INTELLECTUAL PROPERTY TOOLS, INNOVATION AND COMMERCIALISATION OF R&D: OPTIONS TO ASSIST DEVELOPING COUNTRIES IN POSITIONING THEMSELVES TO REAP THE BENEFITS OF A STRONGER INTELLECTUAL PROPERTY REGIME, WITH SPECIAL REFERENCE TO THE ROLE OF INTELLECTUAL PROPERTY MANAGEMENT IN RESEARCH ORGANISATIONS

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Introduction

There is growing acknowledgment that a strong national intellectual property (IP) regime will impact differently on countries at different stages of development.[2] Whereas in the past, nations in the process of industrialising had some freedom to choose when to adopt different types of IP protection and how strong the protection granted should be, today's developing countries do not have the same flexibility of options as a result of the prevailing multilateral trade and IP environment (epitomised by, but not confined to, the World Trade Organisation's TRIPS Agreement),[3] together with increasing pressure to implement higher IP standards in order to benefit from bilateral relationships with powerful international trading partners.

It is widely accepted that knowledge is a prerequisite for development to take place in the current "knowledge economy". This knowledge must be acquired, absorbed and diffused. An aspect which has generated much debate is the role that intellectual property rights (IPRs) can play as both enabler and inhibitor of the learning processes of knowledge acquisition, absorption and diffusion. On the one hand, holders of technology are reluctant to transfer their technology if they cannot be guaranteed protection against unauthorised and uncompensated use of the technology developed as a result of their investment. IPRs are a tool for providing such protection and, as such, a strong IP regime is likely to improve the prospects of attracting cutting-edge technology. On the other hand, by restricting who can utilise the acquired technology and on what terms, IPRs can also result in limiting the absorption and diffusion of technology, for example by preventing reverse engineering, or by imposing high costs on use of incremental innovations based on the acquired technology. This means that the benefits of accessing the technology are diluted. However, as acquired technology is mastered, technological capabilities are built up locally, facilitating increased indigenous innovation, which is in turn incentivised by IPRs.

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[2] Eg Commission on Intellectual Property Rights (2002) *Integrating Intellectual Property Rights and Development Policy*; Lall, S. (2003) *Indicators of the Relative Importance of IPRs in Developing Countries* ICTSD & UNCTAD; UNIDO (2002) *Industrial Development Report 2002-2003.*

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights.

But in developing countries where domestic innovation remains low, the lion's share of patents issued by national patent offices goes to foreign applicants rather than to local innovators. While fairly substantial technical assistance has been supplied to help countries meet their TRIPS obligations,[4] through amending and introducing new IP legislation and building capacity in national patent offices, efforts to assist potential local innovators to use the IP system remain largely inadequate, short-term and unsustainable. What options, then, are available to developing countries to leverage their TRIPS-compliant or even "TRIPS-plus" IP frameworks in such a way as to maximise effective acquisition, absorption and diffusion of knowledge and technology?

It would seem that an integrated set of interventions is called for, targeted at different levels: institutional, national and international. Institutional capacity (in both firms and research organisations) must be developed to manage IP. At the level of national government, enabling policies should be implemented to encourage increased public and private sector research and development (R&D) expenditure, coupled with measures for building capacity in research management (of which IP management is one aspect), and creating a positive environment for business to thrive. At international level, developing country governments must ensure that their interests are represented and codified in multilateral and bilateral fora and instruments. This requires thorough understanding of the "rules of the game", as well as of national needs.

This paper focuses mainly on institutional approaches to managing IP for the promotion of development, and attempts to situate this within the broader policy environment.

Institutional Management of IP

In a well-functioning national system of innovation, much emphasis has been placed on the importance of closer ties between universities and public research institutions on the one hand, and the private sector on the other. One of the main instruments for facilitating these linkages is the institutional technology transfer office (TTO),[5] which is tasked with ensuring that research results emanating from the institution concerned are transferred to society for social and economic benefit. The typical model for institutional technology transfer involves licensing the institution's IP to an existing or a start-up company, which will engage in further R&D to add value to the IP in order to develop a market-ready product. The institution benefits financially from licence fees paid by the licensee company, useful new products reach consumers, employment opportunities are created and tax revenue is generated.

This model is considered to have been particularly effective in the United States (US), its success widely attributed to the stimulus provided by the 1980 Bayh-Dole Act,[6] a statute aimed at promoting the transfer to industry of federally-funded technology developed within universities and other non-profit and small business recipients of federal research funding (and later extended to all recipients of federal research grants).

Lessons from Bayh-Dole

Prior to Bayh-Dole, the US federal government owned the IP in federally-funded technology, but had a poor record of successful exploitation of the thousands of patents it held. By giving grantees the right to own the IP developed from federally-funded research, they were incentivised

[4] From a range of organisations including World Trade Organisation, World Intellectual Property Organisation, UNCTAD and the European Patent Office.
[5] Sometimes referred to alternatively as a licensing office, business development office, industry liaison office or IP office.
[6] The Bayh-Dole University and Small Business Patent Procedures Act of 1980.

to become actively involved in the commercialisation of their technology, and by permitting grantees to issue exclusive licences to industry, companies were incentivised to invest in further development of the technology leading to the manufacture and sale of goods.

Bayh-Dole applies to all research carried out in terms of a federal funding contract, even where the work may be only partially government-funded. Grantees take on certain obligations when they elect to retain title to intellectual property developed under such a contract. These obligations include reporting to the relevant federal funding agency, filing a United States patent application, taking active steps to commercialise the invention concerned, sharing any income generated from exploitation with inventors and using the balance of such income for research or educational purposes. Grantees may licence the technology concerned to industry on an exclusive or non-exclusive basis.

In an effort to ensure a balance between private and public interests, the US government is entitled to a non-exclusive, non-transferable, worldwide, royalty-free right to practise the invention, and may additionally exercise "march-in" rights to take ownership of the technology, or to require that a third party be granted a licence, where this is in the public interest (eg for health or safety reasons, or if the invention has not been commercialised within a reasonable time).[7] In addition, manufacture of products under a licence governed by Bayh-Dole must take place substantially in the United States, and preference must be given to small business licensees, unless it can be shown that they lack the capacity to bring the invention to market.

While some maintain that much of the commercialisation of public-funded research would have taken place even without Bayh-Dole, the legislation has been given credit for the availability of useful new products on the market, job creation and the establishment of new businesses, all of which have contributed to economic development and provide taxpayers with a worthwhile return on their investment in the federal research enterprise.[8]

Other experiences

The US TTO model has subsequently been adopted (with certain adaptations) by most industrialised states in some form or another (in most cases in the absence of "Bayh-Dole-type" legislation), and increasingly many developing country R&D institutions are establishing technology transfer functions. However, even as institutional technology transfer is being heralded for the contribution it makes to economic development, questions are simultaneously being raised about whether the cost of this activity is justified by its impact, as widely differing returns are seen by different institutions, as well as in different national systems. Analysis of the data shows that the costs involved in generating these benefits are substantial, and that the

[7] Interpretation of the statutory conditions under which march-in rights may be exercised has recently been a topic of debate in the US Congress.

[8] Council On Governmental Relations (1999) 'The Bayh-Dole Act: A Guide to the Law and Implementing Regulations', www.cogr.edu; Henderson, J.A. and Smith, J.J. (2002) 'Academia, Industry, and the Bayh-Dole Act: An Implied Duty to Commercialize', Center for Integration of Medicine and Innovative Technology, October, http://www.cimit.org/coi_part3.pdf; Valoir, T. (2000) 'Government Funded Inventions: The Bayh-Dole Act and the *Hopkins v CellPro* March-In Rights Controversy', *Texas Intellectual Property Law Journal*, Vol. 8, No. 2, pp. 211-239; Wolson, R.A. (2004) 'Towards the establishment of a vibrant South African biotechnology industry: will the recent policy interventions achieve their objectives?', *International Journal of Biotechnology*, forthcoming.

distribution of returns is very skewed.[9] Significant investment is required to operate a functioning TTO, which must be able to support professional salaries for highly specialised multi-skilled staff, patent filing and prosecution costs, travel costs, training and marketing expenses. Returns on this investment are only realised after a time lag of several years. Even in the US, few institutions have been fortunate to have "blockbuster" inventions that bring in substantial income,[10] and it appears that many do not even recover the full costs of running their technology transfer operations out of licence fees.[11]

Options for developing country institutions

For developing country institutions, where pressure on resources is usually severe, some question whether this investment is a wise or indeed a necessary one, especially since research budgets will often be too small to guarantee a sufficiently broad portfolio of IP, and qualified staff are few and far between. It is therefore opportune to look more carefully at what relevance this model might have for developing country institutions, including whether Bayh-Dole-type legislation ought to be considered as a potential driver of innovation, or whether alternative models should be explored, which might better promote effective linkages between the various components of the national system of innovation.

"Pre-licensing TTO"

It is worth distinguishing different tiers of activity carried out by TTOs. Arguably, in developing country institutions, an expanded (and/or alternative) role is called for over and above the typical "licensing model". IP management involves more than protection and exploitation of IP (traditionally measured in terms of benchmarks such as number of patents issued and amount of licence income generated), and a TTO can add value to an institution's R&D enterprise in a number of other ways, if IP management functions are integrated into the wider research management functions. The growing importance of IP means that failing to manage it at institutional level could expose an R&D institution to serious risk: for one thing, to lost opportunity where a commercialisable invention is not exploited, but perhaps more alarmingly, to potential liability which could arise out of infringement, breach of contract or statutory liability.

As institutions attempt to grow the number of research collaborators and funders with whom they interact and transact, TTOs[12] can assist in optimising the relationships by structuring beneficial and creative contractual arrangements which, at the least, guarantee freedom-to-operate (including ensuring that researchers are not restricted from building on their research after the funded project is concluded) and publication rights, and ensure that free enquiry is not constrained. Where appropriate, the institution should attempt to retain rights to IP (and/or share in benefits arising out of IP exploitation), and development goals can be advanced by seeking opportunities for access to know-how and equipment, as well as capacity building. Useful roles

[9] Scherer, F.M. and Harhoff, D. (2000) 'Technology policy for a world of skew-distributed outcomes', *Research Policy*, 29, pp. 559-566; Association of University Technology Managers – note 19; Heher, A.D. (2003) 'Return on investment in innovation: implications for institutions and national agencies', The First Globelics Conference on Innovation Systems and Development Strategies for the Third Millennium, Rio de Janiero, November.

[10] Only 1.3% of active licences and options yielded over one million dollars of income in FY 2002, and royalties earned amounted to less than 3% of total research expenditure (Association of University Technology Managers (2003) *AUTM Licensing Survey, FY 2002 Survey Summary*).

[11] Heher – note 8; Wolson – note 7.

[12] The term "TTO" is used broadly here, and the functions mentioned here could alternatively be housed in a sponsored research, industry liaison, research development or similar office, depending on the structures of the institution concerned.

can also be played in facilitating partnerships with other developing country institutions, and in ensuring that the special considerations attaching to research with genetic resources and traditional knowledge are properly handled. Assistance can be rendered to ensure that projects are properly budgeted, and compliance with national legislation and ethical practices can be checked.

So, even if an institution decides that it cannot afford to invest in a traditional "licensing model" TTO, it is submitted that some level of IP management function is essential. This lays the building blocks for understanding the landscape, for equipping institutions to enlist outside assistance if needed, and for improving negotiating capacity that can be deployed down the line should the institution engage in licensing activity at a later stage, when its research capacity has matured. The specific functions taken on by any particular TTO can be tailored to institutional needs, and in particular, the level of development of the institution's R&D enterprise.

"Licensing TTO"
For developing country TTOs which are engaging in licensing activity, appropriate practices should be cultivated, which incentivise innovation and promote exploitation and availability of the technology concerned. Patenting decisions should be made strategically, taking into account whether patent protection is a prerequisite for obtaining a commercial development partner, and selecting territories accordingly. Similarly, "pro-development" approaches to licensing should be followed wherever possible. Mechanisms and practices to consider include:[13]

- Preference for licensing over assignment:
  Often companies wishing to gain rights to a technology insist on assignment of the IP in order to ensure that they have full control. This limits options for market segmentation and should be avoided if possible.

- Non-exclusive versus exclusive licensing:
  While it is accepted that in certain cases exclusivity must be guaranteed in order for a licensee to take the risk of investing in further development of the technology to take it to market, non-exclusive use should be encouraged wherever feasible, and exclusivity should be limited to need (ie only for markets, territories and fields of use in which the licensee is actively practising the invention, enforced via diligence provisions such as minimum royalty payments).

- "Open source" models and compensatory liability regimes:
  These can be considered forms of non-exclusive licensing which make technology widely available to anyone wishing to obtain it, subject to compensation where this is warranted, and subject to the condition that improvements and follow-on applications are made available on a similar basis, thereby expanding the "knowledge commons".

- Requirement to deliver in developing countries:

[13] Lybbert, T.J. (2002) 'Technology Transfer for Humanitarian Use: Economic Issues and Market Segmentation Approaches', *IP Strategy Today No 5-2002* pp17-25; Nelson, L. (2003) 'The Role of Universities in Assuring Access in Developing Countries' in *MIHR Handbook of Best Practices for Management of Intellectual Property in Health Research and Development*, ed Mahoney, R.T.; Reichman, J.H. (2003) 'Managing the Challenge of a Globalized Intellectual Property Regime', ICTSD-UNCTAD Dialogue, 2nd Bellagio Series on Development and Intellectual Property, 18-21 September.

A licensee can be obligated to guarantee availability of product in designated developing country markets. This type of provision can be enforced by coupling it with a provision for compulsory sub-licensing (including sub-licensing of related know-how), which requires the licensee to issue a sub-licence if it is not itself making the licensed product accessible.

- Market segmentation:
  The licensor can require the licensee to make the technology available on different terms (including differential pricing) in developed and developing countries, or to the public and private sector.

- "Humanitarian use" clauses:
  Provisions can be inserted to oblige the licensee (or entitle the licensor) to make the technology available free or at nominal cost for "humanitarian use". This requires agreement on a suitable definition. Also, licensees must be able to be assured that "leakage" will not take place (ie that "free riders" will not take advantage of the exemption and make uncompensated for-profit use of the technology).

- Preference for licensing to local firms:
  This can create opportunities for employment creation and regional economic development.

- Donation of technologies which are unlikely to be commercially profitable, or which serve a compelling public interest:
  Where a technology offers little profit potential, but may have significant social benefit, a licensor could serve the public good by donating the technology to a public or private sector partner who is willing to exploit it.

This should not be viewed as an exhaustive list. Some of these provisions are commonly used, whereas others are more innovative, and as such might be viewed with suspicion by conservative licensees. As a contractual agreement, a licence is the subject of negotiation and the final outcome will depend on the relative bargaining power of the parties. The main objective of a development-oriented TTO will be to ensure that the technology is made easily accessible to all who can benefit from it, rather than on maximising returns to the institution. This calls for some flexibility on a case-by-case basis, depending on the parties involved and the nature of the technology.

Policies to support TTOs in developing country research institutions

TTOs require significant budgets. Even where income generation is prioritised, it is recognised that a significant lag period must be allowed before a TTO can be expected to become self-supporting. If development imperatives are being emphasised, a TTO might not ever aspire to generate sufficient finance to cover its operating costs. However, since the impact of this activity extends far beyond the institution, benefiting the broader economy and society, an argument can be made for state support. Types of support which could be offered include the following:

- Bayh-Dole?:
  In considering whether Bayh-Dole-type legislation could provide effective incentives for commercialisation of public funded research, it must be borne in mind that Bayh-Dole was enacted to remedy the failure of the US government to commercialise the IP it owned from research it funded. In many countries, government does not claim rights to IP arising from public-funded research, and in such cases, it can be questioned whether there is a need for

such legislation. For example, a recent British report[14] explicitly recommends that the United Kingdom not adopt similar legislation, observing that their current circumstances differ markedly from those which led to the need for Bayh-Dole. In South Africa, the proportion of university research funded by industry is much higher than in most developed countries. Since sponsoring companies usually claim ownership of the IP from the projects they finance, the proportion of research leading to unencumbered IP (which the universities are free to commercialise) is much smaller. As a consequence, the impact of Bayh-Dole-type legislation would be significantly weaker, as it would only apply to a much smaller subset of the institution's research. But this does not mean that alternative legislation or other forms of support (which might borrow certain Bayh-Dole provisions) cannot play an important role in promoting innovation. The form that interventions of this type take, however, should be tailored to meet the needs of the particular environment, and different interventions would therefore be expected to be relevant for different institutions in different countries.

- Training and capacity-building:
  The most critical support needed is in developing the human resources to staff TTOs. Without the requisite expertise, TTOs will not be able to provide the necessary services to their home institutions. It would seem that context-specific training programmes containing elements of on-the-job training, secondments, internships and mentorships will be more effective than formal graduate education programmes.

- Funding for patenting and marketing expenses:
  The cost of filing and prosecuting patent applications, particularly internationally, can be prohibitive to institutions with limited budgets. Likewise, marketing technologies to potential developed country licensees can require substantial investment. Government support could facilitate activity that could not take place otherwise. However, the mechanisms for accessing such funding must be practical: bearing in mind the non-negotiable time-lines involved in the patenting process, bureaucratic delays will render such assistance meaningless.

- A centralised TTO:
  Many developing country institutions will lack the capacity, resources or both needed to establish a TTO (and in particular, the licensing functions of a TTO). For institutions performing only a small amount of research, it will be difficult to justify setting up a TTO, despite the potentially valuable role a TTO could play in growing the institutional research endeavour. In such cases, a centralised national or regional TTO could fill this gap, by serving multiple institutions (including the private sector), which together could provide a critical mass of technology to make the effort worthwhile. In addition to providing services to institutions and firms, a centralised TTO could act as a repository for model agreements, case studies and collections of "best practices", and access to subscription databases could be provided. A centralised TTO could also co-ordinate national capacity-building efforts. There are however some potential pitfalls which might arise from a centralised office, and which must be avoided. Geographical location must be chosen carefully to ensure accessibility by client institutions. Issues of confidentiality are important, and distrust can arise if researchers believe that competitors at other institutions could get access to their ideas, or if there is any perception of conflict of interest. Even within a country, very different institutional cultures might prevail in different organisations, and these must be

[14] Crown Copyright (2003) 'Lambert Review of Business-University Collaboration', December.

considered. A bottom-up approach taking heed of the needs, culture and conditions of the client institutions is likely to be more successful than a top-down assessment of what the needs ought to be.

Complementary Policy Approaches

The impact of this activity on strengthening local research and innovation leading to the generation of technology capable of reaping the benefits of higher levels of national IP protection will only be realised if the activity is firmly anchored within a well-supported national system of innovation. It will be further enhanced with appropriate complementary policy interventions at both national and international level.

It is to be expected that different government departments and agencies will be responsible for interventions at different levels. For this multi-pronged approach to be effective, mechanisms must be put in place to co-ordinate the efforts of different policymakers, to avoid possible conflicts between different policies and departments, and to seek synergies.

National
At national level, these will include (amongst other things):

- Increased public spending on science and technology

- An enabling policy framework which encourages public-private research collaboration

- Incentives for private investment in R&D (by both foreign and local firms) by means such as tax relief and matched funding

- Creating an environment conducive to attracting FDI, technology transfer and joint ventures and collaborations with overseas firms particularly in areas identified as national priorities (which will differ from place to place)

- Support for research institutions and firms to exploit their IP through obtaining local and foreign protection and in- and out-licensing of technology.

Efforts should also be made to review the national IP framework to assess whether it is adequately serving the needs of local industry. If changes are called for, flexibilities permitted under TRIPS or other instruments should be investigated. Opportunities for advancing areas of national priority and building on any existing comparative advantages through the IP system should also be sought, both through conventional and alternative forms of IPRs. Different countries will of course have different needs in this regard, and many of the options require extensive further study to determine if they can provide viable solutions in a particular context. Some examples are:

- *Sui generis* rights to promote the protection and exploitation of indigenous knowledge

- Utility models as an alternative to patent protection, being better suited to incremental and follow-on innovations, by means of a more accessible, cheaper, and less stringent procedure

- Geographic indications as a form of branding, signifying origin, quality and authenticity of a product

- Access and benefit-sharing regimes for the exploitation of biodiversity

- Robust competition law to ensure that the monopolies inherent in the patent system do not unjustifiably jeopardise the public interest (eg in the area of public health).

International - bilateral

In bilateral negotiations between a developing and a developed country or region, any call for developing countries to implement stronger IP regimes should be balanced with measures ultimately aimed at enabling inventors and institutions in those countries to benefit from the strengthened IP system (with recognition that this goal might take some time to achieve). These could include undertakings to train researchers and technicians, transfer technology (including related know-how), invest in research infrastructure and to set up true research collaborations, where innovative work is not confined to developed country laboratories.

International - multilateral

In multilateral fora, developing countries with similar interests should enter into alliances[15] to increase their bargaining power when presenting their positions or objecting to proposals that are not in their interests. In particular, efforts must be made to give substance to existing developed country obligations to provide technical assistance and technology transfer to developing countries, and where possible and appropriate, to expand these obligations.

Multilateral institutions can play an important coordinating role and act as clearinghouses for information and technology. Multilateral funds could be established to finance research on areas of need for developing countries (preferably in, or in collaboration with, developing country research institutions) and to facilitate transfer of technologies of particular public interest to developing countries. A new multilateral agreement on access to basic science and technology has also been mooted, and although it will not be easy to obtain the political will needed, this ought to be further investigated.[16]

Conclusion

For IPRs to achieve their objective of incentivising innovation in developing countries, it is essential that developing countries build capacity to manage IP "intelligently" – that is, with sufficient knowledge of how the system works, with a comprehensive understanding of the options available, and in a manner appropriate to the surrounding circumstances and environment. One of the most compelling indications that a stronger national IP regime is of benefit, is evidence of increased use of the system by domestic users. Under the new rules imposed by TRIPS and other instruments, this is unlikely to be achieved without policies targeted at supporting public and private sector innovators, both in their R&D endeavours generally and, more specifically, in using IPRs to promote exploitation of new technology they develop. Concerted efforts must be made to integrate the full suite of relevant policy interventions and support measures as seamlessly as possible for maximum impact.

[15] Such as the G-20 in the World Trade Organisation.

[16] Maskus, K.E. (2003) 'Transfer of Technology and Technological Capacity Building', ICTSD-UNCTAD Dialogue, 2nd Bellagio Series on Development and Intellectual Property, 18-21 September.