Public sector IP management in the life sciences: reconciling practice and policy

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Public Sector IP Management in the Life Sciences: Reconciling Practice and Policy—Perspectives from WIPO

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ABSTRACT

This chapter reviews the options for effective public sector management of intellectual property (IP) in the life sciences, focusing on the need for a judicious, pragmatic choice of options along two axes: (1) deployment of exclusive rights over technology and (2) use of market mechanisms to bring a new technology to the public. The essence of public sector IP management is finding the right settings along these two axes that will deliver tangible outcomes in line with defined public-interest objectives. Experience shows that ex ante assumptions about how to gain optimal leverage from exclusive rights, and the appropriate degree of reliance on market mechanisms, are unlikely to serve a public sector IP manager well. In clarifying objectives and the practical means of achieving them, pragmatic coordination between the practical and policy levels is essential. Public sector IP managers are more likely to be assessed against public interest expectations than their private sector colleagues. In IP management in the life sciences, policy and practice are ultimately two sides of the same coin; practitioners cannot hope, expect, or plan to operate outside the broader policy perspective. Policy-makers therefore need to consider the actual practice of IP management when assessing a policy framework for innovation in the life sciences. IP managers should be open to using legal mechanisms flexibly for inclusion, or exclusion, as required to achieve their goals. Finally, managers should seek mechanisms to pragmatically structure and promote partnerships with those who have the resources necessary to bring life-sciences innovation to the public. Such partnerships may be centered in the public, philanthropic, or private sectors, but more likely fall into a hybrid mix of these categories.

1. OVERVIEW AND CONTEXT

1.1 *Toward policy-rich practice and practice-informed policy*

Researchers, technology managers, and intellectual property (IP) advisors who work in the life sciences and who use the IP system are not operating in a policy-neutral, strictly technical environment. An overarching public interest in life-sciences innovation means that the accumulated impact of many seemingly independent, individual choices will in fact have implications for how the IP system is perceived by policy-makers and will therefore help to determine policy directions. The practical choices made when managing IP rights therefore ultimately influence public policy debate. Indeed, given public expectations for life-sciences innovation, choices over when and how to exercise IP rights are inevitably assessed from a policy point of view.

Practitioners need to be sensitive to the policy environment and alert to the debates that swirl around two related aspects of public concerns: (1) the impact of life-sciences developments in themselves and (2) the impact when intellectual property is applied to life-sciences innovation. While this may frustrate legally trained practitioners, how the IP system is used, and the perceived equities of access to the benefits of a life-sciences

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technology, can affect public perceptions of the legitimacy of that technology. Juma and Konde write:

Resistance to new technologies is likely to be reduced by changing perceptions of access to the new technologies as well as to their markets. This has not been the case with agricultural biotechnology, which involves worldwide exports with the potential for product displacement, while leaving wide margins of uncertainty for technology followers.[1]

Moreover, the policy debate cannot operate in isolation from the practical realm. Policymakers need a robust, practical understanding of the technologies concerned, of the nature of life-sciences innovation, of the overall trends in the IP landscape, and of the real-world impact of the actual exercise of IP rights. Only then can policymakers effectively balance concerns about equity of access with the proper exercise of exclusive rights. Optimal policy choices require the widest range of distilled, neutral empirical information about the use of intellectual property in relation to key life-sciences technologies. Indeed, the experience of practitioners contributes valuable insights needed to guide and buttress policy debate over the future of life-sciences innovation.

1.2 *Resolving the paradox: public interest through private rights*

Reconciling the public policy role of the IP system with the management and exercise of private IP rights addresses the central paradox of IP policy: what legal exclusions from the public domain are required to promote the public interest? And how can those exclusive rights, once granted, be best deployed for IP law to function as a public policy tool? Life sciences concern the basic human needs of food, health, and a safe environment. How then can IP rights be best managed to promote public welfare by making available the fruits of life-sciences innovation and spurring economic development? These benefits arise not from the mere presence of a formal system of assessing, granting, and enforcing IP rights, but from the judicious, skillful application of these legal mechanisms in practice. Positive welfare gains from IP mechanisms emerge from an accumulation of individual choices, not just from the abstract process of shaping a legislative framework This is most directly illustrated by the experience of managing rights held by public sector institutions, which can be held more immediately responsible than their private sector counterparts for securing tangible benefit gains directly from public investment in research and development. Thus, we see the emergence of public sector IP management as a distinct subset within the broader discipline of IP management. For instance, pharmaceutical public-private partnerships "*must be as aggressive in the way they use IP as any commercial unit, but for a different purpose—namely to pursue their social objective of getting quality, affordable products to developing country patients.*"[2]

The optimal implementation of IP rights requires a practical understanding of the full range of options for exercising exclusive rights and a capacity to assess and implement those options as part of a broader strategy. IP rights are exclusive in their formal legal character, but the modes of exercising such rights are highly diverse and will correspond to an institution's broader objectives. A predetermined license template, for example, will not lead to best practice in IP management in the life sciences, because its use may effectively foreclose the full range of choices available and preempt the objective assessment of the implications of each option. A good manager will instead judiciously use IP mechanisms to leverage the resources needed and obtain the freedom to operate, while prudently assessing the likely impact of various forms of IP rights exploitation.

Workable public sector–management models do not normally entail an exclusive reliance on release into the public domain nor on wholly exclusive licensing. While it is rare to see a life-sciences product delivered without some engagement of private sector actors responding to market signals, it is usually misleading to set the full product development pipeline wholly in the public or private sectors. Given especially the necessarily stringent regulatory environment confronting the life sciences and the need to garner resources for the full product development process, investments will likely draw on both public and private resources. Therefore, rather than employing simple public/

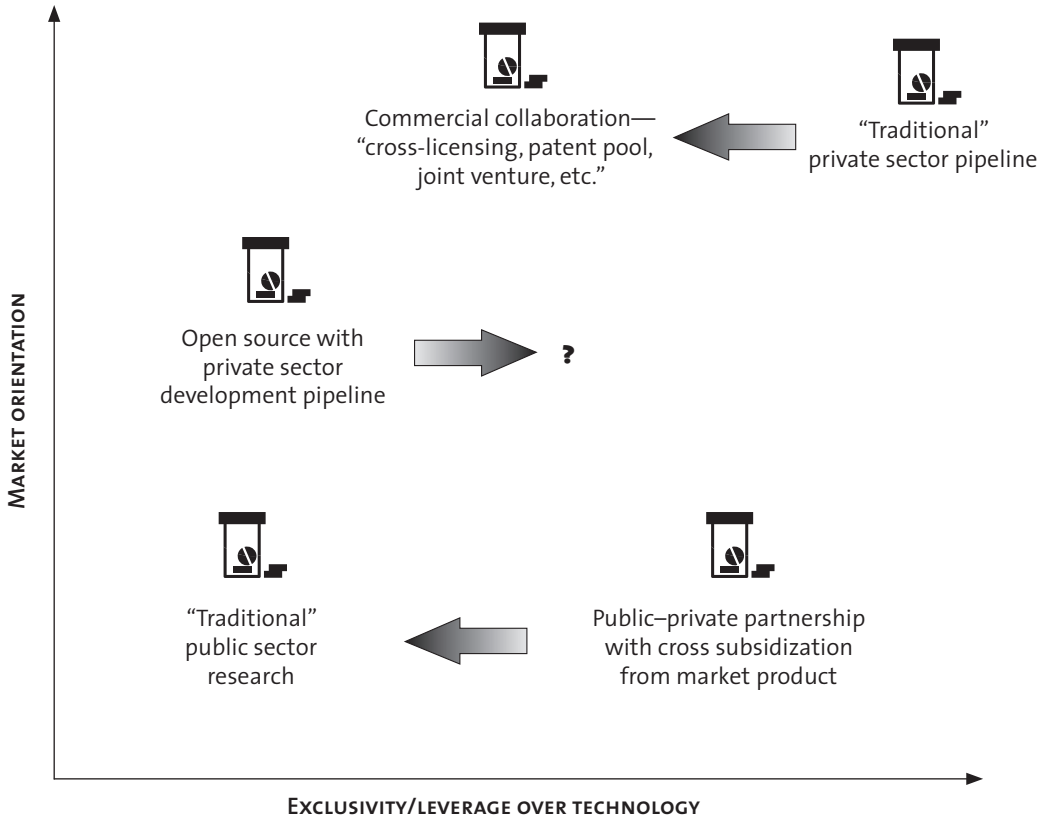
private or open/exclusive labels, the full range of options available to public sector IP managers can be more usefully analyzed along two continuums: (1) degree of exclusivity, ranging from defensive publishing in the public domain through open source or commons-based constructs, and nonexclusive and exclusive licensing, to direct exploitation of exclusive rights; and (2) degree of market engagement, from pure research, through making some use of private resources in the development pipeline, to various modes of outsourcing product development and the dissemination of a proven life-sciences technology, including spinoffs and transfer of rights to private firms. *Even if* a public sector IP manager's core responsibility is to deliver welfare gains to the public in the form of accessible new life-sciences technologies, she or he is likely to have to assess the full range of options across these two spectra when formulating a practical strategy. These options are presented schematically in Figure 1 (which is also further discussed in section 4.2 below).

1.3 *The meaning of global intellectual property*

Participation in the international patent system continues to grow and diversify in three overlapping ways, each with direct ramifications for the field of public sector IP management:

1. Greater geographical and cultural diversity. Membership in the Patent Cooperation Treaty (PCT) has shifted from an early

Figure 1: Public Interest IP Management Goes Beyond Licensing Arrangements



Source: A Taubman[3]

preponderance of developed and transitional economies to a clear majority of developing countries. In terms of the actual use of the system, patent applicants from the developed world continue to predominate, but current trends reveal double-digit growth, sustained over five years or more, on the part of certain key developing countries. This trend, if sustained in the medium term, would significantly shift the center of international patent activity. PCT international applications received from developing countries in 2005 rose 24.8% compared to 2004, and constituted 6.9% of all filings. China, Mexico, and the Republic of Korea are among those countries registering double-digit percentage increases in use of the PCT.[3] (Figure 2)

2. Greater use of the system by public sector and not-for-profit entities. In the life-sciences domain, these are as diverse as India's Council of Scientific and Industrial Research, Empresa Brasileria de Pesquisa Agropecuaria (Embrapa), the Korea Research Institute of Bioscience and Biotechnology, the International Aids Vaccine Initiative, the Medicines for Malaria Venture, and CAMBIA.
3. Growth in use of the system in life-sciences technologies stronger than the general trend. For instance, PCT publications in the technical field represented by IPC Class A61K (Preparations for Medical, Dental, or Toilet Purposes) rose 5.1% in 2005. In the next highest field (G06F—Electric Digital Data Processing) the growth rate was 4.6%.[4]

Public sector users of the patent system who are working in the life sciences face practical questions about how to manage a patent estate to advance their institutional objectives. While this has been the subject of a longstanding debate in the developed world, it is increasingly a practical issue for developing countries as well. The rate of public sector patenting in life-sciences research in developing countries is growing exponentially. These countries are, of course, starting from a small base, so the actual impact will be felt over time as international activity translates into distinct national rights. It is certain, however, that government agencies and other public sector institutions in developing countries will be increasingly responsible for managing a growing stock of life-sciences intellectual property resulting from investment of public resources, or from combined private and public sector inputs. These governments will assume the task in light of their overarching responsibility to promote the public interest through the management of this intellectual property. Doing so entails working on a broader canvas than the mainstream management of intellectual property the essential focus of which is to promote commercial outcomes.

Such social or institutional responsibilities require that public sector IP managers develop and apply practical skills to manage intellectual property effectively. They may need to look beyond conventional, private sector methodologies to find appropriate ways of managing intellectual property to ensure the desired public interest outcomes. These might include ensuring the development and effective dissemination of new technologies to the public (for example, new pharmaceuticals), promoting economic and social development, creating skilled jobs, or enhancing urgent research funding.

Effectively managing public interest IP is a task that requires judgment and acute sensitivity, acutely so in life-sciences domains. It requires advanced skills. There is a wide spectrum of possible approaches, and there are many distinct objectives that may be pursued. IP management to produce public health outcomes is particularly demanding, yet vitally important for the public interest.

1.4 *Choices for public sector IP management*

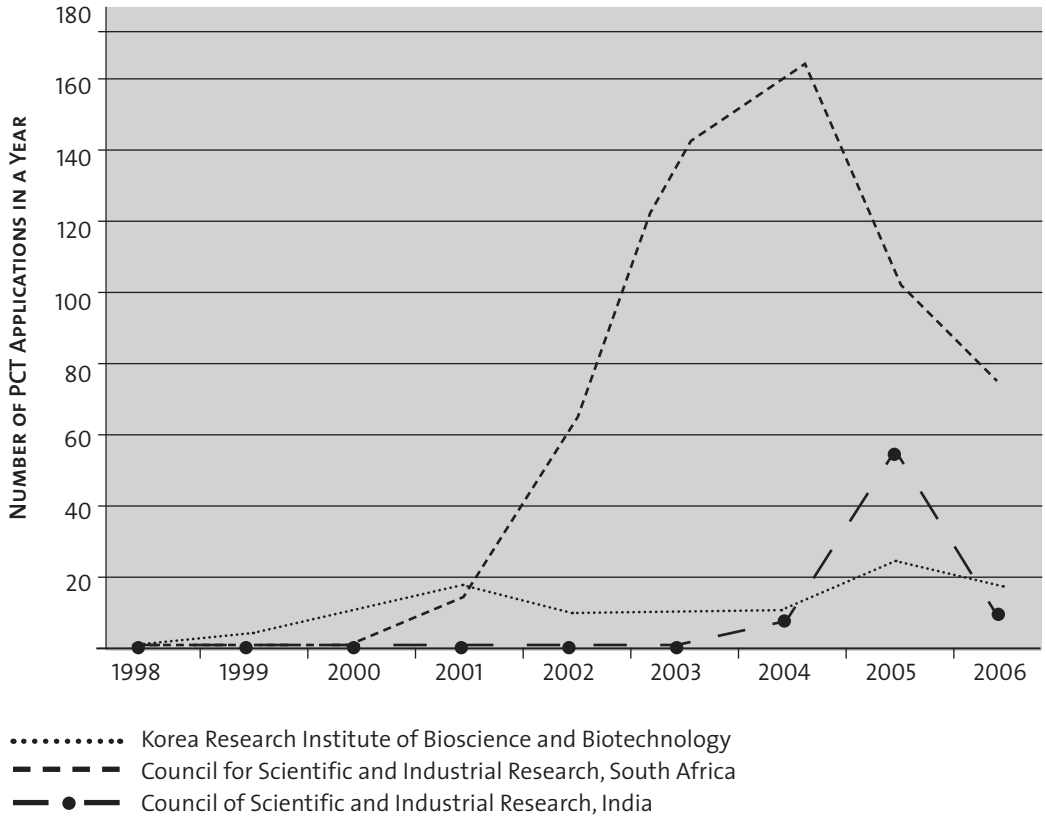
While often debated in abstract terms, the impact of IP laws and IP rights is ultimately determined by a series of practical, yet critical, choices. For the public sector, these choices are increasingly guided by IP management policies. Tom Ogada has categorized these choices in terms of:

- Who owns the intellectual property generated by government-funded research activities?

- How will revenues/benefits from the commercialization of intellectual property be shared between the researcher/inventors, the department, the institution, and government funding providers?
- Which, if any, government rights/stipulations are attached to the commercialization of intellectual property generated under government-funded research?
- In the case of privately funded research, who will own any resulting intellectual property?
- Will spinout companies or licensing contracts be used to transfer technology to the private sector for commercialization?
- Who will manage IP assets, including the negotiation of licenses and royalty sharing?
- To what extent will the institution encourage research commercialization through entrepreneurial activity?
- How will the costs of IP protection and maintenance be paid?
- How should any invention disclosure procedure be managed?
- How will conflicts of interest between teaching/research duties and commercially driven projects be handled?

To assist public sector IP managers and policy-makers in making these decisions, Ogada has authored *Guidelines on Developing Intellectual Property Policy for Universities and R&D Institutions in African Countries*.[5] Other relevant

Figure 2: PCT Applications of Select Research Centers in India, the Republic of Korea and South Africa



Source: PCT Patent Statistics, 2006.

World Intellectual Property Organization (WIPO) resources include:

- *Successful Technology Licensing*. This booklet, written for use by business managers, technology managers, and scientists who deal with licensing questions, aims to help its readers negotiate win-win licensing agreements, in which all parties receive and exchange approximately equal benefits and value.
- *Exchanging Value—Negotiating Technology Licensing Agreements: A Training Manual*. This text focuses on the practical business needs and concerns of nonspecialists who have to deal with licensing in or licensing out of technology. The manual includes an outline for a program schedule and practical guidelines for creating and managing teams/groups for conducting mock negotiations. (These are from a five-day practical workshop on negotiating technology licenses, including a case study on tuberculosis vaccines.)
- *Advanced Distance Learning Course on Biotechnology and Intellectual Property*. This addresses aspects of patenting biotechnological inventions and the plant breeder's rights systems, as well as IP in research and development, and the management and practical use of IP rights.

2. BIOMEDICAL INNOVATION AND DEVELOPMENT

2.1 *Capturing the benefits of indigenous innovation*

Concentrating on technology transfer as a key innovation strategy, mainstream discourse on innovation and development tends to cast developing countries as recipients of technology produced elsewhere. While access to foreign technology is clearly integral to development, it is increasingly important to focus directly on capturing the indigenous innovation potential of developing countries.[6] Given that developing countries hold significant traditional knowledge and genetic resources, this arguably applies in the life sciences more than in any other field. At least one of the lessons of the biopiracy debate is the need to ensure that custodian countries derive social and economic benefits from these vital feedstocks for life-science research. Accordingly, delivering on the promise of life-sciences innovation requires outcomes tailored to the circumstances of individual countries. This means democratizing innovation to address neglected diseases that disproportionately afflict the developing world, or to respond to the agronomic, environmental, and nutritional context of developing country agriculture.

Many developing countries possess the human capital necessary for life-sciences innovation, and they seek the practical pathways to realize this potential, not only from the point of view of economic development, but also from the broader perspective of public welfare. For instance, local health practitioners have extensive practical experience in traditional knowledge systems, as heirs of generations of "clinical trials." In dealing with endemic diseases, the knowledge reserves of the health practitioners need to be drawn on more systematically as part of a sustainable, bottom-up approach to development. The recent launch of the South African Indigenous Knowledge Systems (Box 1) places traditional knowledge policy squarely in the context of innovation policy and the equitable sharing of benefits.

2.2 *Innovation and intellectual property—the practical context*

Debate continues over the overall role and impact of IP protection in relation to meeting the twin goals of fostering innovation and promoting the effective dissemination of the fruits of innovation.[8] Adopting the approach of this *Handbook*, this chapter does not enter into the debate beyond pointing out that the policy context is a highly dynamic one, greatly influenced by feedback from the actual and perceived impact of the accumulated choices of IP managers. It is clear that the effectiveness of the patent system for attaining these objectives depends on its practical context, which can be addressed on three levels:

1. the regulatory and administrative level (discussed in more detail below)
2. the level of skills and capacity (As a complex policy mechanism, the patent system requires skilled operators.)

3. the level of individual users of the system: applicants, opponents, licensees, advisors, and advocates, with a special focus here on public interest users

At the regulatory and administrative level, the key elements of a practically effective system include:

- patent quality, construed here as the greatest possible convergence between actual patenting outcomes and the public interest as delineated in the principles of patent law, especially the conventional criteria for patentability
- the transparency, clarity, and predictability that effective administration provides in terms of the practical accessibility of timely patent information, the clarity of scope and title, and functional patent quality
- practical equity of access to the system, so that the skew of accessibility that favors already dominant private sector players can be reduced
- persuasive deterrents and remedies against the misuse of patent rights once granted

2.3 *System functionality and the capacity to make the system function*

In sum, much of the public welfare impact of the system and actual delivery of equity depend on system functionality—not merely on the formal legal settings that form the focus of international debate. Effective functionality depends on deploying three special skill sets:

1. The legal and policy skills required to draft and implement suitable legislation and policy mechanisms within the framework of international standards but also tailored to national needs and priorities
2. The technological know-how and legal skills required to draft patent documentation and to objectively assess the validity and legitimate scope of patents in patent examination and judicial processes
3. Technological management skills, including valuation of disclosed innovations in light of institutional goals (not just in terms of commercial value), assessment of potential technology development and dissemination pathways, and the formulation of patenting and licensing strategies

As a rough generalization, capacity-building processes in developing countries have tended to focus on each of these skill sets in turn, beginning with a top-down legislative perspective. This has been most conspicuous in the decade of the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This sequence of shifting priorities for capacity building reflects a natural evolution from a legalistic view of implementation and a reactive, or defensive, posture followed by a greater concentration on building administrative and institutional capacity,

Box 1: Traditional Knowledge and Innovation in South Africa

South Africa's Indigenous Knowledge Systems (IKS) Policy aims at "*positive synergy between South African IKS and the South African National System of Innovation*" through:

- the creation of a legal benefit-sharing framework
- the establishment of a formal recording system for IK
- legislation to ensure minimum standards in information and material transfer agreements with respect to IK research
- the promotion of IK links with the science base by means of targeted funding instruments
- amendments to patent legislation to enforce IK prior art declaration

Source: WIPO.[7]

to the current growing emphasis on strategies that practically and proactively capture direct benefits from indigenous research capacity and comparative advantage in knowledge resources. This *Handbook* is emblematic of the culmination of this last trend. But capacity building must continue on these three tracks in parallel, mutually informing and reinforcing one another, especially in the life sciences. In particular, the practical view from the bottom up should inform the view from the top down in a respectful dialogue between policy-conscious practitioner and practically informed policy-maker.

2.4 *The policy impact of effective users*

Clearly, it is the central role and responsibility of administrators to promote the effective and efficient functioning of the system as a system. But users are not just customers of the system; they function as active agents engaged in safeguarding patent quality: "users" have responsibilities as patent applicants, as patent opponents, as litigants, and as licensors or licensees. Adversarial legal processes have shaped much of the important detail of patent law. The costs and limitations of the existing administrative and legal systems have led to calls to more systematically include a user perspective on patenting outcomes.[9] The growth in life-sciences patent filings by government agencies and public sector institutions may lead to further blurring of the boundaries between administration and knowledge management within public sector agencies and to the implementation of a broader, more holistic array of innovation policy settings. Ideally, the responsibility to efficiently manage IP portfolios will be understood in relation to the broader responsibility to contribute to public policy outcomes. This extra layer of operational and ethical complexity creates a distinct challenge for the public sector IP manager. Managers of private sector IP portfolios in the life sciences may need to consider ethical and social constraints, such as professional ethics and corporate social responsibility programs, but this chapter concentrates on the public sector manager.

2.5 *The public sector IP manager as a system user*

Since the informed, judicious management of life-sciences IP is the most realistic way of boosting actual availability of vital life-sciences technologies, the public sector IP manager has fundamentally important responsibilities. IP management is a practical craft, not a rigid legal discipline, difficult to capture in terms of checklists and licensing templates. This section reviews best practice for public sector IP managers in life-sciences technologies. The discussion focuses on two broad categories of responsibility: policy-oriented, or systemic, and outcome-oriented, or practical. Experience has shown that early assumptions about the right mix of exclusivity or openness of access, and the right proportion of a reliance on public resources and an engagement of private interests, are unlikely to be effective or even defensibly fair. Public sector research programs that routinely consign publicly funded research to the public domain can attract just as much criticism as those programs that seek excessive exclusivity in the management of public-funded intellectual property. Inattentively letting research outcomes fall into the public domain can allow richer and more nimble private interests to benefit disproportionately from access to this publicly funded knowledge. Public sector IP management must therefore be viewed with a strong pragmatic, empirical perspective. Accordingly, an outcome-oriented approach to public interest IP management includes:

- promoting an in-house invention disclosure under effective confidentiality rules
- analysis of disclosures in the light of institutional objectives
- assessment of technologies against priorities, categorizing them for public domain release or defensive publication, for open licensing, for nonexclusive licensing, or for a strategic in-house focus
- review of the obstacles to the effective use and dissemination of the new technology, including resource limitations, regulatory obstacles, and constraints on freedom to operate in target markets, noting that developing countries generally have greater freedom to operate due to the relatively low levels of patenting
- formulation of strategies, and identification of potential partnerships, that aim to

bring a life-sciences innovation to targeted groups, which entails considering commercial, technological, and regulatory issues, as well as an assessment of external requirements that include background intellectual property, project management capacity, technological and manufacturing capacity, regulatory process capacity, and investment capital
- leveraging intellectual property holdings to:
  - promote the dissemination of technological knowledge
  - ensure the availability of improvements, further applications, and derivatives of licensed technology
  - secure access to regulatory data and background/platform technology
  - reserve rights for third-party use in humanitarian applications
  - reserve exclusively licensed rights in the event that licensees fail to meet public interest performance criteria (such as low-cost or cross-subsidized distribution to target markets)
  - safeguard grant-back of background intellectual property, project intellectual property, or regulatory dossiers in the event that licensees fail to meet public interest performance criteria
  - bolster institutional research capacity, through licensing fees, partnerships, access to research tools and other platform technologies

In the hands of the public sector IP manager, an IP portfolio is not necessarily viewed purely as a commercial asset, although commercial valuation and product development and dissemination will normally be essential. An IP portfolio also functions as:
- a transactional asset, used to promote, expedite, and clarify the formation of technology partnerships, and to define and structure specific contributions and expectations in partnerships
- an institutional asset, used to leverage access to necessary resources to achieve institutional goals, ranging from specific R&D expertise to research financing
- a policy asset, used to influence choices of technology partners, including private sector partners in public–private partnerships, and to promote humanitarian or cross-subsidized access to life-science technologies in developing countries or in other beneficiary groups

The public sector IP manager in the life sciences may also need to consider the public-policy expectations placed upon her or him, explicitly, implicitly, or even retrospectively. She or he should, in particular, consider the following policy-oriented or systemic responsibilities:
- influencing positive innovation patterns, promoting the effective collaboration and open dissemination of upstream research findings, both for the inherent value of the knowledge as a public good and as a means of promoting the widest possible application of upstream biotechnologies, such as research tools, diagnostic tools, and genetic modification technologies
- promoting analysis, adaptation, and uptake of practical-innovation structures that make effective use of diverse resources, such as strategic partnerships with other public institutions, public–private partnerships, and open collaborative mechanisms
- good-faith participation in the patenting process, focusing on strategic and systemic outcomes, rather than on the tactical use of the system, and actively promoting patent quality
- fostering an interdisciplinary approach to public policy formulation in the life sciences and a comprehensive view of the innovation process within the broader policy context
- promoting open licensing models for research or for humanitarian uses in public health and agricultural development programs for the benefit of developing countries

Exemplifying the crossover between policy and practice is the humanitarian licensing of

medical and agricultural research generated by universities or other public research institutions. "Humanitarian licensing" describes a range of public policy licensing strategies. These might include providing an open license to developing country technology users to sell derivative products back to commercial markets, as in the case of agricultural biotechnology. Humanitarian licensing might also mean establishing reach-through rights reserving access to derivative innovations (for example, for use in licensing early-stage pharmaceutical research). These practices may be seen as a movement to promote certain technology licensing norms, even to create de facto exceptions to patent rights in the life sciences. They might also be imagined as a suite of practical options for public sector technology managers to deploy in pursuit of institutional objectives. But the movement towards humanitarian licensing or reserving rights for humanitarian use still begs important questions at the core of public sector IP management:

- How does the deployment of exclusive rights over life-science technologies promote the public welfare, and when is deployment of exclusivity contrary to humanitarian goals (the exclusivity axis)?
- To what extent, and how, should public sector IP managers engage private interest and private sector resources to draw technologies through a demanding product development process, and when will humanitarian interest be enough to impel a product through the product pipeline (the market axis)?

See Box 2 for a recent exchange that highlights the broader range of options open to public interest IP managers who have objectives that extend beyond the simple commercialization of research.

3. PUBLIC POLICY IP MANAGEMENT IN THE LIFE SCIENCES

IP management is not an end in itself, but an essential part of a wider array of policy tools that need coordinated implementation to achieve desired outcomes. The efficiency and effectiveness of IP management needs to be measured against broader objectives, including its ability to complement innovation policy and public investment in R&D infrastructure. Optimal use of intellectual property in the life sciences requires a well-managed IP system, clear policies about the ownership of intellectual property generated by the public sector or from public sector inputs, adequate R&D resources and infrastructure, technology transfer centers at universities and other research institutes, and mechanisms to bring research outcomes to the market. We focus on three elements in particular:

1. Setting the regulatory and policy framework
2. Building functioning public institutions
3. Managing public–private partnerships

3.1 *The examples of Jordan and Indonesia*

3.1.1 *Overview*

This section reviews information gathered in field interviews with practitioners in biomedical innovation in two disparate developing countries: Jordan and Indonesia. Despite fundamental differences in size, structure, resources, and geopolitical context, Indonesia and Jordan have both set up IP strategies to promote the social benefits of domestic biomedical innovation. The countries have sought the right institutional framework to link IP policy and IP management for the advance of public welfare. Indonesia is the fourth most populous country in the world and, after Brazil, is host to the greatest range of biodiversity worldwide. Jordan, with four million inhabitants, is a relatively small country with little biodiversity, few natural resources, and no oil reserves. Both countries have strong potential for biomedical innovation. Indonesia's opportunities are linked to the natural medicines market. Jordan's pharmaceutical industry is the country's second largest export earner, after textiles.

Jordan's pharmaceutical industry is making a structural shift from focusing solely on generic manufacturing to promoting biomedical innovation. Six out of 12 Jordanian pharmaceutical

Box 2: Alternatives to Commercialization in Public Sector IP Management: Four Points of View

According to Tom Ogada, who is responsible for putting in place a formal policy for dealing with IP issues at Moi University, "*an institutional IP policy serves to promote the generation, protection, and commercialization of IP rights. Universities and R&D institutions are key generators of IP assets, but there are many stakeholders involved in the process—researchers, students, private sponsors, technology transfer units, national patent offices, the public, and so on. An IP policy is needed to harmonize the conflicting interests of the various stakeholders.*" Thus, a university's IP policy should aim to "*create an environment that encourages and expedites the dissemination of new knowledge for the greatest public benefit, while protecting the traditional rights of scholars to control the products of their scholarly work. It should ensure that the financial or other benefits of commercialization are distributed in a fair and equitable manner that recognizes the contributions of the inventors and the institution as well as other stakeholders. It should promote, preserve, encourage, and aid scientific investigation and research. It should sensitize students to IP and tap the creativity of the young. It should create incentives for researchers to conduct research and provide rewards for intellectual capital. In developing country universities, it should also stimulate research efforts to find solutions for pressing problems, such as medicines, clean water, and energy.*"

Dana Bostrom, Industry Alliances Office, University of California, Berkeley, adds that "*most university technology transfer offices do not have a primary goal of revenue generation. Professor Ogada captures the goals of technology transfer well, including: promoting the dissemination of knowledge, and assuring stakeholders that risks, benefits and credit are distributed equitably. The Association of University Technology Managers (AUTM) does not tend to use revenue generation as an indicator of benefit. Rather, [AUTM] uses information about how the university distributes revenue received under licenses to benefit the university community; how products which are brought to market benefit everyone; and how innovative, university-led licensing programs can push an industry or technology forward (among other measures). A blanket give-it-away approach, on the other hand, usually benefits large companies, who are able to create and patent improvements to the "free" intellectual property more rapidly than other organizations or individuals. For developing economies, or early-stage technology of all kinds, "free" can come with a heavy cost. Although free intellectual property can still achieve the best outcomes for everyone, this strategy is best determined on a case-by-case basis. Without resources to sustain a free commons, often only those with resources can benefit from what was released. More than* 500 *new products became available last year as a result of licenses from U.S. and Canadian academic technology transfer efforts. More intangibly, universities benefit from the interaction with companies, to see how academic thinking and solutions can be applied to commercial problems. Ironically, universities also benefit from our academic community's greater awareness of intellectual property; we live in a world where intellectual property plays a greater role, and companies, in their interactions with universities, demand greater accountability. Ultimately, universities are increasingly being asked to demonstrate to their community the benefit they provide in the knowledge economy.*"

Gavin Moodie, Principal Policy Advisor at Griffith University, Australia, notes that "*the fundamental question for a public university's IP policy should not be: 'How can the commercial potential of the property be maximized?' but 'How can the transfer of new ideas be maximized?' Commercializing intellectual property is only one way—and often the worst way—to transfer new ideas. Concentrating on commercializing intellectual property encourages universities to overvalue their property, leading to protracted negotiations using lawyers and other intermediaries, which frustrates rather than facilitates the free flow of ideas necessary for research and innovation to flourish. Revenue from licensing intellectual property in fields other than biotechnology is a trivial*

(Continued on Next Page)

Box 2 (continued)

proportion of university revenue. And, of course, licensing revenue isn't all surplus or "profit"—with their business development managers, IP lawyers, and accountants, commercialization units are very expensive. They also impose heavy indirect costs on researchers who must explain their research and its implications to intermediaries. Joshua B. Powers reported in The Chronicle of Higher Education (September 22, 2006) that more than half of U.S. universities consistently lose money on technology transfer. And as the Australian policy and management consultant John Howard observes, researchers and research organizations will, except in very rare situations, earn more from being paid for their work input in contracts and consultancies than from licenses and royalties flowing from intellectual property or from income earned in spinout companies. I therefore suggest that—with the exception of biotechnology—public universities simply give away most intellectual property as a contribution to the general good. This could be subject to universities including in their IP licensing agreements a standard "blockbuster" or "jackpot" clause that provides that should their intellectual property contribute to blockbuster revenues of, say, $50 million over 10 years, there would be a sharing of revenue determined by a nominated commercial arbitrator."

Bernardo Marcos Diez, Secretariat for Technology Transfer (New Technologies Research Group), Faculty of Law, Universidad Nacional de Mar del Plata, Argentina, advised that the Governing Council of the University had "*recently approved a regulation which defines the scope, players, and procedures regarding the protection of any intellectual creation resulting from scientific or cultural research carried out within the university and/or with third parties. We have adopted an active IP awareness policy to reach those involved in this process, from the researchers, teaching staff, and students, to members of the decision-making bodies. We are running conferences in the different academic units in order to explain the objectives, implications, and advantages of IP protection, as well as of technology transfer between the university and external social/commercial milieu. We have also applied to join the WIPO University Initiative in order to appoint a coordinator and benefit from relevant IP reference materials. So we are in the early phase of what will be a lengthy process, but one which, it is already clear, will bring economic, scientific and developmental benefits, not only to our university, but also to our broader society.*"

Source: WIPO Magazine.[10]

companies have now developed patent portfolios, several of which are potential blockbusters (remarkably, until recently most of these companies made no use at all of the patent system). Indonesia is taking several measures to bolster its overall innovation strategy. It is, for instance, promoting awareness among public research institutions and the private sector of the opportunities in the natural medicines market. This market offers annual growth rates as high as 20%.

These countries are steadily increasing their IP holdings on indigenous research activities, particularly in the critical areas of the life sciences: medical and agricultural research. As they do, broad public interest issues arise. How can or should private firms be encouraged to manage their IP holdings to contribute optimally to national social and economic development? Additionally, how can public sector or public-funded IP estates be best managed to safeguard the public interest by capturing and equitably distributing the benefits of innovation? Finally, what broader institutional settings are needed to bolster public welfare outcomes from research? A public interest IP management perspective can help technology transfer centers at public research institutions find answers to these questions. Additionally, effective IP management encourages public–private partnerships that address humanitarian goals, in particular, the creation of affordable new medicines.

The experiences of both Indonesia and Jordan illustrate the broader need for appropriate domestic institutional settings in order for the countries to be able to reap the benefits of biomedical innovation. Their experiences of Indonesia and Jordan also reveal the importance of the interplay between investment in institutional infrastructure and the more diverse and tailored approaches to managing intellectual property within a public interest paradigm. The discipline of IP management has focused on the needs of firms. However, the high level of public concern with capturing public benefits from life-sciences research underscores that countries, and public sector institutions, also need to make strategic decisions about the deployment of intellectual property on a broader base than the traditional focus of private firms.

3.1.2 *Setting the regulatory framework*

IP law and practice cannot be viewed in isolation from the broader regulatory context. This is especially true in the field of life sciences, which is concerned with needs as basic as health, food, and the environment. Public interest IP management in biomedical innovation therefore needs to reconcile public health needs with commercial goals, ideally helping to harness private sector resources to achieve public welfare outcomes.

Indonesia and Jordan have effective IP legislation in place, and both have undertaken extensive legislative programs to bring their laws into compliance with the TRIPS Agreement. Indonesia also adhered to the PCT in 1997, and Jordan has entered a bilateral trade agreement with the United States, which has implications for Jordan's IP laws. In both countries, IP policy has been developed in an interdisciplinary way, as part of a broader public policy mix, rather than as a narrow, specialized discipline. Jordan's Ministry of Planning is responsible for coordinating public policies regarding innovation, and for measuring Jordan's global competitiveness in achieving this goal. Jordan's main innovation policy, King Abdullah II's Vision 2020, proposes the strategic use of IP mechanisms to achieve society's goals. Likewise, Indonesia coordinates intellectual property across policy portfolios, in cooperation with the Ministry of Research and the Directorate General of Intellectual Property, which screens research grants given to public research institutions and conducts patent searches, supplementing the conventional literature review. Indonesia also provides funding to patent applicants to make patent protection more affordable to local companies and public research institutions, which is one way to address the issue of practical equity in access to the IP system.

Jordan is reviewing possible legislative initiatives regarding the management of intellectual property generated in public institutions. Indonesia has passed laws that give ownership over intellectual property generated within public research institutions to the institutions

themselves. This regulatory measure has been accompanied by the establishment of technology transfer offices (TTOs). Ten TTOs were created throughout the country with modest start-up capital. The offices have confounded some expectations by establishing successful business operations in recent years. The Technology Institute of Bandung, for example, has struck international licensing agreements and research collaborations with local companies that are actively seeking to meet local needs. One public-private partnership resulted in the development of a new machine for harvesting local agricultural crops.

3.1.3 *Building accountable and effective public institutions*

The benefits of the regulatory framework will depend on establishing public institutions that are both accountable to the public and effective in serving it. These obligations go beyond the traditional institutional objectives of IP offices concerning administration of the patent system. Their responsibilities broaden into a wider policy role in the knowledge economy. IP mechanisms are actively harnessed to promote the overarching public interest. In both Indonesia and Jordan, the IP office reports to the ministries responsible for commerce and industry. This helps align IP policy with the countries' overall economic and trade policy objectives. As in all countries, there are important choices to be made between the value of administrative independence, self-sufficiency and direct accountability to political masters, and the benefits of linkages to a major policy ministry that can encourage high-level political attention to IP policy-making. In both Jordan and Indonesia, the IP offices focus on the operational challenges of using limited resources to serve diverse stakeholders. The two offices differ in size: Indonesia currently deals with a higher patent filing rate (4,303 applications in 2005); it was reported that Jordan had 200. But Indonesia confronts a problem experienced in many developing countries–that of finding and retaining suitably qualified technical staff to deal with the increasingly complex field of life sciences, effective examination capacity being one important safeguard of patent quality.

3.2 *Managing public–private partnerships*

Life sciences R&D is often characterized by upstream, or basic, research conducted by public sector or academic researchers. Public sector institutions then depend on the private sector to take life-sciences innovations through the development pipeline to yield finished products. Thus, life-sciences innovation pathways are increasingly characterized by an array of public–private partnerships. Those conducting early research and those investing in the product development phase will naturally have different approaches to the relationship. But because life-sciences research has such a strong public interest element, close attention has been paid to how to manage intellectual property for specific public interest outcomes. Public sector research institutions are learning to pursue the option of leveraging their IP holdings to ensure adequate returns from public investment in research, whether those returns are conceived in terms of narrow financial benefits or broader social ones. And public sector IP managers are trying to ensure that promising innovations are not left on the shelf for want of practical mechanisms to garner the necessary resources—finance, expertise, regulatory approval capacity, product development, and manufacturing know-how. TTOs, situated within universities, have also discovered the dual goal of helping to meet humanitarian needs and to mediating between academics and the market, which ultimately may determine a society's capacity to nurture innovation based growth.

The interaction between the public and the private sector in health innovation can result in philanthropic achievements that also satisfy business interests. Successful examples of this in the field of public health include the Medicines for Malaria Initiative, the Drugs for Neglected Disease Initiative, PATH, One World Health, and the Bill and Melinda Gates Foundation.

Publicly funded innovation provides an additional mission and incentive system for businesses. A tension is usually perceived to arise between research and development. Research is often guided by the search for new insights; market interests are generally of secondary relevance. In development, however, the market is

the defining element, since the substantial costs and risks associated with the development of new products and services can often only be justified by expected earnings.[11] Currently, research tends to be concentrated in the public sector, whereas development is most often left to business. The relationship between research and development is usually mediated by the protection and subsequent exchange of intellectual property between the public and private sectors. This means that it is crucial to establish equity and negotiating symmetry between these sectors, bridging between distinct sets of goals and cultural settings. By using the IP system, public research institutions avoid giving away valuable knowledge without maintaining some leverage over how it is developed and disseminated, and without securing an adequate return, whether that return is in the form of money or social return. In this way, intellectual property provides a mechanism to achieve equity with the private sector.

Motivating researchers to patent innovation judiciously is an essential part of participating in the IP system, and institutions need to raise awareness about the necessity and advantages of an active but selective patenting strategy. Incentive structures for academics often help to pave the way from the research lab to the TTO. One way to achieve this is to allow academics to generate additional revenues from consulting agreements, royalties, and licensing agreements. Clearly, this should not provide businesses the opportunity to dictate the research agenda of public research institutions, nor should it compromise the fundamental freedom of research. Institutional policies need to protect these values. Nevertheless, relaxing the institutional restrictions on the interaction between the public sector and business in health-related innovation might allow public research to generate new questions and find alternative approaches to a subject. Engagement in product development in health-related innovation has proven to be a valuable experience that enhances the quality of basic research. Faculty, for example, might develop innovative insights while resolving problems encountered in industrial consulting. Mansfield found that coauthorship by industry and academics increased the overall research productivity in health-related innovation, concluding that such activity can bring a new sense of urgency and reality to the public sector.[12] In Sweden, for example, 10% of articles on health-related innovation are coauthored by scientists working in the private sector.[13] Government funding for such exchanges can provide a useful push to such initiatives. Austria illustrates how such a program can operate. In Austria, academics have the opportunity to spend a year or two in a company and then return to their university. They are guaranteed their post and granted funding for the exchange.

To obtain the best outcomes for public health, researchers and institutions must understand the value of intellectual property, communicate the worth of their intellectual property to potential trading partners, negotiate attractive licensing agreements, and enter agreements that will generate appropriate returns. IP management comprises several components, including the prioritization and identification of research targets, decisions as to whether and which form of IP protection to seek, and methods to gain the attention of prospective investors/buyers of the product.

Technology transfer centers within public research institutions fill an important role in securing IP rights. They help researchers understand the need for intellectual property, give support in the application for IP protection, and help to transfer research results to the market. As in many other developing countries, the staff at these centers needs IP management training. In fact, a train-the-trainers program is often needed to enhance IP management competencies. An exchange with IP management centers in the developed world may, in this context, be beneficial.

To accomplish all of this, researchers and public institutions need to identify potential licensees, facilitate research collaboration, pool patents, and avoid unnecessary duplication. Other ways of encouraging public–private partnerships include commissioning research projects, operating joint research studies, financing doctoral studies with industrial laboratory funds (with due regard to the needs of the doctoral student to publish results), encouraging faculty consulting work,

and creating spinout companies. Establishing research clusters, in which public and private sector researchers and institutions work on common research projects, provides opportunities to exchange both tacit knowledge (know-how) and formal knowledge (such as publications and patents). Through the provision of a clear, transparent regulatory framework and publication of basic research, anticompetitive problems can be avoided.

From a health-equity point of view, the effectiveness of licensing agreements will depend on the conditions negotiated in these agreements and the overall innovation market. Licensing can lessen competition and raise anticompetition issues, even when there is no cumulative aspect. Exclusive licensing arrangements may hamper public health if the cost reduction of one market participant forces competitors to exit the market, or if the licensing agreement facilitates collusion.[14]

Indonesia and Jordan both report positive experiences with public–private partnerships in biomedical innovation. Indonesia has developed an excellent framework for public–private partnerships. The Indonesian Science Foundation (LIPI) may be taken as a best practice example of public interest IP management. LIPI provides IP courses for its researchers, has developed its own in-house IP policy, and manages an active technology transfer center that has already issued several licenses. LIPI has also entered into alliances with research institutions abroad, such as the Max Planck Institute, with whom jointly generated intellectual property is jointly owned.

Technology transfer centers in Indonesia are attached to research institutions, such as public universities or research organizations. These technology transfer centers use different names, such as Gugus HaKI (IP Units), Sentra HKI (IPR Centers), Klinik HKI (IPR Clinics), IPR Management Office, or IPR, and Licensing Office. With the exception of the Eijkman Institute, all major public research institutions dealing with biomedical innovation have their own technology transfer center. The extent of the activities carried out by these centers varies from the most advanced, which provide assistance on IP licensing agreements, to those that assist primarily with applying for IP protection or helping raise awareness about intellectual property among researchers. The statutes of Indonesia's technology transfer offices suggest very clearly that intellectual property held by public institutions should be licensed under a public interest paradigm.

In Jordan, there are several examples of faculty–private sector biomedical R&D collaborative projects, but the emphasis so far has been on research led by the private sector. Discussions reportedly continue regarding a suitable framework for the ownership of innovation created in the public domain. The Royal Scientific Society of Jordan has an applied, rather than a research, orientation.

Jordanian universities do not have TTOs to administer patent applications or negotiate licensing agreements. However, companies increasingly refer to universities as subcontractors for specific biomedical tests. So far, the universities provide skilled labor and conduct some basic research. These activities appear to promise more institutionalized partnerships and the beginning of a relationship between academia and the private sector.

4. CONCLUSIONS: RECONCILING POLICY AND PRACTICE

4.1 *Exclusivity or inclusion: public or private interest?*

The long history of patent law and patent policy has been a dynamic record of attempts to reconcile two complementary goals:

1. The promotion of innovation by directing resources toward beneficial research and development
2. The practical and equitable availability of the fruits of innovation

Public interest IP management in the life sciences is itself a search for practical means of achieving these twin goals. It seeks first to garner necessary resources and then to focus them on finding technological solutions to neglected needs in the public health and agricultural domains. The tangible and intangible resources required for IP development include know-how, research, and product

development capacity, clinical or field trial expertise, regulatory infrastructure, background/platform technologies, and the investment of public and private capital. IP management strategies will be effective if they help to apply these resources toward unmet needs. This requires finding these resources via new private resources (such as incentives and market interventions) and via new public resources (additional funding and infrastructure development). IP managers must also work to better apply existing resources by leveraging access to technologies and by drawing on private sector development skills and R&D infrastructure, indigenous research and innovation capacity, and traditional medical knowledge.

It is tempting to argue that the traditional conception of two distinct public and private spheres in the life sciences is breaking down. But it is more accurate to characterize it as a form of evolution, a broadening of the scope of interaction, and the creation of a far-broader policy canvas that can accommodate more geographical, cultural, and economic diversity in the use of the patent system. Figure 1 (see section 1.2 above), as discussed earlier, illustrates the options for IP management in pharmaceutical product development. The figure illustrates how workable mechanisms for bringing new biomedical innovations to the public may require (1) a range of strategic choices to engage or eschew market mechanisms to various degrees in order to secure the necessary resources and freedom to operate, rather than electing a wholly "public" or "private" technology development and dissemination model, and (2) deployment of exclusive rights afforded by IP protection to greater or lesser degrees of exclusivity and openness, ranging from direct exclusive exploitation or exclusive licensing, through a range of options of decreasing exclusivity, to simple public-domain disclosure.

Though it may seem counterintuitive, some public sector technology-development strategies may require exceptional degrees of exclusivity. This may be useful, for example, when seeking access to a private sector compound library or when negotiating access to an existing regulatory dossier. In contrast, as the SNP consortium (single-nucleotide polymorphism) and the human genome project have demonstrated, private sector players may see commercial advantage in deploying nonexclusive IP management structures, particularly for technologies that are considered precompetitive. No single template is likely to be anything but an indicative guide or catalog of options. Ultimately, good practice is good policy: the same exclusive right may be viewed very differently if it is held by a private firm, by a public sector agency, or by a private charity. Equally, the exclusive right will be viewed very differently depending on how it is deployed in practice.[16]

4.2 *Fostering interdisciplinary IP policies*

Indonesia and Jordan provide complementary and contrasting examples of the role of judicious institutional settings in promoting investment in life-sciences research, tailored to the social and economic needs of developing countries. A country's capacity to set up an effective institutional framework for public-interest-minded intellectual property is the decisive factor. Used in an effective, informed and judicious manner, it creates a positive link between the exercise of exclusive commercial rights and a fairer distribution of the benefits of technological advancement, with strategies carefully tailored to a country's level of wealth or economic development. ■

DISCLAIMER

This chapter does not represent the views of WIPO, its Secretariat or its Member States, and is intended to provide only technical-level contributions to assist in the review of options for public sector IP management in the life sciences.

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