

Using the power of intellectual property to strengthen equitable access



Article by Anatole Krattiger

Over the last decade, many countries around the world revised their laws related to intellectual property (IP). These changes were driven by a true “explosion of IP legislation at the international level”¹: in the last 15 years ten new IP specific treaties were concluded², and nearly every international treaty today includes IP clauses.

Because of its feared impact on low- and middle-income countries, the most discussed treaty in the context of health research and development has been the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Whether or not and to what extent TRIPS will impact the pricing and availability of health products are certainly legitimate concerns. But access to health products and services depends on many factors. One key factor is the successful innovation of new technologies, either as new drugs, vaccines, or services, or as adaptations of existing products to the contexts and frameworks of low- and middle-income countries.

Indeed, innovation management is a complex endeavour. Government and institutional leaders need to address a wide range of issues, ranging from policy choices to implementation strategies. Some of the most important elements to consider in this context are:

1. Intellectual property is just one of several factors that determine innovation in health research and development (R&D).
2. When assessing the impact of legislative and policy choices, intellectual property must be considered in the context of other competencies:
 - a. Supportive R&D policy
 - b. National health programmes that sustain domestic markets, including distribution systems in both the public and private sectors
 - c. High-quality manufacturing standards for drugs and vaccines
 - d. Effective regulatory systems
 - e. Mechanisms to facilitating trade in health products and technologies
3. Mechanisms and best practices to harness the global IP regime in a manner that promotes both private and public interests, including the improvement of poor populations’ access to health products.

As a pre-requisite for countries to participate in the global marketplace and benefit from emerging technologies, strong institutional IP capabilities are needed. This should be coupled with careful consideration of the tremendous latitude provided by TRIPS in terms of national implementation. These should be coupled with national policies and practices that support the public sector’s endeavours to meet the needs of the poor. These need not be compulsory licensing that may bring advantages in the short term. Such approaches are unlikely to be effective in the medium- to long-term in enabling – let alone sustaining – collaborative efforts between the public and private sectors.

It is not argued here that the IP rights system is perfect. It is a compromise and an imperfect solution³. IP rights systems represent the search for balance between making all knowledge freely available within the *public domain* and granting *ownership* of valuable discoveries to the inventors. Historically, we have seen that this balance encourages investment – and reinvestment – in innovation, primarily by the private sector. Unfortunately, this innovation is too infrequently directed towards the needs of the poor. The failure is not in the IP rights system *per se*, but in part due to the fact that insufficient attention has been paid by the public sector to managing intellectual property. This lack of focused attention must be corrected.

Legislative frameworks

The IP legislative explosion mentioned above has unsurprisingly led to suspicions about IP rights, which are often viewed as controversial and complicated. Indeed, if one considers these numerous treaties from a purely legal perspective, one easily gets entangled in legalities requiring a cohort of lawyers (and, arguably, very deep pockets). Yet this view perhaps misses the point of what IP rights are all about. First and foremost, they are intended to encourage investments in innovation. Second, IP rights systems were created to regulate access to and sharing of the less familiar “intellectual” form of property. Put differently, IP systems today are meant to enable the orderly conduct of business in the realm of intellectual property. The purpose of statutory IP rights, the related contract laws, and the court systems is to enable predictable, transparent business dealings between and among institutions and individuals.

The changes in international IP legislative frameworks through treaties are rapidly changing national legislation. And these changes are profoundly affecting how health innovations reach the poor and how public and private research and development institutions pursue their work. IP rights are sometimes viewed as barriers to innovations in health and other areas. In some circumstances, they are. But this paper argues that overall it is not intellectual property, *per se*, that obstructs access, but rather *how* intellectual property is used and managed. What matters most is how creatively public sector institutions integrate IP considerations into their overall business models and approaches. Seen in this light, the legislative framework provides a solid foundation for a stable, predictable judiciary, which also allows the public sector to use a national IP system as a tool to achieve its goals. A stable IP system empowers the public sector to imagine, anticipate, and act.

The policy choices

Determining how institutions can adopt and adapt the advantages conferred by TRIPS and other legislative initiatives is crucial. For example, government policies are hugely important for establishing to what extent public sector institutions will practise IP management. In the United States, no other policy choice had a more significant impact than the Bayh-Dole Act and other legislative and policy decisions in the early 1980s. They created conditions that spurred investment in biotechnology R&D, leading to numerous health innovations. But above all, these policy choices greatly affected how universities and public sector research institutions manage intellectual property and their relationship with the private sector.

Although the circumstances of countries vary enormously, the following set of questions are nearly universally relevant: when should public sector R&D centres or universities seek patent protection for their inventions? What information related to research should they keep confidential, if any? Under what circumstances should the public sector grant access (in other words license) their intellectual property? And under what terms? And to whom? These questions do not have simple answers. This is largely because the answers will depend on the context in which they emerge. Even within the same institution, the answers may be diametrically opposed for different types of inventions. Given these complexities, what should be the government's role in the area of policy?

First of all, establishing an open, transparent government policy for the ownership of publicly funded research is an important foundation for building sound institutional IP management. Institutional leaders have little latitude when the underlying rules are opaque or not spelled out.

Second, the policy rationale for technology transfer in public sector institutions should not be based on anticipated revenue flows; instead, long-term national, social, and economic objectives should structure policy decisions – with public benefit as the key factor. Indeed, since government funds much research at national R&D and academic institutions, it has the prerogative to mandate certain conditions for the benefit of these institutions' public

In the United States, no other policy choice had a more significant impact than the Bayh-Dole Act and other legislative and policy decisions in the early 1980s

missions. Policy-makers have a lot of latitude when it comes to ensuring that investment in research is returned as a public benefit. They could certainly require, for example, that products developed and marketed commercially from publicly funded research have some provision for delivery to the poor.

Third, governments can also strengthen the courts and recognize their important role in balancing conflicting IP policies. Such efforts will provide useful guidance with regards to business, technology, and science planning and strategy. Not every dispute, however, should be resolved in court. For public research and product development in general, and for equitable access and meeting the needs of the poor in particular, governments have tremendous opportunities to promote policies that foster alternative dispute resolution procedures⁴. Such approaches are often preferable for settling differences between parties. Court action is often stymied because of cost, length of procedure, legal uncertainty, a decision-maker's lack of expertise, conflicts between confidentiality and publicity, the difficulty of seeking action in foreign jurisdictions, and the negative impact on existing business relationships. Arbitration is an attractive option for all of these reasons, and while it is a private mechanism, it is not altogether free from regulation by national laws. Governments and public institutions can help make arbitration or mediation procedures accessible and available by identifying and supporting neutral institutions that can provide cost-efficient, timely dispute resolution services. Such approaches would also take much of the negative public perception out of IP rights, especially from legal disputes that can deter increased private participation in meeting the needs of the poor.

Finally, it should be recognized that Product-Development Partnerships (PDPs) allow the private sector to invest and apply its expertise to address the needs of the poor. Many such PDPs are now driving the drug development pipeline in neglected disease R&D. A pioneering new institutional structure, PDPs will become increasingly prevalent in developing countries and contribute to the development of products in less viable markets. National governments have tremendous opportunities to promote policies and capacities that facilitate these innovative partnerships, especially in such areas as effective clinical trials and ethical review capacities, appropriate regulatory bodies for clinical research and product approval, and national and institutional IP policies that stimulate health and agricultural R&D.

Institutional strategies

Whatever the impact of TRIPS and of strengthened patent regimes, institutional IP management capacities will need to be strengthened so that the legislative and policy changes can

be adapted – and harnessed – to a nation’s advantage. In the increasingly interconnected global network of science and innovation better IP management at the institutional level enables earlier and easier access to indispensable emerging tools, technologies, and know-how.

Better IP management can be achieved through capacity-building efforts. And these can be sustained through sound national and institutional IP policies. Specific initiatives at the institutional level should include capabilities for negotiating contracts, streamlining statutory protection (copyright, patents, trademarks, and dealing with confidential information), patent searching and filing, freedom to operate reviews and strategy (a particular challenge for public sector institutions)⁵, technology valuation, and business strategy development. Governments should be cautious, however, not to develop policies that mandate public research institutions and universities to adopt a single approach. IP management is very context specific, and flexibility is a precondition for its creative and successful use.

Further, the increasingly ubiquitous PDP works by building on the comparative advantage of public and private sectors and managing that interface authoritatively. Any institution that wishes to participate needs, at a minimum, to be in a position to negotiate complex contracts, manage newly generated intellectual property, and respect third party intellectual property. This requires mastery of a range of specifics, from laboratory notebook policies to good practices in managing confidential information to name but two.

Since the mission of many public institutions is increasingly shifting from purely academic research to making a social and economic impact at the local and national level, IP management is an even stronger imperative. It is an integral part of a public sector’s toolbox that allows it to meet its entire mission more effectively to create hitherto unsuspected opportunities.

One such opportunity lies in the manner in which drug and vaccine development is changing shape in developed countries. The blockbuster-focused business model of multinational pharmaceutical companies is fundamentally being reshaped⁶. The drivers for this change are complex but due in part to emerging opportunities offered from novel technologies (diagnostics for personalized medicine, gene therapies, and so forth). As a result, a new range of mergers and acquisitions are taking place. In due course, an entirely new array of alliances will be created to further multinationals’ quest to create niche remedies that target much smaller populations than blockbusters did in the past. Conceptually, there is nothing that stands in the way for a multitude of developing country institutions, including public sector ones, to participate in this new business model and concurrently gain advantage in serving their own local national niche markets. But it will require some institutional changes.

Institutional culture and individual mindset

To harness the power of IP, management capacity and skills are fundamental. Such skills make it possible to get earlier access to emerging tools, technologies, and resources that can dramatically improve the health and welfare of their

citizens. For example, the private sector in India has taken quick advantage of TRIPS by a) channelling its resources into the research and development of drugs for diseases that dominate in developing countries and b) building IP management capacity well before the entry into force of TRIPS⁷. This dual approach provided many companies in India with substantial foreign investments and access to foreign markets. In fact, more drug approvals are being submitted to the US Food and Drug Administration (FDA) from India than from all other foreign companies combined. Similarly, effective IP management can also be made to benefit public research institutions. Without knowledge of sophisticated IP management techniques, however, such efforts to enter into effective public-private partnerships that can direct the power of industry to the needs of the poor will be stymied.

As previously mentioned, innovation in health relies on sophisticated, global IP rights systems and on science that is increasingly complex, specialized, and globalized. This complexity requires a more open system of knowledge sharing than previous research and development programmes, and many studies suggest that successful innovation requires developing clusters of institutions, businesses, and personnel. “Location, location, location,” the battle cry for real estate agents everywhere, is increasingly becoming the key word in studies of innovation dynamics and knowledge-based growth. Prime locations in R&D are referred to as “clusters” – groups of similar-minded institutions and individuals who grow together. Although companies and various not-for-profit entities in the same sector or product market have traditionally located themselves in specific geographic regions (rather than spreading out evenly across a country), the deliberate search for ways to encourage clustering has only recently begun. Institutions have much to gain from being located in clusters or strongly linked with them. Indeed, this strategy is one of the most effective ways to bring about institutional change and attract entrepreneurs.

Governments have an important role to play in the process of cluster formation. In order to create clusters, governments could usefully redirect some of their funds from bricks and mortar and product investments towards soft investments in institutions and platforms that create collaborations. Local and national governments can also foster cluster formation by, for example, offering tax incentives to companies to set-up their operations within a defined zone of geographical proximity. It is universities, however, that have the power to lead the way in supporting productive research networks. These networks have the potential not only to generate new knowledge but also the ability to bring in and adapt global knowledge to local needs. Indeed, research collaborations are important both for a university’s academic status and for the commercial and economic prospects of a research-based cluster. Universities should strive, therefore, to encourage and support research that engages with the larger community.

Putting the power of intellectual property to work for the poor

As mentioned, when it comes to combating diseases and

promoting health in developing countries, the past decade has seen an unprecedented pace of change. One big change is the range of new actors – particularly the private sector – contributing to this agenda⁸. To ensure that this agenda is sustained, the private sector must continue to be engaged by the public sector to achieve public sector goals.

For intellectual property to be put to work by the public sector for public sector goals, an urgent reconceptualization of the relationship between the IP system and developing countries is needed. This requires, first and foremost, best practices in IP management by and for the public sector⁹. Much can be achieved with this relatively simple emphasis – as opposed to efforts aimed at changing international treaties or negotiating yet another global treaty with impact only in the long term, if any¹⁰. Broad access for the poor can be strengthened significantly – with tangible and near-term benefits – through creative IP management and licensing practices.

Good institutional IP management capabilities,

strengthened IP court systems and patent offices, and policies that encourage meeting the needs of the poor are the tools that will create more effective R&D endeavours and provide equitable access to valuable health innovations. □

Anatole Krattiger is Research Professor at the Biodesign Institute, Arizona State University (ASU), Adjunct Professor at the Sandra Day O'Connor College of Law ASU, and Adjunct Professor at Cornell University's College of Agriculture and Life Sciences. He works on strategic and intellectual property aspects related to health and agricultural innovation management and at the crossroads of development, government, science, businesses, and philanthropy. Originally a farmer in Switzerland, he worked among others at the International Maize and Wheat centre in Mexico, served as Executive Director of the International service for Acquisition of Agri-biotech applications, and as Executive to the Humanitarian Board for Golden Rice. He is a member of the Advisory Board of the Franklin Pierce Law Center, founding Board Member of the Black Sea Biotechnology Association and Editor-in-Chief of Innovation Strategy Today.

References

- ¹ Gurry F. Foreword. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. Krattiger A, Mahoney RT, Nelsen L et al), 2007, MIHR: Oxford, UK, and PIPRA: Davis, California, USA. www.ipHandbook.org
- ² These are: Madrid Protocol (1989), Washington Treaty on Integrated Circuits and the Film Register Treaty (1989), UPOV 1991 Act (1991), TRIPs (1994), Trademark Law Treaty (1994), WIPO Copyright Treaty, WIPO Performances Treaty (1996), WIPO Phonograms Treaty (1996), Geneva Act of the Hague Convention (1999), and the Patent Law Treaty (2000).
- ³ These five reasons are cited from Krattiger et al. From Best Principles to Best Practice: Message from the Editorial Board. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. Krattiger A, Mahoney RT, Nelsen L, et al), 2007, MIHR: Oxford, UK, and PIPRA: Davis, USA. www.ipHandbook.org
- ⁴ See, for example: Min EJ. Alternative Dispute-Resolution Procedures: International View. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. Krattiger A, Mahoney RT, Nelsen L, et al), 2007, MIHR: Oxford, UK, and PIPRA: Davis, USA. www.ipHandbook.org
- ⁵ Krattiger A. Freedom to Operate, Public Sector Research and Product-Development Partnerships: Strategies and Risk-Management Options. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, (eds. Krattiger A, Mahoney RT, Nelsen L, et al), 2007, MIHR: Oxford, UK, and PIPRA: Davis, USA. www.ipHandbook.org
- ⁶ See for example a recent discussion in *The Economist*: Beyond the blockbuster, 30 June 2007.
- ⁷ For example, Indian drug companies have been combining their re-engineering skills with legal ingenuity to challenge patents held by the world's leading drug companies. See for example: Generic Drugs From India Prompting Turf Battles, *The New York Times*, 26 July 2007.
- ⁸ Matlin S. Combating diseases and promoting health: setting the agenda for health research. *Global Forum Update on Research for Health*. Vol. 3:11-XX, 2006.
- ⁹ For a more detailed discussion, see Mahoney RT and Krattiger A. The Role of IP Management in Health and Agricultural Innovation. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. Krattiger A, Mahoney RT, Nelsen L, et al), 2007, MIHR: Oxford, UK, and PIPRA: Davis, USA.
- ¹⁰ For example, the Global Medical Research and Development Treaty is one such initiative that may lead to minor benefits in the long term but would consume enormous resources and shift them away from the more immediate and highly beneficial results with authoritative IP management. For detailed analysis of the proposed treaty, see Farlow A. A Global Medical Research and Development Treaty. An answer to global health needs? IPN Working Papers on Intellectual Property, Innovation and Health, 2007, International Policy Press, London. http://www.fightingdiseases.org/pdf/Global_Medical_Research_web.pdf