries. For example, legislation should be formulated to set forth appropriate research exemptions, and patenting and licensing policies should be aimed at maximizing the availability of innovations in order to aid the development of urgently needed products.

For **product patents,** the decision to patent or not to patent is much simpler. For many products, even those aimed at developing countries' needs, patenting provides a mechanism to extend licenses, with specific provisions for licensees to meet these needs according to well-understood and well-defined market conditions. But this only works if best licensing practices are adopted (such as those defined and spelled out throughout the *Handbook*). A compelling reason for best practices in IP management is well illustrated by Stevens[11] who discusses how student activists ensured that Yale University and Bristol-Meyers Squibb quickly adopted humanitarian licensing (also called fair-access licensing).[12] The objectives for such **humanitarian licensing provisions** should be to maximize the possibility that the patented invention will be produced and to structure arrangements for tiered pricing, which will allow the poorest countries access to the drug at the lowest cost.

Best practices adopted by PDPs have also had the following important effects:

- Large companies have been motivated to contribute their drug-discovery skills and resources because they are assured that others are responsible for funding late-stage clinical development.
- Small companies have secured funding to develop technologies with dual-market uses, with the PDPs securing license rights for developing countries at zero or low royalty rates and the small company retaining rights for use in developed countries.
- Academic institutions have had a new channel to advance their neglected-disease discoveries.
- Developing country pharmaceutical companies have found their production and distribution skills in demand.

For products needed in developing countries, it could be argued that the question of patenting should not even arise. Some argue that not to patent would be the best strategy. Others believe that **open source licensing** may be an effective option for managing intellectual property. Indeed, the chapter by Hope[13] discusses the possibilities of open source licensing. Open source does not mean to place something squarely into the public domain nor does the decision to pursue open source licensing follow only from altruism: it *can* be based on commercial self-interest. Open source licensing has been most successful in the computer software field (Linux being the most prominent example), where anyone, anywhere, and for any purpose is essentially allowed to copy, modify, and distribute the company's

software (either for free or for a nominal fee) and, therefore, anyone is allowed full access to the software's source code. The only condition is that everyone has to share its improvements with everyone else.

Open source is thus a form of IP licensing, and so it differs significantly from placing technology in the public domain via publication.[14] An open source strategy may indeed be a viable approach to encourage the widespread adoption and development of an innovation. Some innovations (such as software) are automatically protected by copyright, so a license clarifies the terms of its use. An open source license gives the innovator the right to set terms of use and exclude users who will not abide by those terms. But most of the incentives for open source licensing are indirect: cost savings, productivity gains, the capital provided by a good reputation, and, most importantly, an expanded user base, which correspondingly expands complementary goods and services. As the market expands, revenues from sales, one-time licenses, dual licensing, and complementary products and services may be enough to offset the opportunity cost of open source licensing. IBM has successfully used this approach. Importantly, open source licensing can place an institution in a network of innovation with enormous collaborative potential. Finally, open source licensing can encourage the development of alternatives to proprietary technologies. The greater the number of nonproprietary tools in a given tool kit, the greater the incentive for everyone in the field to invest in developing substitutes for the remaining proprietary technologies, since it will allow freedom to operate for the whole tool kit.

All of the foregoing relates to software licensing. Despite several attempts to adapt open source approaches to the biological sciences in both health and agriculture, none has been successful. Given the possible benefits associated with open source licensing, pursuing it further is warranted but will require additional work. Hope discusses the various unresolved challenges in the biotechnological field. She distinguishes between "copyleft" and "academic" forms of open source licensing. Using a proposed five-step decision-making process, Hope shows how open source technologies, for example, can be tailored to serve small agricultural and pharmaceutical markets in developing countries. And given the growing reliance on computer technologies in the life sciences—bioinformatics software programs, for example—the possibilities for open source licensing in this field have great potential.

Returning to the PDPs and their goal of moving candidate products through various stages up to clinical development and eventual distribution, many PDPs face a series of highly practical challenges. The central challenges are ensuring high-quality and low-cost production, sustained supply, affordable pricing, and effective delivery of their products. Indeed, the World Health Organization's Commission on Intellectual Property and Innovation in Health has found that many PDP research-and-development contracts defer issues related to manufacturing and distribution.[15] As a result, PDPs now increasingly face both negotiating and operational challenges regarding manufacturing sites, pricing to the public sector, market segmentation, market sizing, ensuring the lowest sustainable cost of production while guaranteeing sustainable supplies, quality control, and post-launch issues, such as pharmacovigilance and product liability.

Elaborating the requirements and **approaches for global access** early on is critical; otherwise, plans are developed incrementally or even after the product is developed. This leads to delays and creates large inefficiencies for the crucial last steps of distribution in developing countries. In addition, negotiating power may be diminished after development. In such cases, product uptake can be sluggish or stalled due to a variety of downstream considerations. A useful way to approach these situations is to **apply milestones** in the initial licensing agreements to ensure that key goals are met along the product development pathway. The kinds of milestones will vary based on product profiles and target markets, but in all cases, as Oehler[16] states, milestones require the following:

- intensive preparations
- detailed knowledge of the processes related to developing and marketing the product
- realistic forecasting of product potential

- persistence in quantitative forecasting and establishing a master plan for the entire product rollout
- a mission-driven mindset to establish optimum goals for the public sector

When public-private partnerships manage intellectual property, they are trying to **balance the private sector's commercial interests with the public sector's goal** of obtaining access to pharmaceutical products at the lowest possible cost. Although the goals and paradigms of the public and private sectors may appear too far apart, this chapter provides the tools and materials required to build the contractual architecture to span that divide. According to Oehler, a large part of the problem is simply a failure to communicate between the public and private sectors. Discussions between the public sector and industry are cross-cultural, no matter how well public sector players think they understand industry. In such a cross-cultural environment, there is nothing more dangerous and conducive to misunderstandings than to *assume the obvious*, since what is obvious for one person with a public sector background will not necessarily be the same for the other partner. Obligations and contractual performance cannot be left to vague *best efforts* and *common sense*.

The experiences of the Concept Foundation, which are the platform for the chapter by Oehler, demonstrate the successful use of milestones as a tool. The Foundation's business model initially considers downstream issues such as product delivery, and it utilises contractual milestones to achieve its principal goal of providing developing countries access to new medicines.

Milestones and open source are but one way for institutions to have easier access to inventions from third parties; there are many other mechanisms to assemble intellectual property. Krattiger and Kowalski[17] provide a brief overview of different **IP assembly options** (royalty collection agencies, information clearinghouses, technology clearinghouses, open source innovation clearinghouses, brokers and other kinds of facilitators, IP management services, IP commercialization agents, integrated commercial services, company-to-company arrangements, and other public technology transfer and financing mechanisms). The authors focus on the pros and cons of patent pools, which are receiving more and more attention as possible tools for improving technology transfer to developing countries.

There are many forms of **patent pools**: essentially they all allow for the interchange (cross-licensing) of rights to essential patents by a number of entities. They also include an agreed-upon framework for out-licensing the pooled intellectual property to third parties. A patent pool offers several benefits, a major one being that it cuts through patent thickets. But patent pools are also risky: the agreement to share technologies may run into problems based on antitrust legislation. Other considerations vis-à-vis patent pools include:

- They allow for the transfer of intellectual property. Know-how and trade secrets may also be required to use the intellectual property.
- They have generally flourished when all companies in a sector are stymied by restrictions on access to intellectual property. This makes them willing to compromise. It is unclear whether or not pharmaceutical companies feel similar inclinations. In agriculture, the interests of companies are not aligned to make patent pools feasible at the moment but this could be different for public sector organizations.
- They have been most successful in the electronics industry, since they facilitate industry-wide standards that create larger markets. Again, this may not apply to drug or agricultural biotechnology companies.
- They are typically expensive to create and maintain.

Despite these reservations, the benefits of patent pools are strong. They create an efficient "one-stop shop" for intellectual property, eliminate stacking licenses, avert litigation, decrease research and administrative costs, and can greatly improve the speed and efficiency of technological development. It is worth remembering, however, that patent pools are not the only ways to achieve these benefits. To help policymakers

determine the appropriateness of patent pools for their unique situations, Krattiger and Kowalski provide a ten-step checklist for deciding whether or not to set up a patent pool and a ten-step procedure for setting one up. The authors point out legal pitfalls associated with patent pools and general suggestions are offered for identifying and avoiding them.

In sum, the reservation of rights, open source licensing, milestones, and different forms of IP assembly are all part of the toolbox of best practices that facilitate access to innovation. But to determine which specific rights should be retained, which elements should be licensed on an open-source basis, which milestones lead to the best results, and which assembly option works best, will always be difficult to determine because the answers depend heavily on the context. The context will include the actors involved in the innovative process, their relationships, and their connectivity within a global innovation network. Irrespective of which options are selected for greater global access, all strategies will require highly intensive preparations, detailed knowledge of processes related to the development and marketing of the product, detailed knowledge of markets, realistic anticipation and forecasting of product potential, and persistence in quantitative forecasting, as well as a master plan for the entire product rollout. The tools described in this section can be powerful for achieving public sector goals, and they are certainly worth the effort. ■

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 In the context of modern technologies, specifically food biotechnology, acceptability is particularly relevant.

2 The choice of the six strategic components stems from work in innovation theory and management and has been adapted for health by RT Mahoney (see Chapter 1.2 titled Building Product Innovation Capability in Health, p. 13).

3 See part 11 on Technology and Product Licensing, and part 12.

4 Chapter 2.1 by AB Bennett titled Reservation of Rights for Humanitarian Uses, p. 41.

5 See Chapter 11.8 by SL Shotwell titled Field-of-Use Licensing, p. 1113.

6 Chapter 2.2 by AL Brewster, SA Hansen and AR Chapman titled Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation, p. 47.

7 The special insert in this *Executive Guide* offers 24 successful case studies.

8 Chapter 2.3 by R Eiss, KE Hanna and RT Mahoney titled Ensuring Global Access through Effective IP Management: Strategies of Product-Development Partnerships, p. 63.

9 These encompass a wide range of resources, including genes and gene fragments, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as the polymerase chain reaction or PCR), methods, laboratory equipment and machines, databases, and computer software.

10 Chapter 2.4 by C Clift titled Patenting and Licensing Research Tools, p. 79.

11 Chapter 2.5 by AJ Stevens titled Valuation and Licensing in Global Health, p. 89.

12 Yale University had granted an exclusive license for an anti-HIV compound to Bristol-Meyers Squibb, which also gave the company the right to file for patent protection in foreign countries. Fatefully, the company filed in South Africa, Mexico, and Egypt, among other countries. South Africa (and the rest of Africa) needed this anti-HIV drug (D4T), but it was far too expensive for all but a very few. Pressure was put on Yale University to make this drug available generically in South Africa. Yale resisted, but student activists brought the issue to the attention of the national press, and Bristol-Myers Squibb quickly acted to make the drug available at no cost to treat AIDS in South Africa.

13 Chapter 2.6 by J Hope titled Open Source Licensing, p. 107.

14 For a detailed discussion on patenting versus the public domain, see chapter 10.1 by S Boettiger and C Chi-Ham titled Defensive Publishing and the Public Domain.

15 WHO. 2006. Public Health Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. WHO: Geneva. www.who.int/intellectualproperty/en/.

16 Chapter 2.7 by J Oehler titled Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries, p. 119.

17 Chapter 2.8 by A Krattiger and SP Kowalski titled Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms, p. 131.

FOR GOVERNMENT POLICYMAKERS

- ✔ One of the **benefits of enabling public research institutions to own IP rights** is that institutions can control how technology is deployed through the terms of licensing contracts, thus meeting both commercial and noncommercial goals.

- ✔ Well-crafted contracts, based on best practices, can be instrumental in achieving **global access**, provided the entire innovation process is given due consideration from the outset. This includes consideration of R&D capabilities, regulatory environment, manufacturing capabilities, IP management, access to markets, and trade-related concerns. Such an approach requires a lot of preparation and detailed knowledge of the processes related to developing and marketing the invention; realistic forecasting of product potential; persistence in quantitative forecasting and establishing a master plan for the entire product rollout; and a **mission-driven mindset** to establish optimum goals for the public sector.

- ✔ One of many components of best practices by the public sector is incorporating **humanitarian-use reservation** provisions in commercial licensing contracts. This is becoming increasingly common with certain universities around the world, particularly with respect to agricultural inventions. There is conceptually no reason why this should not become common practice globally.

- ✔ Public sector institutions should have explicit IP policies and **demonstrated institutional capacity** to implement best practices in IP management. Any licensor, public or private, is more willing to give licenses to institutions that proactively protect third-party-property, which leads to confidence building and a higher degree of motivation to proceed with more licensing and technology transfer arrangements.

- ✔ **Open source** may offer an alternative mechanism for facilitating access to innovations in health and agriculture, provided the open-source approaches that are so popular and effective in the software area can be successfully adapted to the biological sciences. More conceptual research is needed to make open source an effective way to accelerate innovation in health and agriculture.

- ✔ Other policies and laws can foster and enable efficient IP assembly (or in-licensing by national institutions to obtain freedom to operate and the freedom to license bundles of technologies to manufacturers). These may include **patent pools** and other mechanisms.

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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- ✔ One of the central elements for public sector institutions is to have explicit IP policies and **demonstrated institutional capacity** to implement best practices in IP management. Any licensor, public or private, is more willing to license to institutions that proactively protect third-party property, which leads to confidence building and a higher degree of motivation to proceed with more licensing and technology transfer arrangements.

- ✔ Humanitarian licensing can benefit both the research and public service missions of a university or public sector research institution. Consider creating an institutional policy that standardizes the **reservation of humanitarian rights** on all technologies, including, as appropriate, the right to practice the invention for nonprofit goals. Potential licensees are less likely to resist if they know that the terms being requested are "standard" and part of the deal in doing business with an institution.

- ✔ Implementing the various best practices discussed and presented in this section is complex and requires experience. Public sector institutions need to plan and implement focused **capacity building in IP management**.

- ✔ **Networks** with individuals and organizations, such as foreign universities, corporations, product development partnerships (PDPs), and government agencies, should be seen as critical elements that enhance the innovative potential of any institution.

- ✔ Indeed, partnerships are an important way to fill in the capacities that are required to **make an institution innovative**. Few, if any, institutions have the entire range of capacities to bring ideas to market.

- ✔ Under many circumstances, patenting may be unnecessary and publication might offer the widest dissemination. The decision to **place inventions in the public domain** should be calculated and made on a case-by-case basis. **Open source** licensing might be another complementary component of an IP management strategy.

- ✔ Whenever possible, consider **nonexclusive licensing** as a strategy to maximize the utilization of research tools. On product patents, **exclusive licensing** may, in many circumstances, be more effective to reach broad dissemination, particularly if coupled with strong milestone clauses.

- ✔ Complementary strategies are the segmenting or apportioning of markets, whereby different licensees obtain exclusivity but only for one portion of the **field of use**. This strategy can also be used to implement tiered pricing.

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

- ✔ As the inventor, in most circumstances, you can **significantly influence how your technology is used**. For example, you can very reasonably request that your technology transfer office draft license terms that reserve for you the rights to continue research using your inventions or terms that reserve the rights for humanitarian uses of your technology.

- ✔ Notwithstanding the above, you must follow the IP policies of your institution. And there is no reason a priori that your interests in licensing practices should not be reflected in your institutional IP policies. Changing them, if necessary, **requires a dialogue** with senior management and technology transfer personnel and a good understanding of the purpose of intellectual property and how sound IP management can be put to work for the benefit of the public sector.

- ✔ Your interest and activities in licensing and partnership building can **raise the profile** of your research program and also of your institution. It may create goodwill, catalyzing additional scientific and development interest by partner organizations and individuals. And it can lead to earlier and more efficient translation of your research findings into useful products or services.

- ✔ In particular, **collaboration with private sector entities** can be a most valuable contribution to your institution's broader participation in innovative initiatives, particularly as it pertains to product development.

- ✔ The R&D work that you carry out in your program can often (perhaps serendipitously) lead to the invention of new **research tools**. But the patenting strategies for research tools may need to be different from those related to products if maximum dissemination and use are sought.

- ✔ One such avenue for research tools in particular may be open source licensing. This is a complex and evolving area in the biological sciences and requires further refinement to be effective and useful.

- ✔ Importantly, open source licensing is not the same as placing an invention into the **public domain. Open source entails contractual obligations.** An open source license may be extremely complex and may require your institution to agree to certain obligations. Several universities are unable to sign such open source licenses because they cannot, in good faith, agree to the conditions. Make sure you always consult your technology transfer officers before signing any agreement.

- ✔ Increasingly contracts will include **milestones**, which may affect your work, although quite often not directly. Research schedules and goals may be directly linked to specific milestones, and you need to know how such milestones might influence your program.

- ✔ Accessing other people's intellectual property can be facilitated through networks of committed professionals; your contributions in this area can be substantial, and **strong professional networks** will make you a more valued and essential member of the team.

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

- ✔ **Licensing and valuation practices between a public sector institution and product-development partnerships** show that one valuation formula is to ask for the licensees in developing countries to take over responsibility for future patent costs but to ask for no up-front fees, no milestone payments, and no running royalties. Any financial return to the university should be derived from opportunities in developed countries.

- ✔ **Both nonexclusive and exclusive licenses can be applicable to meeting socio-economic goals**. Within exclusive licensing, there are many feasible options, such as exclusivity limited to a certain field of use, or geography, or for limited periods of time.

- ✔ Certain **equitable access provisions** in licenses can be instrumental in enabling competition in low- and middle-income countries.

- ✔ The practice of **reserving rights for humanitarian use** may require additional work and will likely not generate licensing revenue; conversely, such provisions, if used in a strategic way, are unlikely to lead to loss of revenues.

- ✔ Potential licensors of intellectual property connected to critical agricultural and health care technologies will be **motivated by your institution's demonstrated IP capacity**, and will be more likely to enter into more licensing agreements.

- ✔ If you are a licensor, **put yourself in the position of the other party**. If the roles of licensor/licensee were reversed, would your position seem unreasonable? Inflexibility may be detrimental when the licensee has technologies you may wish to utilize.

- ✔ IP managers should **be cautious of simply imitating the open licensing procedures** of the software industry. Such licenses are not generic enough to cross fields of endeavor, and it is still unclear whether and to what extent biotechnology innovations in general will lend themselves to open source licensing.

- ✔ The **public sector must specify in writing exactly what it wants to accomplish with a commercial partner**, detailing when and how this will be achieved by specifying milestones—and related penalties should these milestones not be fulfilled.

- ✔ Avoid "best effort" clauses in agreements. Instead, make the extra effort to draft **comprehensive contracts with articulated milestones**. This up-front investment in time and effort will pay off if a problem arises. During the drafting and negotiation of agreements containing milestones, do not hesitate to involve people from other departments (including business schools), outside consultants, and experts in the relevant industries and markets.

- ✔ Developing meaningful **milestones that provide the appropriate balance of incentives, rewards, and penalties** requires detailed preparations, a sound understanding of the processes related to developing and marketing the product, realistic forecasting of product potential, persistence in quantitative forecasting and in putting together a master plan for the entire product rollout, and above all, a mission-driven mindset.

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.