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Intellectual property, commercial needs and humanitarian benefits: must there be a conflict?

Review

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'*By far the best proof is experience,*' wrote Francis Bacon. Given the experience of countries – both developing and developed – that have used intellectual property (IP), IP protection and IP management to stimulate innovation, there is ample proof that good IP management has benefited multitudes of people around the world with new technologies, products and services. Innovations in health and agriculture have greatly enriched lives. But does this experience apply to all countries? If the best proof is experience, then what can be said authoritatively about the effects of using IP systems wisely in developing countries?

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Introduction: What is intellectual property (IP) in the context of international development?

First, IP (comprising essentially patents, copyright, trademarks, trade secrets, plant variety protection and geographic indications) is a tool to foster innovation. IP is here, and here to stay, because of its undisputable value as a business asset and an instrument to achieve humanitarian objectives. Because inventions can become property and can therefore be owned and sold, many individuals have been encouraged to invest in innovation, based on the profit potential from resulting technologies. But because IP protections by definition, or by design, exclude competitors and encourage higher pricing, they limit and, in some cases, can altogether prevent access by some individuals and populations. There are many ways, however, for IP to be distributed and utilised and put to work for the public interest. Hence IP should be neither feared, nor blindly embraced; rather, it should be managed to maximise the benefits of innovation for all of society, especially the poor.

Second, IP rights are a compromise and an imperfect solution, representing the search for balance between *public domain* and granting *ownership*. This balance encourages investment, and reinvestment, in innovation, although the innovation too infrequently is directed towards the needs of the poor. Fortunately, as numerous case studies have shown, the public sector can craft effective solutions that can approach or even achieve a suitable

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balance. This can be accomplished by the existing IP system, especially as it addresses situations in which companies agree to donate or otherwise share their IP.

Third, genius can flourish anywhere, and the emerging global systems of innovation in health and agriculture open up new prospects for innovation everywhere. This notion has profound implications for the management of innovation, technology transfer, market competition and economic development in every country. Irrespective of whether inventions are home grown or originate abroad, authoritative IP management will play a crucial role in enabling and preserving access to the resulting technologies.

Fourth, policies to promote the creation and management of IP by public sector institutions should give the first priority to advancing the mission of those institutions. Put differently, technology transfer should support the larger mission and not merely be seen as potential revenues.

Fifth, IP has historically benefited mostly the affluent. This is, in part, because insufficient attention has been paid by the public sector to managing IP. This lack of focused attention must be corrected. Fortunately, there is growing interest, within both the public and private sectors, in putting IP to work for public benefit, although concurrently, there is a lack of knowledge and capacity to use IP appropriately and responsibly.

This chapter is designed to present case studies in health and agriculture that demonstrate how these complex issues have been addressed successfully in practice. It is hoped that they will inspire and encourage others to take greater advantage of the unprecedented opportunity in strategically managing IP to benefit especially those who have been unable to benefit from technology. Seizing this opportunity will lead, in turn, to a healthier and more equitable world.

Experiences from around the world

Developing countries already have a vast amount of experience with IP protection, and this experience proves that they can use IP to their advantage. This chapter reviews how developed and developing countries alike are deploying and adapting IP management to meet their needs. Tapping into the dynamism of product development partnerships (PDPs) and utilising the potential of their universities, public sector institutions and private companies, many developing countries are quickly and creatively building on the experience of their own institutions, of neighbouring countries and of countries around the globe.

India's experience in the pharmaceutical sector during the past 50 years is described by Satyanarayana [1], demonstrating how the country has made great strides in science through a series of policy initiatives promoting high-quality research. But especially since 2005, when India became fully compliant with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), big changes have occurred. India's rigorous IP rights regime and professional IP management in both private sector companies and public sector research institutions are driving success. But this is only part of a larger coordinated attempt that includes increased public and private R&D expenditures, new policies governing traditional medicines, overhauled regulatory regimes for new drugs and biotechnologies, initiatives to emphasise and build on already competitive regions or technologies, and newly created governmental, research and educational institutions.

In the pharmaceutical sector, the effects of these policies can be seen in:

- a shift in the Indian pharmaceutical industry from an approach based solely on the low-cost manufacture of generic drugs to research-driven innovation of novel drugs for the global market,
- the emergence of an entrepreneurial biotechnology sector in India,
- the consideration by multinational pharmaceutical companies of investing in R&D and manufacturing operations in India.

In agriculture, these effects are apparent in a rich pipeline of innovations that promise to make India's agricultural sector more competitive and profitable. Besides a substantial allocation of funds for R&D by the government, two new initiatives were started in 2005: the National Agricultural Innovation Project (NAIP) and the Indo-U.S. Agricultural Knowledge Initiative (AKI). India's transition from a protected economy to an open, global economic power has prompted the government to take a series of steps to address the new challenges of globalisation, and the lessons it has learned apply broadly to many developing countries. Strengthening R&D, establishing policies to create and manage IP and fostering PDPs are all important steps for making important health products available for public distribution available in all countries.

Changing contenting, and according to Wolson [2] who writes from South Africa, technology transfer offices (TTOs) are a crucial part of IP management. But several problems challenge nascent TTOs there: a weak flow of invention disclosures, scepticism or a lack of awareness amongst faculty about the TTO's role, low levels of research funding, high patenting costs, few experienced technology transfer practitioners and unrealistic expectations about financial returns. Indeed, many there believe that the main motivation for undertaking technology transfer activities at a university is to generate income. Solutions to these problems are being addressed organisationally by the Southern African Research & Innovation Management Association (SARIMA), legislatively by the Framework for Intellectual Property Rights from Publicly Financed Research (the Framework) and financially through the Innovation Fund. Established in 2002, SARIMA is a stakeholder organisation providing a platform for those from government, academia and industry with an interest in using research and innovation management to foster networking and promote common interests. The Framework is intended to bridge the 'innovation chasm': the gap in South Africa between knowledge generators (in particular, universities and research institutions) and the market. It calls for a consistent approach to protecting IP developed with public financing and draws heavily on the U.S. Bayh-Dole Act. Of course, as other countries have discovered, the Bayh-Dole Act cannot simply be imported. Its principles must be adapted to local frameworks and needs. In South Africa, for example, research funding comes mostly from external sources and requires a different structure for determining the use and ownership of project IP.

TTOs in South Africa have already met with success. Some have been operating for several years and more are being launched. A vibrant stakeholder organisation provides a platform for networking and professional development in the field, and links have been forged that strengthen international research collaborations and technology transfer partnerships. All of this has government support.

For completeness, notable case studies from other countries are published about Brazil [3], Chile [4], China [5], the EU approach by Blaya [6] and Japan [7].

Public sector institutions and universities

Salicrup and Rohrbaugh [8] provide more evidence of the ability of for-profit and nonprofit institutions in developing countries to bring new products to market that meet critical regional public health needs. The authors discuss the technology transfer and licensing approach of the U.S. National Institutes of Health (NIH). The institution's technology transfer experience has shown that many combinations of licensing strategies can be used to segment the world market to meet each region's needs. Even when patent protection is unavailable, unique biological materials (for example, an essential component of a vaccine) can be licensed for commercial use.

Institutions in developing countries have been found to be dependable licensees and partners. With careful review, a capable institution with commercialisation capabilities may be found, and one should keep an open mind because, depending on the country, it may be a for-profit company, a nonprofit or government entity or a semi-privatised company. NIH has several examples of different strategies involving various types of institutions that have reached the early stages of the commercialisation process. Although discussions continue about IP capacity building in developing countries, some leading institutions are simply forging ahead and building their own capacity.

The State University of Campinas, or Unicamp, one of the leading research universities in Brazil, is an example [9]. A large university with a diversity of affiliated research institutes, Unicamp has moved up the patenting league tables in recent years to become the single largest patentor in Brazil. The university's current portfolio includes almost 50 granted and 400 filed patents. Unicamp emphasises chemistry, which accounts for close to half of its portfolio, and engineering, which accounts for a third. In addition, Unicamp conducts significant research in the life sciences (for example, a soy-based phytoestrogen for hormonal therapy licensed to a Brazilian pharmaceutical company).

These major advances in technology transfer at Unicamp are largely because of the efforts of its new TTO, *Inova Unicamp*, founded in 2003. *Inova* began its operations by assessing all of the technologies being researched in Unicamp's many laboratories and institutes. It then aggressively pursued new patent applications and licensing deals for the most promising technologies. In the short space of two and a half years, the office signed 128 technology transfer agreements with both private industry and government agencies. It also saw ten start-up companies in the university's business incubator become self-sustaining.

What lies behind these successes in Brazil? New public policy. In particular, the work of *Inova* is directly informed by two pieces of legislation. A 1996 law gave the university ownership rights to employee inventions. A 2004 law on innovation, however, gives the university the option to either hand over title to the employee inventors, or share 5–33% of any royalties with them. In addition, the government has instituted several sector-specific incentives to support innovation in Brazil, including tax deductions on royalty payments, R&D investments and foreign IP filing fees, as well as subsidies to firms to help pay scientists' salaries.

The 2004 innovation law requires all government universities and R&D institutions to open an IP management or a TTO. One major consequence of these policies will likely be increased patenting and licensing activities at universities throughout Brazil. Currently, Unicamp's rapid establishment of a functioning TTO stands as a sterling example for other institutions in Brazil to emulate. Other case studies that are noteworthy of public sector institutions include Arizona State University [10], Chinese Universities [11], the Donald Danforth Plant Science Center in the United States [12], the National Health Service in England [13], Stanford University's Office of Technology Licensing [14], the University of California System [15] and the University of California Agricultural Experiment Station [16].

Product development partnerships (PDPs)

Banerji and Pecoul [17] describe the Drugs for Neglected Diseases Initiative (DND*i*) that seeks to give patients in developing countries the opportunity to directly benefit from new products of drug R&D for diseases that lack a viable market. Only a tiny fraction (1.3%) of the drugs that came to market from 1975 to 2004 targeted tropical diseases (such as human African trypanosomiasis, Chagas' disease, leishmaniasis, helminthic infections, schistosomiasis, onchocerciasis, malaria and tuberculosis) that together make up 12% of the global disease burden and kill more than 35,000 people a day. The drugs that do exist are either inaccessible to patients or unbearably costly. DND*i* believes that drug research can exist in the public domain, and that patented products do not always benefit those who need them most.

As clearly articulated in its IP policy statement, DND*i* is committed to managing IP to pragmatically and effectively advance its mission of providing the most vulnerable populations in developing countries with equitable access to critically needed medicines. As the preamble of DND*i*'s IP policy states: the DND*i* IP approach will be pragmatic, and decisions regarding the possible acquisition of patents, ownership and licensing terms will be made on a case-by-case basis. DND*i* will put the needs of neglected patients first and will negotiate to obtain the best possible conditions for them. The DND*i*'s decisions regarding IP will contribute to ensuring access and encouraging further innovations.

DND*i* has led two successful campaigns to negotiate terms that allowed them to get important drugs to the world's neediest people at minimal cost. In the first case, DND*i* approached French pharmaceutical giant Sanofi-Aventis in 2003 to develop artesunate–amodiaquine, a fixed-dose combination therapy for chloroquine-resistant malaria. That negotiation process eventually led to a contract with very favorable terms for DND*i*; the drug was made available for production by generic manufacturers with no payment owing to either Sanofi-Aventis or DND*i*, and Sanofi-Aventis agreed to supply the drug at cost to the public sector, NGOs and international organisations. In the second case, DND*i* successfully collaborated with the University of California, San Francisco's (UCSF) business development office to support research leading to treatments for the lethal human African sleeping sickness. Whilst conventional wisdom holds that a university should always seek the largest possible return on research investment, DND*i* was able to convince university officials of the seriousness of its mission, and a compromise was reached that advances the effort to bring new treatments to persons suffering

from this deadly and largely neglected disease. In pursuing its humanitarian mission, DND*i* has learned that it is crucial to thoroughly familiarise all parties with the organisation's aims and guiding principles. By the end of contract negotiations with UCSF, for example, decision makers expressed great personal satisfaction at helping to advance DND*i*'s work. Through similar efforts DND*i* hopes to have developed and made available, by 2014, six to eight field-relevant treatments.

Boadi and Bokanga [18] describe the building of public–private partnerships (PDPs) in Africa by the African Agricultural Technology Foundation (AATF). AATF emerged from a Rockefeller Foundation initiative in the early 2000s following a wide-ranging and unprecedented consultation amongst African, European and North American stakeholders who were, and are, actively seeking to improve food security and reduce poverty in sub-Saharan Africa. AATF recognises that new and unique PDPs are needed to remove many of the barriers that have prevented smallholder farmers in sub-Saharan Africa from gaining access to existing agricultural technologies. Focusing on the creation of these PDPs, it promotes efforts to create sustainable markets and seeks to dramatically improve access to agricultural technologies, materials and know-how. AATF has two unique characteristics: first, it is prepared in license technologies from the private sector, which it then sublicenses to its partners. This is no small issue and requires careful considerations of a range of issues, including liability. Second, AATF strongly focuses on downstream activities or, to put it more broadly, on technology stewardship. This includes facilitating access to local, national and regional markets for products based on transferred technologies. The goals are to create more sustainable technology transfer mechanisms and to allow national institutions to more effectively absorb new technological concepts and adopt them for productive use.

But the fundamental raison d'être of AATF goes much deeper than 'merely' IP management. As Gordon Conway, then president of the Rockefeller Foundation, put it in the AATF annual report of 2005: *We should examine the current system and ask ourselves, 'How can those who care about the fate of the small-scale farmer make technological options more available?' The rise of a sophisticated global IP system covering many building block technologies has meant public researchers [in Africa] have little access to new ideas and tools in their field. Left to its own devices, the gap is likely to grow—with wealthy nations' farmers using techniques that are ever more sophisticated and poor farmers left with the same tools they have used for centuries*.

Other case studies sharing PDP experiences describe PATH [19] and ICIPE, a nonprofit institute that partnered with Africert Ltd. in transferring standards certification know-how, crucial for the introduction of new products [20].

Focus on solutions: accelerating product development and delivery

Numerous partnership efforts are underway to accelerate access and delivery for agricultural and health products in developing countries. For example, in the tropics, where just about everyone eats eggplant, it is commonly infested with eggplant fruit and shoot borer (EFSB), which inflicts a 70% crop loss. Conventional efforts to breed for resistance have been unsuccessful, so farmers rely heavily on pesticides. These chemicals, however, are expensive, and the pest is becoming more and more resistant to them. Moreover, some pesticides damage the environment and/or are illegal. Recently, a new solution to the problem of EFSB was developed in partnership with many organisations [21], including by MAHYCO, a private Indian company. It was the first company in India to develop a transgenic hybrid eggplant genetically engineered with a gene that provides resistance to EFSB. The gene (cry1Ac) is obtained from the bacterium *Bacillus thuringiensis* (Bt). A spore-forming bacterium, Bt produces crystal proteins (Cry proteins) that are toxic to many species of insects, including EFSB. Cultivation of the hybrid eggplant reduces the need for pesticide applications.

This breakthrough was made possible when MAHYCO obtained the rights under license for the use of the Bt cry1Ac gene technology for insect pest management from the Monsanto Company. The license also allows for sublicensing of the technology on a royalty-free basis to a partnership of public institutes and agricultural universities in India, Bangladesh and the Philippines. This consortium is developing a nonhybrid form of Bt eggplant for use by farmers in developing countries. The nonhybrid form will be less expensive, but the yield is higher for the hybrid technology. Therefore, more farmers might choose the hybrid technology.

Commercial release of the first transgenic Bt hybrids developed by MAHYCO is planned for India by the end of 2007, after the fulfilment of all regulatory requirements. The transgenic Bt open-pollinated varieties under development by the PDP are expected to be commercialised about six months later. This approach to EFSB is an excellent example of how biotechnology applications can be concurrently commercialised for the market and subsidised for poorer market segments.

In health, a prominent example of improvement regarding access to innovations in health is the PATH Malaria Vaccine Initiative (MVI), a programme funded by the Rockefeller Foundation that analysed whether consolidating patents in the malaria vaccine field could streamline access by advancing and accelerating the development of vaccines. The project was designed to ensure market access for the malaria vaccine candidates that are most likely to receive regulatory approval and be developed as products. The study assessed the status of the relevant patents, determined their availability for licensing and explored the potential of patent consolidation or technology trust to enhance access to the vaccine [22]. Developing a broad-based technology trust for existing malaria antigen patents was not recommended. Instead, several other steps were recommended for consolidating available rights and improving access with regard to future patent families.

Before this study, MVI had identified some potentially obstructive IP issues for a malaria vaccine for developing-country markets. Public and academic institutions – institutions with missions that in many cases include some form of public benefit – hold many of the patents related to malaria antigens. As the study's findings reveal, with few exceptions the patents held by public and academic institutions have been assigned or exclusively licensed to private companies and, therefore, are currently unavailable for licensing from the original public institution patent holders.

Although it may be possible to sublicense these malarial antigen patents from the current private holders of the technology, it is likely to be more difficult and costly; engaging the patent holders to contribute to a patent pool or clearinghouse also might be challenging. Moreover, a patent pool for a malaria vaccine might generate further obstacles: potential antitrust issues, real

or perceived, might trigger scrutiny by the U.S. Department of Justice and the Federal Trade Commission. Although the concept of a technology trust or patent pool may be useful for patents filed in the future, even some of those would be under option for license by the private companies holding the current patents. Finally, the number of high-priority cases for any malaria antigen is small, as is the number of entities likely to seek access to any given patent family. This makes the expense of a patent pool even less justifiable. Taking all of these things into consideration means fewer missteps and faster progress towards a vaccine for malaria.

Other notable accounts of important case studies relate to the Cohen–Boyer patents at Stanford University [23], IP issues related to molecular pharming, specifically for plant-derived vaccines [24], corn/maize breeding and the impact of biotechnology on the breeding and commercialisation process [25], the University of California's Strawberry Licensing Program being the most successful programme in terms of the generation of licensing revenues of any U.S. university [26], the successful resolution of IP constraints that led to the introduction of virus resistant papayas [27] and a project on the somatic embryogenesis of grapes in Chile [28].

Conclusions

If indeed the best proof is experience, then the case studies described here indeed speak for themselves. The experiences represented by these case studies provide all the evidence needed to spur further efforts to build upon the IP strengths of developing countries. Many forward-thinking people have seen the possibilities, and this section broadly maps out work that is already underway around the globe to make these possibilities into realities. Such experiences offer the most powerful proof of the benefits that can be obtained through creative IP management in developing countries and indeed around the world.

Acknowledgement

Portions of this chapter draw heavily from Krattiger *et al.* [29] which is a summary of Krattiger *et al.* [30].

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