The Stockholm Network Experts' Series on Pharmaceutical IPRs

Promoting Technology Transfer in Developing Countries: Lessons from Public-Private Partnerships in the Field of Pharmaceuticals

By Rachel Diamant, Helen Davison and Dr Meir P. Pugatch

STOCKHOLM NETWORK

Promoting Technology Transfer in Developing Countries: Lessons from Public-Private Partnerships in the Field of Pharmaceuticals

November 2007

By Rachel Diamant, Helen Davison and Dr Meir P. Pugatch

Rachel Diamant is a PhD student at the University of Haifa, Helen Davison is a Researcher at the Stockholm Network and Dr Meir P. Pugatch is Director of Research at the Stockholm Network and a Senior Lecturer at the University of Haifa

Contents

I. Introduction p. 5

II. A Brief History of University Technology Transfer in the Developed World p. 6

III. IPRs: An inherent conflict between the developing and the developed world? p. 7

IV. IPRs and Technology Transfer in Developing Countries in the Fields of Pharmaceuticals and Biotechnology: The Evidence p. 9

V. Case Studies

- Singapore: From Manufacturing Hub to Knowledge Economy p. 10
- India: The Path from Generic Manufacturer to Innovative Drug Developer p. 14
- China: Becoming a Global Competitor in the Technology Transfer Game p. 17
- South Africa: Technology Transfer for Economic Growth p. 21
- Kenya and Nigeria: Recognising the Importance of Domestic Technology Transfer Activities p. 23
- Latin America: Commercialising the Results of Strong Research Capabilities p. 25

VI. Conclusions and Policy Recommendations p. 28

Abstract

This paper highlights the opportunities that intellectual property rights (IPRs) present to developing countries in the area of technology transfer.

One of the key debates over the nature and function of IPRs concerns the extent to which IPRs promote innovation and encourage the transfer and exploitation of new technologies in developing and less developed countries. In this context an important question is raised – can developing countries make positive use of IPRs, or does the intellectual property (IP) system merely inhibit the economic development of these countries?

This paper suggests that there is growing evidence that IPRs are, and have been, important for the promotion of innovative, inventive and technology transfer activities in developing countries, including in industrial sectors such as pharmaceuticals and biotechnology. In fact, the paper suggests that in parallel to the international debates currently taking place about the desirability of IPRs to developing countries, there is significant and visible activity in these countries concerning the local exploitation of IPRs.

The basic premise of this paper is that there are already activities taking place in developing countries concerning the local exploitation of IPRs. One just needs to know where to look for them. Indeed, it is suggested that one area in which IPRs currently play a crucial role in promoting technology transfer and innovative activities is via local public-private partnerships.

Though addressing and acknowledging the statistical evidence regarding the positive linkage between the level of protection of IPRs and the rate of technology transfer, this paper is ultimately based on concrete case studies and empirical examples. Accordingly, it focuses on case studies of successful enterprises that have emerged from partnerships between universities, public research organisations (PROs) and industry in a number of developing countries, and provides examples of the successful commercial exploitation of the knowledge that was produced in the process.

I. Introduction

This paper focuses on technology transfer activities that are based on the voluntary transfer of proprietary knowledge and know-how from public and governmental bodies to private entities, for the purpose of developing usable technologies, products and services. In particular this paper focuses on technology transfer activities leading to the transformation of public research into new life saving treatments and medications.

Technology transfer activities that are based on public-private collaborations provide a significant and distinct contribution to the economic strength and well being of countries in which such activities take place. The process enables public research institutions to obtain access to commercial research funds, state-of-the-art equipment and leading-edge technologies, while allowing industry to benefit from the extensive knowledge and ingenuity of academic researchers.

In this context, IPRs provide the platform through which the proprietary knowledge of a non-profit research organisation may be actively transferred to an industrial company which then develops this knowledge and brings it to market in the form of a new product or service. This transfer usually takes place via a contractual arrangement (such as a license agreement) that defines the terms and conditions for the use of that proprietary knowledge and its related IPRs.

Today, there are heated discussions about the extent to which IPRs assist or hinder technology transfer activities in developing countries. This debate is placed under the broader topic of whether and how the protection of IPRs might help developing countries to achieve economic and social development, and crucially, whether IPRs hinder or stimulate access to medicines[1].

This paper highlights the opportunities that IPRs present to developing countries in the area of technology transfer. It suggests that there is growing evidence that intellectual property (IP) is, and has been, important for the promotion of innovative, inventive and technology transfer activities in developing countries, including in industrial sectors such as pharmaceuticals and biotechnology. The paper focuses on successful enterprises that have emerged from academia-industry partnerships in a number of developing countries, and provides examples of the successful commercial exploitation of the knowledge that was produced in that process.

It should be noted that, while acknowledging the positive link between the overall level of IP protection in a given country and its ability to successfully engage in technology transfer activities (as discussed in

[1] Pugatch, M. P. 'What Does the Deal on Drugs Patents Aim to Achieve?', in: *Africa After Cancun: Trade Negotiations in Uncertain Times*, The South African Institute for International Affairs, Trade Report No. 2, (SIIA, December 2003)pp. 31-41

section 4), this paper is arguably inward looking. That is, the paper seeks to discuss the importance of IPRs to technology transfer activities in developing countries from a micro-economic perspective. Accordingly, greater empirical emphasis is given to the specific technology transfer activities of public research bodies in various developing countries, although as discussed in the paper these activities are also linked to the overall intellectual property reforms undertaken by these countries at the macro-economic level.

II. A Brief History of University Technology Transfer in the Developed World

To better understand technology transfer it is important to look at mature systems like that of the US where academic institutions have been engaging in the process for several decades and the government has worked hard to provide a nurturing environment for the process.

In the 1980s the United States passed two path-breaking pieces of legislation; the Patent and Trademark Law Amendments Act of 1984 and 1986, commonly referred to as the Bayh-Dole Act[2], and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialisation Act in 2000[3]. This legislation attempted to supply federal laboratories (such as the National Institutes of Health – NIH) and universities with the incentives needed to work with industry for the purpose of translating early stage research into usable products in the market place for the benefit of the public.

The Bayh-Dole & Stevenson-Wydler Acts sought to secure the above goals through three major changes to the IP system. First, they allowed universities and federally funded bodies to retain ownership of the proprietary knowledge stemming out of the research and daily activities of these institutions, including the ability to own patents on their inventions. Second, they encouraged these institutions to become much more proactive and professional in the management and exploitation of their IPRs by creating professional technology transfer offices. Finally, the legislation sought to stimulate the commercial and financial aspects of public-private collaboration, with the intention of creating new businesses (such as spin-off companies) and generating income for the institutions, as well as for the researchers.

One has to recall that prior to Bayh-Dole & Stevenson-Wydler the output from public-private technology transfer activities was very low. This was despite the United States Congress providing an annual budget of $15 million to the National Science Foundation to conduct research at universities[4] with the aim of translating academic knowledge to practical applications and technologies

[2] US Code, Title 35, Chapter 8 – Patent Rights in Inventions made with Federal Assistance
[3] US Code, Title 15, Chapter 63 – Technology Innovation
[4] Bremer, H.W. "University Technology Transfer: Where Have We Been? Where Are We Going?", *Journal of the Association of University Technology Managers*, Vol 1, (March 1989)

The Bayh-Dole & Stevenson-Wydler Acts led to a flood of technology transfer activities based on the exploitation and commercialisation of IPRs. A decade after the legislation was passed the combined campuses of the University of California became the top recipient in the US of biotechnology patents; a position formally held by pharmaceutical company Merck[5]. In 2005 alone 3,278 US patents were issued, 4,932 new licenses signed, 527 new products launched and 627 spin-off companies created[6]. The total income of research institutes was estimated at 1.4 billion USD[7].

In December 2002, *The Economist* called Bayh-Dole "Possibly the most inspired piece of legislation to be enacted in America in the last half-century"[8]. Indeed university technology transfer activity is recognised by policy-makers to be a powerful driver of national economic growth[4].

Since the US technology transfer system of public-private partnerships was put in place many countries have sought to emulate it. Canada (1985), Japan (1998), Great Britain (1998), Germany (1998, 2001), France (1999), Austria (2002), Italy (2001), Belgium (1999), Spain (1986), Denmark (2000), Switzerland (2002), Netherlands (1998) and Korea (1998, 2000 and 2001) have all adopted frameworks aimed at promoting technology transfer between public private partnerships through the exploitation of IPRs[9].

The evidence suggests that in countries that have adopted these frameworks, technology transfer activity has steadily increased. For example, in Germany in 2001, 747 patents were granted, 555 licenses and 37 spin-off companies generated revenues of approximately 66 million Euros. In Australia, the income from licensing was estimated to be 100 million Euros (498 granted patents, 417 licenses, and 47 spin-off companies). In Canada, in 2002, the income from licensing was estimated to be $33 million (172 granted patents, 362 licenses, and 49 spin-off companies). The income of public research institutions in 2000 in the Netherlands reached 11.5 million Euros, with 167 granted patents, 368 licenses, and 37 spin-off companies and Norway received licensing revenues of 10 million Euros, with 115 granted patents, and 51 spin-off companies from governmental research institutes alone[10].

---

[5] United States Patent and Trademark Office (USPTO) 2006. Technology Profile Report: Patenting Examining Technology Center Groups 1630-1660, Biotechnology (Washington 2006)
[6] Association of University Technology Managers (AUTM) *FY 2005 Licensing Survey*, (Northbrook IL, AUTM: 2005)
[7] Ibid
[8] The Economist "Innovation's Golden Goose", Technology Quarterly Section, p. 3. in *The Economist* (December 14, 2002)
[9] Organisation for Economic Cooperation and Development (OECD). *Turning Science into Business – Patenting and Licensing at Public Research Organisations* (OECD: Paris, 2003)
[10] Ibid

III. IPRs: An inherent conflict between the developing and the developed world?

Over the last 20 years or so, the level, scope, territorial extent, and role of IP protection have expanded. The World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) extended minimum standards for IP protection globally and there are continuing discussions in the World Intellectual Property Organisation (WIPO) aimed at further harmonisation of IP systems worldwide. Moreover, bilateral or regional trade and investment agreements between developed and developing countries often include mutual commitments to implement IP regimes that go beyond TRIPS minimum standards[11].

Debate over the implementation of higher IP standards by developing countries and least developed countries is far from settled, particularly in the area of pharmaceutical patents. The discussion over the extent to which the internationalisation of IPRs affects the ability of poor countries to gain access to affordable medicines has extended beyond the domain of trade policy. This debate has become as emotional as it is rational and encompasses legal and health issues and even questions of business ethics and morality[12]. Currently there are many discussions taking place in the international arena on the future of the IP system and the development of new medicines in developing countries, for example the discussions of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)[13].

There is some evidence that, when IPRs are strengthened, technology transfer is likely to flow as a consequence. From a technology transfer perspective, weak levels of IP protection in developing countries prevents both down-stream and up-stream technology transfer activities; the fear of the unauthorised use of proprietary knowledge prevents foreign companies from entering into technology transfer activities with local entities (down-stream technology transfer); on the other hand it also deprives local innovators of the opportunity to license their inventions to foreign entities (up-stream technology transfer). A study by Lippoldt and Park (2005) examined the association of change in the strength of patent rights with change in trade & FDI via licensing agreements. The study found that patent rights have a positive effect on FDI inflows; a 1% increase in the strength of patent rights (as measured by the so called GP index) is associated with a 0.5% increase in the stock of FDI. They find that this effect is stronger for least developed countries than for other developing[14].

---

[11] Pugatch M.P. "The International Regulation of IPRs in a TRIPs and TRIPs plus World", *Journal of World Investment and Trade*, vol. 6:3 (July 2005) pp. 430-465

[12] Pugatch, M. P. "Political Economy of Intellectual Property Policy-Making: Theory and Practice - An Observation from a Realistic (and Slightly Cynical) Perspective", in: Macmillan F. (ed.) New Directions in Copyright Law. Volume 5 (Edward Elgar: Cheltenham,UK and Northampton, MA, USA, 2007a) pp. 95-118

[13] World Health Organisation (WHO*), Draft global strategy and plan of action on public health, innovation and intellectual property*, (Geneva: WHO Inter Governmental Working Group, July 2007).

[14] Lippoldt, D. and Park W. *International Licensing and the Strengthening of Intellectual Property Rights in Developing Countries during the 1990s*. (Paris: OECD Study 2005)

Leger (2006) conducted a similar study, focusing on developing countries only. The author estimates the link between innovation and IPR, and corrects for other main determinants of innovation such as market demand, past innovative activities, economic conditions, political stability, human capital, financial capital and openness to trade. Comprising observations from 36 developing countries and 26 years (1970-1995), Leger reports that IPRs have a strong positive impact on innovation[15]. Robbins (2006) finds that based on an index of patent rights (the GP Index), countries that have a robust system of patent rights (including developing countries, such as Taiwan and S. Korea) are the largest recipients of income from IP based activities (in the form of royalties and license fees). The author finds that these countries benefit considerably from activities that are based on the licensing of patents and trade secrets[16].

Putting statistical evidence aside, the current discussion that is taking place in the international arena – concerning the relationship between IPRs and technology transfer in developing countries – suffers from a rather misleading, and to some extent misinformed, assumption: that developing countries that are critical of the system of IPRs or even oppose it, do so on the basis of insufficient or non-existent domestic technology transfer activities that are based on the exploitation of IPRs. This assumption is incorrect as will be highlighted in the sections below.

IV. IPRs and Technology Transfer in Developing Countries in the Fields of Pharmaceuticals and Biotechnology: The Evidence

Developing successful technology transfer platforms for public-private partnerships is not a simple task, even in developed countries where such activities have long been established. An effective technology transfer platform depends on a wide range of factors, such as the establishment of a technology transfer office which employs intellectual property experts and marketing professionals; industry oriented scientists; entrepreneurs and companies seeking seed technologies to license from the university and then develop; governmental grants to support the process and a strong intellectual property system that allows the university to protect and license its inventions[17].

The following sections highlight some of the public-private technology transfer activities that take place in developing countries (as well as countries who have recently come to be considered as developed). We submit that, despite the fact that developing countries are new to the 'technology transfer game', there is

---

[15] Léger, A. *Intellectual Property Rights and Innovation in Developing Countries: Evidence from Panel Data*. In Proceedings of the German Development Economics Conference (Berlin 2006)
[16] Robbins, C.A. *Measuring Payments for the Supply and Use of Intellectual Property*. In International Association for Official Statistics (IAOS) (Ottawa, Canada: 2006)
[17] Diamant, R. and Pugatch, M.P. *Measuring Technology Transfer Performance in Public-Private Partnerships - A Discussion Paper*, in IP Academy, Meeting of the Tech Transfer Group. (Tel-Aviv: 2007)

none the less impressive empirical evidence to suggest that such activities are becoming an important part of the scientific and commercial objective of native public research bodies. In this regard, and as described below, it would seem that public research bodies in developing countries consider IPRs to be a strategic element of their technology transfer activities and act accordingly to try to maximize the benefit arising from the exploitation of these IPRs.

Case Studies

1. Singapore: From Manufacturing Hub to Knowledge Economy

Singapore provides a clear example of how successful development of local R&D capabilities and technology transfer infrastructure, achieved through a strong IP environment and significant government support for R&D, has boosted economic growth.

Traditionally, Singapore largely relied on a strategy of attracting foreign direct investment (FDI) from global multinational corporations (MNCs) and leveraging this to exploit technologies and know-how developed elsewhere[18]. In particular, Singapore's strong regime for intellectual property protection and sound regulatory framework made it an attractive destination for FDI[19],[20].

The global MNC-leveraging strategy served Singapore well, making Singapore a leading information technology and electronics manufacturing and services hub in the world. The same leveraging strategy appears to have worked in terms of developing Singapore into a major pharmaceutical manufacturing hub. Virtually all of the 40 pharmaceutical manufacturing firms in operation in Singapore in 2004 were foreign owned. GlaxoSmithKline (GSK) has invested over S$1 billion and in 2004, announced an additional S$100 million to expand existing manufacturing facilities. Schering-Plough built 3 manufacturing plants in Singapore with a total investment of US$730 million. Novartis invested S$310 million, and employs 200 people. Total pharmaceutical manufacturing output in Singapore grew rapidly between 1990 and 2004, with annual average growth exceeding 20%, reaching S$415.2 billion in 2004[21].

R&D in Singapore

After suffering recession in the mid 1980s, Singapore sought to create and commercialise its own intellectual capital as part of a strategic shift towards a knowledge-based, innovation-driven economy.

[18] Wong, P.K., Ping, H.Y. and Singh, A. *Singapore as an Innovative City in East Asia: An Explorative Study of the Perspectives of Innovative Industries*, National University of Singapore, Entrepreneurship Center, Working Paper no. 3568 (Singapore: 2005) pp. 66
[19] Singapore's Biomedical Sciences (BMS) Initiative (2007)
[20] Pugatch, M. P. "Measuring the Strength of National Pharmaceutical Intellectual Property Regimes: Creating a New Pharmaceutical IP Index", *Journal of World Intellectual Property*, vol. 9: 4 (July 2006)
[21] Wong, P.K., "Commercialising biomedical science in a rapidly changing "triple-helix" nexus: The experience of the National University of Singapore", *The Journal of Technology Transfer*, vol 32:4 (2007) pp. 367-395

Initially the government of Singapore began fine-tuning its global MNC leveraging strategy by putting increased emphasis on attracting global MNCs to conduct their own R&D activities in Singapore. The government of Singapore invested US$1 billion to co-fund new R&D projects by global pharmaceutical firms and a Biomedical Research Council (A*STAR) was established, to allocate public R&D funding for strategic biomedical research areas.

Four new public research institutes in bioinformatics, genomics, bioprocessing, and nanobiotechnology were established over the period 2000–2002, while the existing Institute of Molecular & Cell Biology was expanded. Public funds amounting to US$200 million have been committed to bioscience venture capital. A further US$100 million has also been allocated for attracting up to five globally leading corporate research centres[17]. All four new life science-related public research institutions have been located in Biopolis, a new hub for life sciences costing S$500 million when completed. Biopolis also provides integrated housing and recreation facilities for the many foreign scientists attracted to work in the research facilities[22].

The Singapore strategy readily produced results: GlaxoSmithKline invested S$62 million in 2004 in building a preclinical research facility for the treatment of neurodegenerative diseases and schizophrenia, employing 30–35 scientists. Affymetrix established a microarray R&D facility, investing US$25 million; Eli-Lilly built a systems biology R&D center employing 29 Singapore scientists, and PharmaLogicals invested S$142 million in cancer research. The expansion of R&D activities by foreign firms in Singapore contributed significantly to its rapid growth in recent years. Foreign firms accounted for more than 30% of total national R&D expenditure and 60% of total private sector R&D in recent years[23].

Entrepreneurship, IPRs and Technology transfer

In its drive to become a leading hub for enterprise and innovation, Singapore set in place a sound IP protection framework with particular emphasis on the protection of IP in biomedical sciences to spur innovation and encourage more R&D activities in this area[24]. The government also sought to put in place a parallel supportive environment for commercial exploitation of the intellectual assets created within public research institutes.

In 2002 the government of Singapore formed the Economic Review Committee (ERC), to recommend ways to strengthen the spirit of entrepreneurship of Singapore-based companies. Among the many important recommendations made by this report included:

[22] Pugatch M. P. (2006) pp. 373-391
[23] Wong, P.K. (2007)
[24] Singapore's Biomedical Sciences (BMS) Initiative. 2007. http://www.biomed-singapore.com/bms/sg/en_uk/index/singapore_at_a_glance/why_singapore.html

- Incorporating entrepreneurship education programmemes in schools and universities to enhance the creation of an entrepreneurial culture.
- Capability building to attract more entrepreneurial talents from overseas and encourage greater mobility of talents between the public and private sector, to foster the development of industry clusters and to improve access to capital by start-ups and SMEs[25].

The ERC report was adopted by the government of Singapore and mostly implemented through the establishment of a number of agencies and bodies who focus on stimulating innovation.

Through the Agency for Science, Technology and Research (A*STAR), the government put in place policies, resources, and a research and education architecture intended to build indigenous biomedical science R&D competencies. More than $500 million has already been invested in new research centres up to 2005, with another S$1 billion in 2006.

Exploit Technologies was founded as the strategic marketing and commercialisation arm of the Agency for Science, Technology and Research (A*STAR). Its mission is to support A*STAR in transforming the economy through commercialising the R&D results of research institutes. The Intellectual Property Management Division manages the IP generated by A*STAR's research institutes. The division's functions include evaluation of technology disclosures, prosecution of patent applications, and maintenance of granted patents, all with a common objective of obtaining a licensable patent portfolio. Currently, the Division manages more than 2000 active applications and patents. The division also develops and organises training programmemes to enhance A*STAR researchers awareness to IP issues, and latest IP developments[26].

The Science & Engineering Licensing unit actively markets and licenses to the industry technologies developed by A*STAR's science & engineering research institutes. The incubators and spin-off division supports business spin-offs started by budding technopreneurs from A*STAR research institutes[27].

These institutes actively seek opportunities to partner industry players in order to carry out collaborative research and development.

[25] Singapore Government, Ministry of Trade and Industry, *Report of the entrepreneurship and internalization,* subcommittee economic review committee, (Singapore: 2002)
[26] Exploit Technologies, 2007. http://www.exploit-tech.com/
[27] Ibid (2007)

The National University of Singapore (NUS) and the Nanyang Technological University (NTU) have both established dedicated technological transfer offices known as INTRO and ITTO respectively, to catalyze commercialisation opportunities and facilitate interaction between universities and industry[28].

Success Stories

In early 2003, Severe Acute Respiratory Syndrome (SARS) plagued an alarming number of countries, taking over 500 lives and infecting over 7000 individuals worldwide. Researchers at the Genome Institute of Singapore (GIS) were able to quickly determine the genetic code of the SARS virus and together with Roche Diagnostics formed an agreement to bring together their respective expertise to develop a SARS detection kit based on Roche's patented Polymerase Chain Reaction (PCR) technology. The SARS research product was developed after only eight weeks of development time. Today this kit is used in standard laboratory testing of suspected SARS samples throughout the world[20].

Founded in 2003, Singapore start-up Veredus Laboratories is a molecular diagnostics company engaged in the development, commercialisation and manufacturing of diagnostic assays for malaria, dengue fever and Avian Influenza Virus of the H5N1 strain. The company's focus is to aid patients via faster, more precise, and better diagnostics to enable pathogen-specific treatment of infectious diseases at the earliest detectable stage. Veredus Laboratories Pte Ltd has launched three patented molecular diagnostic kits using home-grown technologies licensed from Exploit Technologies Pte Ltd – the commercialisation arm of the Agency for Science, Technology and Research (A*STAR) and the National University of Singapore[29].

Chiral Sciences was co-funded by two professors from the chemistry department in 2002, in order to commercialise their proprietary technology for separating left-handed molecules from right-handed ones. The technology was protected with six core patents, filed and granted both in Singapore and in the US[30]. The company was able to quickly obtain an exclusive technology licensing agreement with NUS that involved equity in exchange for a royalty payment. The company also received seed funding from NVS Seed Fund in 2004 on fairly generous terms, and was given space to operate in the NVS Business Incubator. Financial assistance was also given to the company to co-finance a trip to the US to pitch to potential venture capitalists and to seek prospective business partners[31].

There are many other examples of spin-off companies launched from the National University of Singapore (NUS), all based on proprietary knowledge owned by the university and licensed to entrepreneurs: Biomimetico Pte Ltd. developed a system for water purification and bio-pharmaceuticals purification. ES

[28] Singapore's Biomedical Sciences (BMS) initiative (2007)
[29] National University of Singapore (NUS) Entrepreneurial Center, 2007. http://www.eng.nus.edu.sg/research/ResAchievement%20-%20Spin-Off.htm.
[30] Chiral Sciences and Technologies. 2007 http://www.chiralpure.com/references.htm
[31] Ibid

Cells International is a regenerative medicine company and a leading provider of products and technologies derived from human embryonic stem (hES) cells. The company's portfolio contains about 24 granted or published patents, mostly for the use of human stem cells in diabetes, generation of cardiomyocytes, and neural cell progenitors. Osteopore International Pte Ltd (2005) markets a biodegradable mesh-like plastic that facilitates bone to grow back when used to cover holes in the skull after surgery. The revolutionary material was developed by a multi-disciplinary team of researchers from the NUS and National University Hospital (NUH)[32].

There were 31 active licensees of biomedical related patents, ranging from NUS spin-offs to local DBFs and global pharmaceutical companies at the end of 2004. Although the cumulative amount of royalties generated to-date is not yet published, it is likely to remain modest, since the majority of the licensing deals were concluded only over the last 2–3 years.

2. India: The Path from Generic Manufacturer to Innovative Drug Developer

The Focus on Generic Capacity

In 1972, the federal government passed a law which essentially removed patent protection from pharmaceutical products[33]. The Act allowed local generic producers to manufacture drugs that were still under patent, as long as they used different processes. The lack of a patent system that conformed to international standards was aimed at creating a domestic generic industry that would specialise in reverse engineering of novel drugs with the objective of launching copycat versions at home and abroad.

Today, India is one of the leading manufacturers of generic drugs in the world, currently producing more than 20% of the world's generics[34] and exporting its generic drugs to both developed and developing countries. Indeed, a weak level of protection of pharmaceutical IPRs allowed Indian pharma companies to develop generic substitutes for eight of the world's top 10 blockbuster drugs within 1-3 years from the time of global market launch. For example, specialized rheumatic analgesic blockbuster drugs such *Celecoxib* and *Refecoxib*, which were globally launched in 1999 by Pfizer and Merck were launched in India in 2000 by leading domestic firms, Sun Pharma and Torrent respectively; *Sildenafil Citrate* (popularly known as Viagra) for erectile dysfunction, globally launched by Pfizer in 1998 was introduced in India by Ranbaxy and Cadila in 2001. Likewise, cardiovascular blockbuster drug *Atorvastatin*, globally launched by Pfizer in 1997, was also introduced in India by domestic firms Ranbaxy, Zydus Cadila and Sun Pharma within

[32] National University of Singapore (NUS) Entrepreneurial Center (2007)
[33] Indian Patents Act, in patAct 1970-3-99. 1999 http://ipindia.nic.in/ipr/patent/patAct1970-3-99.html.
[34] PriceWaterhouseCoopers publication "India- A Prescription for Growth" (July 2005)

3 years. More striking is the example of the anti-diabetic drug *Rosiglitazone Maleate* that was imitated and launched by leading domestic firms within the first year of its global launch in 2000[35].

Towards National Innovation Policies

Since the 1980s, the Indian government has been aiming to create a national biotechnology strategy, among other things by creating the National Biotechnology Board (1982). Four years later, the board had grown into the National Department of Biotechnology (DBT), under the Ministry of Science and Technology. The DBT oversees India's biotech policy, research and development, international cooperation efforts and manufacturing.

In 1995 India became a member of the WTO and a signatory of the TRIPS Agreement. India was given 10 years, from 1995, to amend its laws into TRIPS compliance. India have taken some significant steps to amended its patent laws in both 2002 in 2005[36], though the debate over the extent to which India have met its TRIPS obligations still continues

Part of the reason why India chose to pass the 2005 amendments to the patents act is based on the growing understanding of leading Indian pharmaceutical companies, such as Ranbaxy and Dr. Reddy, that in order to stay competitive in the global market they must change their business models – moving from imitation to innovation models.

The reorientation of the Indian pharmaceutical industry towards R&D has led many companies to seek innovation in universities and research centres. Industry is therefore investing a lot of money in R&D and in collaboration with public research institutes. Ranbaxy has spent over $100 million for capacity expansion in the year 2003–2004 and Nicholas Piramal were planning an investment of US$50 million on R&D. Lupin invested US$5 million in developing anti-TB products[37].

Subsequently, the Indian government has started to provide incentives for biotechnology R&D investment. These include fast-track clearance for FDI, a 100% rebate on privately funded R&D expenditure and a 25 percent rebate if research is contracted in publicly funded R&D institutions. Researchers and entrepreneurs may currently transfer technology to a third party for commercialisation on an exclusive or non-exclusive basis[38].

[35] Agarwal, S., Gupta, A., and Dayal, R. "Technology transfer perspectives in globalising India (drugs and pharmaceuticals and biotechnology)". *The Journal of Technology Transfer*, vol 32:4 (January 2007)
[36] Patrick, M., 'India - are we TRIPs compliant yet?' in *Managing Intellectual Property*. (Singapore: March 2007) see: http://www.managingip.com/Article.aspx?ArticleID=1254082
[37] Agarwal, S.A (2007)
[38] Devol, R., et al., 'Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialisation', The Milken Institute (September 2006).

Success Stories

Inactivated Japanese Encephalitis vaccine was developed at the National Institute of Immunology, New Delhi. The scientists had grown an Indian strain of Japanese Encephalitis Virus (JEV) in Vero cells to high titers and inactivated them using formalin. The technology was patented and further licensed to New Delhi-based Panacea Biotec[39].

A leprosy vaccine called "Immuvac" was developed at the National Institute of Immunology, New Delhi. The technology was licensed to Cadila Pharmaceuticals, Ahmedabad. The product is also recognised as an orphan drug[40] (and consequently benefits from its exclusivity) and is available on the market[41].

Dr. Chauhan and Dr. Chitnis of the International Centre for Genetic Engineering and Biotechnology (ICGEB) in New Delhi have been working on understanding the biology of the malaria parasite and developing novel therapeutic strategies against it. They were able to produce the recombinant candidate antigens of the malaria parasites under Good Laboratory Practice (GLP) conditions. The method of producing soluble protein from malaria parasite was patented[42], and the recombinant antigen has been scaled up in collaboration with industrial partner, Hyderabad-based Bharat Biotech International Ltd (BBIL). This research collaboration is funded by the Bill and Melinda Gates Foundation, who had devoted an amount of $50 million for research on a malaria vaccine[43].

Anthrax is a disease caused by the gram-positive sporulating bacteria, bacillus anthracis. Prof. Rakesh Bhatnagar, Chairperson of the Centre for Biotechnology at the Jawaharlal Nehru University (JNU) in New Delhi, and his team had constructed the new generation of Anthrax vaccine. The anthrax vaccine that was available until 2001 required a number of booster doses and had several undesirable side-effects. The Indian anthrax vaccine is extremely safe and low toxicity. The vaccine is the result of seven years of research, funded in part by the Indian Department of Biotechnology. Led by Bhatnagar, the research team created harmless mutant forms of the three key proteins that together make anthrax fatal. The mutant proteins were grown and purified to ensure that reactivity and side effects of the vaccine were minimized. The novel recombinant protein was patented in the US, India, Canada, and Australia. Newer PCT

---

[39] Dureha, R., Vaccine development gains momentum, in *Biospectrum*. (September 2006) http://biospectrumindia.ciol.com/content/BioBusiness/10609111.asp

[40] In the US an Orphan Drug is any drug developed under the Orphan Drug Act of January 1983 (ODA), a federal law concerning rare diseases. Companies that conduct R & D into such diseases are rewarded with tax reductions and marketing exclusivity for an extended time (7 years post-approval)

[41] Agarwal, S.A (2007)

[42] Sahal, D., R. Kannan, and V.S. Chauhan, *Method for screening a candidate substance as a potential drug for the treatment of malaria.* Indian Patent Application no. 705/DEL/2002, WIPO Publication no. WO02085947AI, International Center for Genetic Engineering and Biotechnology (April 2001)

[43] Bharat Biotech http://www.bharatbiotech.com/2000_jun25_1.htm. (2007).

applications are pending[44]. The technology was licensed to New Delhi-based Panacea Biotec for commercial production[45].

Leishmaniasis is a disease that causes severe ulcers on the skin or on internal organs. It is caused by a parasite called Leishmania, and transmitted by the bite of the sand fly. SIGNAL-KA, is a rapid test system for early diagnostic of leishmaniasis that was developed by the All Indian Institute of Medical Sciences (AIIMS), New Delhi, with National Department of Biotechnology (DBT) support and transferred to SPAN Diagnostics[46]. The company argues that the test system is able to detect visceral leishmaniasis in the blood of patients with 100 % sensitivity and specificity.

The process and the product were patented internationally in 2003. The company has converted the test into an immunochromatographic rapid test, thereby reducing the test result time to 10 minutes and allowing it to be used in the remotest areas of the country without the requirement of refrigeration or electrical supplies. It has also prolonged the shelf-life and the test results can be read with the naked eye. The company carried out clinical trials at AIIMS, New Delhi and in Kala-azar endemic areas of Bihar. The kit was commercially launched by the Minister for Science & Technology and Ocean Development, Shri Kapil Sibal on February, 2006.

On November 11, 2004 the National Research Development Corporation (NRDC) signed a license agreement with American Biosciences Inc., a US based pharmaceutical company, to develop a non-viral gene delivery technology. The gene delivery technology was developed by Delhi University's Prof Maitra and his associates, and protected under American patents[47]. The technology has been licensed for $345,000. In addition, the company will also pay royalty fees up to 4%. Owing to the recognised adverse effects of viral vectors and low transfection efficiency, gene therapy as therapeutic strategy has not yet made it to clinical practice. This technology may prove to be the breakthrough that the field of gene therapy needed[48].

[44] Bhatnagar, R., S.M. Waheed, and V. Chauhan, *High level constitutive production of anthrax protective antigen*. US Patent Application no US20050054038A1, Europian patent Application no. EP1442052A1 (November 2001)
[45] Bagla, P., "New Anthrax Vaccine Developed in India", *National geographic News* (November 2001)
[46] Span Diagnostics home page. 2007. See: http://www.span.co.in/products/diagnoreagent/infectious_desease/signalKA.htm.
[47] Maitra, A., et al., *Process of entrapping genetic materials in ultra-low size nanoparticles of inorganic compounds to form non-viral carriers.* US Patent no. US6555376 WIPO Publication no. WO2005US0020986 (June 2003)
[48] The Financial Express 2004, "NRDC inks pact with American Bioscience", in *The Financial Express* (November 2004) http://www.financialexpress.com/news/story/118815/

3. China: Becoming a Global Competitor in the Technology Transfer Game

China is one of the world's fastest growing economies. Although an overall IP regime is still lacking, over the last two decades China has been increasingly recognising the importance and value of IPRs to its national economic interest.

Initial enactment of modern IP laws to replace the innovation system that was modeled along the lines of the former Soviet Union occurred in the 1980s, following China's opening to foreign trade[49], The 1985 Patent Law of the People's Republic of China first made patent technology and other technologies a commodity in China. Since then Chinese research institutions and universities began to legally own their patents and other intellectual property[50].

The law was amended in 1992 and 2000. Most significantly, prior to the 2000 amendment, patents for service inventions were theoretically owned by the whole of the Chinese people and, hence, by the government as the representative of the people. If the Government deemed an invention to be of significant importance it could issue a planning license to arrange for an enterprise to exploit the invention without having to consult the research institution or university. Amendments made to the article in 2000 stipulated that the research institution or university now owned the patent. Research institutions or universities can now deal with their patents directly at any time and without any permission from the Government. They can transfer or license their patents and obtain royalties from the assignee or licensee. This has resulted in research institutions becoming one of the most important sources of patented inventions in China[51].

China now ranks among the world's top five in terms of patent applications[52]. Although there has been debate over whether China should focus on developing its manufacturing capabilities by buying technologies from multinational enterprises[53], firms, research institutes and universities in China have increasingly sought to develop indigenous innovation capabilities in order to compete in the global market place[54]. Evidence shows that increasingly, innovation is occurring in Chinese organisations and technology is transferred among them[55].

---

[49] La Croix, S. J. and Konan D.E., '*Intellectual property rights in China: the changing political economy of Chinese-American interests*', in Working Paper No. 02-1. (January 2002)
[50] Wang, B. and Ma J., "Collaborative R&D: intellectual property rights between Tsinghua University and multinational companies", *The Journal of Technology Transfer*, vol 32:4, (2007)pp. 457-474
[51] Intellectual Property Watch, 2007, "China, India Discuss National IP Strategies, Local Innovation" (6 July 2007)
[52] Ibid
[53] Gao, X., Zhang P. and Liu X., "Competing with MNEs: developing manufacturing capabilities or innovation capabilities", *The Journal of Technology Transfer*, vol 32:1, (April 2007)pp. 87-107
[54] Li, M., "Innovation management: Chinese experience and global implications", *The Journal of Technology Transfer*, vol 32:1, (April 2007) pp. 1-8
[55] Farris, G., "Research on innovation management and technology transfer in China", *The Journal of Technology Transfer*, 2007. Vol 32:1, (April 2007)pp. 123-126

Universities play a key role in China's innovation system. They run more than one in ten Chinese science and technology firms, account for one in five patents granted each year and provide venture capital to promising start-ups[56]. In 2005 Chinese universities filed almost as many patents (about 6,000 a year) as US universities[57]. As R&D collaborations between universities and multinational companies have increased, so has their contribution to the national economy. China has moved from being merely an importer of intellectual property to an active user. In accordance with this a broader understanding of IP systems and their benefits has developed and legislation to support R&D collaboration has been adopted by the Chinese government to help encourage creative and innovative inward investment[58].

Supporting R&D in the Biotechnology and Pharmaceutical Industry

The recognition of the centrality of the science system to the modernisation and economic growth of China, spurred on by the desire to catch-up with industrialised nations, has encouraged the government to reorganise its R&D sector, promote linkages between the main R&D actors and address the legal and political environment.

Over the last ten years the policy focus has been on commercialising public research[59] resulting in higher levels of technology transfer in terms of products moving from the laboratory to the market[39]. This has been facilitated by supportive government policy including a legal and regulatory environment to promote the biopharmaceuticals sector, attractive tax incentives to foreign investors and state programmemes like the State Economic and Trade Commission (SETC), launched in 2001, which is aimed at improving support for basic research to create the foundations for a globally competitive R&D base[60].

This has been particularly successful in the biotechnology field where Chinese innovation is steadily increasing under initiatives to promote private sector development in the innovation system[39]. In China, research institutes have traditionally played a central role in science. However, it is only since the 1980s that they have been moving into the research realm. In the biotechnology realm, they have become strong producers of new knowledge in this field, and set up new educational programmemes combining research and industrialisation[39].

Various multinationals have now entered into research collaborations with Chinese medical institutions and universities. According to the Chinese Ministry of Education, approximately 28 percent of the available pool of inventions had been licensed or assigned. Most licenses are nonexclusive. Except in the

[56] OECD (2007a)
[57] Harvey, I., "Comment & Analysis: The west must heed China's rise in the global patent race", in *Financial Times*. (September 2005)
[58] UK Intellectual Property Office, "China: An Enforcement Roadmap" 2005
[59] OECD (2007b)
[60] PriceWaterhouseCoopers "China- A Prescription for Growth" (July 2007)

case of inventions made under sponsored-research agreements with companies; the sponsoring company has a guaranteed, royalty-free, non-exclusive license. The company can contract with the University for Outright Assignment even before filing a patent application; however, the university must receive some benefit under such an agreement[61].

Success Stories

GlaxoSmithKline (GSK) and Hybrigenics SA have both joined forces with the Shanghai Institute of Materia Medica to develop a combinatorial chemistry laboratory; tapping into SIMMs knowledge base and library of plant extracts to develop novel therapeutic agents[62]. To date, GSK has spent about $10 million on research and development in China. It cooperates with the Shanghai Institute of Materia Medica to screen approximately 10,000 herbal medicines and carry out collaborative research at a cost of $7 million[63].

Roche is supporting the Chinese National Human Genome Centre (CHGB) in its work on diabetes and schizophrenia. The CHGB coordinates scientific activities in human genome research with a variety of academic and commercial institutions in order to promote the commercialisation of research products and initiate genome industry in China. So far, CHGB has applied for 20 patents via the global track of the WIPO Patent Cooperation Treaty (PCT) as well filing applications at the national level. Patented technologies brought to market include primers and kits used to forecast susceptibility to diabetes[64].

Astra Zeneca is currently participating in a joint study with Shanghai Jiaotong University to identify the genes linked to schizophrenia[48]. Announcing a US$100 million R&D investment in China's Astra Zeneca cited the Chinese government's continuing policy to recognize investment in knowledge transfer and R&D innovation by strengthening IP protection as one of the major factors behind their decision to increase the number of scientific collaborations with local Chinese organisations such as the Jiaotong University[65].

Sinovac Biotech Ltd. is one of the leading emerging biotechs in China, specializing in the development for vaccines against infectious diseases such as hepatitis A and B, SARS and influenza. In December 2004, Sinovac signed a major co-development agreement with the Chinese Centre of Disease Control and Prevention (China CDC) to accelerate the development of an avian flu vaccine for which Sinovac will own commercial rights[66].

---

[61] DeVol, R. (2006) pp. 313
[62] Hybrigenics Press release, "Hybrigenics and Shanghai Institute of Materia Medica announce screening and discovery collaboration", (Paris: May 2004)
[63] Yuan, R., "Pharmaceutical Operations Expand in China", in *Genetic Engineering & Biotechnology news* (Apr 2007)
[64] Chinese National Human Genome Center, Beijing, 2007 http://www.chgb.org.cn/patent/en_patent.htm.
[65] Astra Zeneca, Press Release, 2007. http://astrazeneca.com/pressrelease/5242.aspx
[66] Sinovac's Avian Flu Vaccine Development, in *Medical news today* (Mar 2005)

Looking Forward

Recent OECD reports state that China needs to do more to support technology transfer from public research institutions and in particular to learn from existing OECD countries experiences with legislation that facilitates public private partnerships[67]. However, the Chinese government is increasingly recognising the importance of IP rights to encourage creative and innovative inward investment in recognition of the centrality of innovation to economic development. It should be noted that China's IP regime in the pharmaceutical field still falls short of the standard of developed countries, not least in regards to the enforcement of IPRs and the battle against counterfeiting[68]. However, since 2001 China has been revising its laws and regulations with the aim of strengthening its IP environment and enforcement activities[69].

4. South Africa: Technology Transfer for Economic Growth

South Africa has a reasonably good research base and technological capabilities to build on. However, since 1994, government investment in R&D as a proportion of GDP has fallen, reaching a low of 0.68% of GDP in 1997. It currently stands at 0.81%, compared to the OECD average of 2.26 in 2004. The proportion of researchers in the labour force is also relatively low (2.2 per 1,000 people employed)[70].

To date, South Africa has a relatively poor record in commercialising technologies. On the whole, the research and innovation system has been fragmented, with insufficient co-ordination between different government agencies and departments, and between the public, private and academic sectors. Sub-optimal institutional arrangements (including in the IP field), a lack of incentives for industry–government cooperation and the lack of an institutional environment that promotes the transfer of university-developed technologies to the private sector have been blamed for this[71].

Moving Forward: A More Sustainable Model of Public-Private Technology Transfer Activities

It has been widely acknowledged in South Africa that significant infrastructure investments, skills development, scientific and technological research and the development and expansion of the knowledge

[67] OECD (2007a)
[68] Pugatch, M. P. “Measuring the Strength of National Pharmaceutical Intellectual Property Regimes in Eight Countries: Using a Pharmaceutical IP Index to Benchmark India”, *Journal of World Investment and Trade*, vol.8:4 (August 2007b)
[69] UK Intellectual Property Office, (2005)
[70] South Africa, Ministry of Science and Technology, National Advisory Council on Innovation, 2002. http://www.naci.org.za/.
[71] Garduño, E., *South African university technology transfer: A comparative analysis* International Intellectual Property Institute (January 2004)

economy should be pursued. The commercialisation of research is now among the primary aims of the focus on economic growth and international competitiveness[72].

As a result, efforts are now being made to support innovation and commercialisation. Patenting activity is at present low but is expected to increase as a result of the recent introduction of support programmemes targeted specifically at commercialising activities. South Africa's National R&D Strategy 2002 includes fiscal incentives to encourage and enhance private sector participation in innovation and advocates a clear approach to intellectual property that arises from publicly funded research[73]. In particular, the National R&D Strategy introduced measures to encourage better protection and exploitation of IP arising from publicly funded research projects. This has recently been expanded upon with the 2006 Framework for Intellectual Property Rights from Publicly Financed Research.[74] This framework draws heavily on Bayh-Dole legislation and is intended to bridge the gap between research organisations and the market[75].

The Government has also put greater emphasis on creating an enabling framework for public-private partnerships in the biotechnology sphere, in particular where the National Biotechnology Strategy has been adopted. The strategy aims to ensure coherence between programmemes, provide linkages with large companies and ensure appropriate amendments are made to the policy and legislative framework to create a more enabling environment for biotechnology development and commercialisation[76].

Three Biotechnology Regional Innovation Centres (BRICs) were set up in 2003 to implement the National Biotechnology Strategy of South Africa. Their objectives are to intervene to grow the biotech sector by expanding the business of existing companies and encouraging new and sustainable commercial entities. Their tasks include the provision of technology platforms for defined focus areas, facilitation of shared capital equipment and specialised expertise, human resource development, funding of selected programmemes at existing biotechnology R&D organisations (including universities, science councils and firms), partnering with international organisations and attracting regional anchor investors. They assist in optimising the process of bringing products to market by sourcing and managing funds for R&D commercialisation, managing project risk to improve returns on investment and leveraging knowledge through collaborative networks[77]. BRICs make cautious investment choices by evaluating all project

[72] National Research Foundation, South Africa, Focus Areas: Economic Growth and International Competitiveness accessed 2007. http://www.nrf.ac.za/focusareas/growth/

[73] Department of Science and Technology, 2002. South Africa's National Research and Development Strategy (2002)

[74] Department of Science and Technology. 2006. Framework for Intellectual Property Rights from Publicly Financed Research Department of Science and Technology: Brummeria, South Africa.

[75] Wolson, R., Technology Transfer in South African Public Research Institutions In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices Ch. 17.7 http://www.iphandbook.org/handbook/about/index.html (2007b)

[76] Department of Science and Technology. 2001. A National Biotechnology Strategy for South Africa. (2001)

[77] BioPad: Growing Biotechnology in South Africa, 2007, http://www.biopad.org.za/history.html

proposals and avoiding any projects which raise questions regarding access to or ownership of intellectual property[78].

One example is BioPAD, a Biotechnology Regional Innovation Centre established by the Department of Science and Technology (DST). Its vision is to broker partnerships between researchers, entrepreneurs, business, government and other stakeholders and to identify commercialisation opportunities in order to promote innovation and create sustainable biotechnology businesses in South Africa. The centre was initiated in 2002 and by 2003, 13 multi-institutional projects had been selected and approved in the areas of animal health and production, industry, mining and environmental biotechnology. These were expanded in 2004 to include Human Health and Bio-processing. By the end of 2006 BioPAD's investments in research projects and private companies were approaching R200 million[79].

Other measures that have been adopted to stimulate innovation include the Innovation Fund which comprises The Intellectual Property Management Office (IPMO) and the Innovation Fund Commercialisation Office (IFCO). The fund is aimed at projects that generate new knowledge and create commercially viable products[80]. More recently, it has assumed a larger role in promoting technology transfer and assisting the technology transfer activities of South African institutions and researchers[81].

Success Stories

Instances where public-private partnerships have facilitated large scale projects include the South African AIDS Vaccine Initiative (SAAVI) and the South African Malaria Initiative (SAMI).

SAAVI, an international public–private partnership that aims to co-ordinate the research, development and testing of AIDS vaccines in South Africa, was formed in 1991 as a lead programmeme of the Medical Research Council (MRC) of South Africa[82]. The project currently has several potential novel candidate vaccines under evaluation. Phase I and II clinical trials are underway on products developed out of these international collaborative ventures and two locally developed products are being manufactured in preparation for trials which took place in 2006/2007[60]. SAAVI is acknowledged to be one of the finest biotechnology programmemes in the developing world and filed 5 patents from 1999-2006[83].

A newer initative is SAMI, a consortium of ten research institutions launched in 2006, established to stimulate cooperation and coordination between government and industry to improve malaria prevention. The programme aims to bring together key researchers in South Africa, strengthen local and international

[78] Department of Science and Technology, 2001, A National Biotechnology Strategy for South Africa, June 2001 (June 2001)
[79] BioPad (2007)
[4] Innovation Fund, South Africa, 2007, www.innovationfund.ac.za.
[81] Wolson (2007 b)
[82] The South African AIDS Vaccine Initiative 2007 http://www.saavi.org.za/index.htm
[83] Medical Research Council, A report compiled for the department of science and technology (February 2006)

networks and develop partnerships to provide access to skills not currently available. At the same time, it engages in capacity building efforts that focus on growth of the local skills base, particularly in the use and application of new molecular and high throughput biological techniques[84].

5. Kenya and Nigeria: Recognising the Importance of Domestic Technology Transfer Activities

Across the continent governments have begun to address IP issues in order to develop their own innovation-based industries. In particular, governments, often in partnership with international organisations have tried to harness traditional knowledge and build up R&D and manufacturing capabilities in order to address the problem of neglected diseases.

Public research is pivotal to meeting these neglected diseases due to the lack of sufficient commercial interest in them and subsequently Bayh-Dole type mechanisms need to be in place to effectively transfer the fruits of this publicly funded research.

The aim of facilitating efficient technology transfer in Africa coincides with the Millennium Development Goals and the popular view that for developing countries to meet them, 'they need access to new and emerging technologies which requires technology transfer, technical cooperation and building a scientific and technological capacity to participate in the development and adaptation of these technologies to local conditions' (UN/ESC Report, 2003). Policy analysts argue that to be effective, policies aimed at stimulating innovation require IPRs as incentives and that the role of universities in developing countries needs to be re-examined[85]. The WHO, for example, is cooperating with organisations like the African Union, the African Regional Industrial Property Organisation (ARIPO) and African Organisation for Intellectual Property Rights (OAPI) to establish mechanisms to protect traditional medical knowledge[86].

The major problem in Africa is that chronic under funding of research means that there are often many people involved in the discovery of a drug. Scientists do not have access to the right equipment or expertise to carry out different elements of research and are thus required to hand over their discoveries to other institutions with the correct tools. As a result, deciding how IPRs are shared is very complex. Uncertainties over IP means that many potential drugs do not get developed as scientists often guard their hard work and do not want to share it if they are not convinced they will be adequately rewarded[87].

[84] South Africa Malaria Initiative (SAMI), Benefits and Purposes. 2007 http://www.acgt.co.za/sami/benefits.html
[85] Sachs, J. Investing in Development: A Practical Plan to Achieve the Millenium Development Goals, Millennium Project (2005)
[86] Chatora, R. An Overview of the Traditional Medicine Situation in the African Region in *Traditional Medicine*, African Health Monitor, Vol. 4, No. 1(Jan – June 2003)
[87] Intellectual Property Watch, "Kenya Works To Identify IP Rights In Its Medical Research", (19 October 2007)

The Kenya Medical Research Institute (KEMRI) is one of several institutions in Africa that are currently reviewing policy towards IP to establish how best to share the commercial benefits of any drugs or active ingredients that are developed from research at public institutes[88].

In Nigeria, there has been a growing awareness of the role of IPRs. In 1979 the National Office for Technology Acquisition and Promotion (NOTAP), was established to act as a national agency for the efficient transfer of technology. Beyond the aim of equitable conditions attached to transfer of technology from developed countries, one of the most important purposes of the agency was to promote innovation and commercialisation of useful R&D results and inventions and encourage skill acquisition by indigenous staff.

NOTAP has established fifteen Intellectual Property Technology Transfer Offices (IPTTOs) in Universities, Polytechnics and Research Institutions in Nigeria, to promote interaction and strengthen the linkage between University/Research Institutions and Industries. The IPTTO is designed to develop a robust IPR portfolio through patenting, copyright and technology licensing and to support the Institution's initiative in developing a patent culture. The IPTTO also sets into motion the formal system of incentives and reward that encourages individual researchers to be involved in partnerships. It enables Universities and R&D institutions to use the IP system as a source of technology information and a source of generating wealth and income[69].

As a result, successful technology transfer has occurred in Nigeria. One example is the development of Niprisan by the National Institute for Pharmaceutical Research (NIPRD), in Nigeria; a drug for the treatment of Sickle Cell Anemia, which was then licensed to Xechem; a foreign company, to manufacture[89].

Another success has involved leveraging traditional knowledge and medicine for commercially successful herbal remedies. NOTAP has promised to support Pax Herbal Clinic and Research Laboratories to assist research in the area of ancient African healing systems with a view to modernizing them and making them available to the public. So far Pax Herbals has fifty innovations in herbal products from their R&D efforts[90].

---

[88] The Kenya Medical Research Institute (KEMRI), 2007 http://www.kemri.org/home.html

[89] Okongwu, D.A., 'IPRs and the transfer of technology –African case study', WIPO-WTO Joint Workshop Intellectual Property Rights and Transfer of Technology: (Abuja, Nigeria: 17 November 2003)

[90] National Office for Technology Acquisition and Promotion (NOTAP), Nigeria, 2007 http://www.notap.gov.ng/iptto_index.php

5. Latin America: Commercialising the Results of Strong Research Capabilities

Life sciences are traditionally the best developed area of academic research throughout Latin America. Biology counts for almost 60% of all the basic research done in the region[91]. In general terms, research in life sciences in some Latin American countries is not only strong in relation to other fields of scientific inquiry, but it is of high quality by international standards. Success in the life sciences field in South America exemplifies how having strong research capabilities enables a developing country to address its domestic problems, whether health or agriculture related. For example, the sequencing of xylella fastidiosa, a pathogen affecting citrus production, achieved through the joint efforts of almost 200 Brazilian scientists from more than thirty research institutions was of enormous economic importance, given that Brazil is one of the main world producers of oranges[92].

The richness of biodiversity in Latin America is a very promising source of materials for new medicines. However, generally speaking, excellence in research has not been accompanied by commercially successful innovations, a pattern that differs from what has happened in many highly industrialized countries, even small ones. There are various reasons for this disappointing outcome, in particular the historical lack of political and social legitimacy exhibited by innovation policies. The weakness of the commercial results of Latin American bio-innovation is not an isolated phenomenon. It is part of a more comprehensive pattern of development, where knowledge production and innovation play a small role: public investment in R&D is small and business investment in R&D is also marginal[93].

Paradoxically, despite the potential for innovation, the laws governing the protection of IPRs at the national levels are generally weak. Latin America's problems with patent protection, data exclusivity and counterfeiting have often been justified on the basis of insufficient public access to medicines, lack of sufficient FDI in the pharmaceutical and biotechnology sector and an overall all scepticism about the IP system as a whole. For example, in its submissions to the WHO's recently established Intergovernmental Working Group on Public Health, Brazil urges consideration to mapping out the flexibilities provided for in international IP agreements and discussion of ways to facilitate access to the subject matter of patents relevant to public health needs[94].

Nevertheless, if we choose to divert our attention from the political discussion currently taking place in the international arenas and focus on domestic activities, the picture that is revealed is quite different. As discussed below, domestic research institutions in Latin America do recognise the potential and

[91] Sutz, J., "Strong life sciences in innovative weak contexts: a "developmental" approach to a tantalizing mismatch", *The Journal of Technology Transfer*, vol 32:4 (August 2007) pp. 329-341
[92] Ibid
[93] PriceWaterhouseCoopers publication "Latin America- A Prescription for Growth" (July 2007)
[94] WHO, "Innovation and Intellectual property", Intergovernmental Working Group on Public Health, Item 2.3 A/PHI/IGWG/1/5, (December 2006)

importance of technology transfer activities via the exploitation of IPRs and act accordingly. The relevant national authorities also attempt to provide frameworks that promote and facilitate such activities.

In fact, in the last few years, governments of the Americas have come to realize the importance of innovation to their countries. Within the framework of the Inter-American Council for Integral Development (CIDI), the Organisation of American States (OAS) organised the First Meeting of Ministers and High Authorities of Science and Technology in Lima, Peru, in November 2004[95]. In this summit it was stated that "science, technology, engineering and innovation play a fundamental role in the creation of wealth, economic growth and the improvement of the quality of life for all citizens of the Americas. They generate employment and well-being through innovation and the commercialisation of new products and services; they help reduce poverty, improve education, health, nutrition and trade"[96]. Many countries began establishing agencies and policies fit to enhance academia-industry relations.

Argentina

The Ministry of Science and Public Education is the main governmental branch responsible for creating and implementing innovation policy. It governs organisations responsible for financing R&D activities. In 2002 more than 100 projects were supported with over US$16 million. The nonprofit Foro Argentino de Biotecnología (Argentine Biotech Forum) works to encourage public awareness and collaboration between business and science[97].

Brazil

Today, Brazil is one of the most dominant opponents of the global standardization of IP systems and a champion of the use of compulsory licenses. However, even Brazil has recently adopted several measures aimed at clarifying the rights and obligations attached to applicable knowledge developed by university researchers and recognizes the claim of universities to their IPRs. For example, the Ministry of Science and Technology (MCT) has published guidelines for universities and other bodies concerning the distribution of funds arising from commercialisation and provides research funding to universities only if the institutes adopt and follow its guidelines[98]. The House of Representatives of the Brazilian Congress passed the Innovation Law in 2004 to improve the nation's ability to develop and commercialise technology. Under the law and proposed changes, professors would be able to work for limited periods of time in the private sector without jeopardizing their academic positions. The law also requires universities to create Offices of Technological Innovation that will focus on intellectual property and

[95] Inter-American Council for Integral Development (2004)
[96] Ibid (2004)
[97] DeVol, R. (2006)
[98] Garduño, E. (2004)

licensing. The Ministry of Science and Technology and the Ministry of Health are the two major branches responsible for development of Brazil's biotech sector. In September 2005, the government announced nearly $5 million in funding for stem cell research[99].

Chile

In Chile, the Chilean Economic Development Agency is the main source of support for the development of scientific and technological initiatives, but numerous funds have been established to finance the overall commercialisation process. These include the Fund for the Promotion of Scientific and Technological Development, which focuses on promoting collaboration between academia and industry; and the National Fund for Technological and Productive Development, which encourages technology transfer[100]. At present, the Chilean biotechnology industry is comprised of 95 companies related to biotechnology; almost all emerged from academic institutions[101].

Technology Transfer Success Stories

Biobras is a bio-pharmaceutical firm, located in the Brazilian state of Minas Gerais. The firm was incubated in the Faculty of Medicine of the Federal University of Minas Gerais, in 1971 and began the production of enzymes in 1976, developing later in the industrial production of insulin. The trajectory of the insulin production began with a commercial agreement with Eli Lilly, by which the American firm transferred the technology for the production of bovine insulin. In 1982 this agreement came to a halt and Biobras embarked heavily on R&D activities and human resources enhancement to achieve highly purified bovine and pork insulin. By the end of the nineties, Biobras belonged to the very exclusive clan of firms that produced insulin by recombinant DNA methodologies, alongside with Eli Lilly, Novo-Nordisk and Aventis. In 2000, Biobras held the vast majority (80%) of the Brazilian market. Interaction with universities was a key element in the firm's success - mainly the Federal University of Minas Gerais, the University of Brasilia and the University of San Pablo at Ribeiro Preto; all of whom were involved in the development of the DNA recombinant methodology. The support given by regional and national development banks was also of great importance[102].

In 2007 Chembio Diagnostics Inc. was awarded a Small Business Innovative Research Phase I grant in the amount of $286,000 from the United States National Institutes of Health (NIH) for the research and development of a rapid diagnostic test for leptospirosis, also known as Weil's disease. Leptospirosis,

---

[99] DeVol, R. (2006) pp 313
[100] Bradley, R., "Biotechnology: A Silent Revolution", in *Business Chile* (2005) http://www.businesschile.cl/portada.php?w=old&id=148&s=0&lan=en&q=main
[101] Biotechnology Organisation, Annual International Convention, April 9 – 12 2006

[102] Sutz, J., "Strong life sciences in innovative weak contexts: a "developmental" approach to a tantalizing mismatch", *The Journal of Technology Transfer*, vol 32:4 (August 2007) pp. 329-341

which is recognised as an emerging infectious disease in the United States, affects as many as 500,000 human cases worldwide each year. Development of the test is done in collaboration with the Oswaldo Cruz Foundation in Brazil, the largest research institution in Latin America. The collaborators have developed unique leptospiral antigens that will be used in the proposed work. Patents protecting the novel surface proteins of leptospira were granted in the US, Brazil and Australia[103]. The goal of this project is to develop a rapid point-of-care test for human leptospirosis[104].

Chagas disease is a debilitating parasitic infection found predominantly in Central and South America. It is estimated that 16 to 18 million people are infected with the disease with nearly 100 million people at risk in 21 countries. This includes approximately 25% of the population of Latin America[105]. A collaboration between the regional biotech academic network Programme of Science and Technology for Development (CYTED), Rio de Janeiro, Brazil, with Chembio Diagnostic Systems in Medford, N.Y., resulted in the production of kits for the early detection of Chagas disease[106].

VI. Conclusion

Can IPRs be used as a vehicle for technology transfer activities via public private partnership? Our research suggests that they can and that they are. And not only in developed countries but also in developing ones.

Arguably, the ability to protect, manage and commercialise IPRs is not the only prerequisite for efficient technology transfer. Other factors such as venture capital, labour mobility between the public and private research sector and public funding for research play a part alongside a comprehensive patent system. Cultural changes within publicly-funded institutions to encourage faculty to engage in technology transfer activity and engage with the private sector are also necessary.

However, an effective IP climate – which includes both the ability to use IPRs at the micro-level as well as to protect it at the macro level - can facilitate public-private partnerships. In particular, the ability to license patents clearly provides a huge incentive to bring new products to market.

The Bayh-Dole/Stevenson-Wydler models first introduced in the United States in the early 1980s - essentially providing public research bodies with the ability to own and commercialise their IPRs - created a revolution in the way in which technology transfer activities between public and private bodies took

[103] Ko, A., *surface proteins of leptospira*. Brazil patent no. BR0308180A, US patent no. US7108853, Australia patent no. AU3215452AA. (2003)
[104] "Chembio Diagnostics Receives NIH Grant to Develop Rapid Point-of-Care Test for Leptospirosis" in *COMTEX News Network* (20 Sept 2007)
COMTEX News Network (2007)
[105] Chembio Diagnostics (2007)
[106] DeVol, R. (2006)

place. This framework has since then been emulated and adjusted wholly or in part in many developed countries, bringing about an explosion of technology transfer activities.

The evidence gathered in this paper suggests that this is also the case for developing countries. The examples outlined in this paper demonstrating that developing countries that support and allow public research institutions to engage in technology transfer activities via the exploitation of IPRs can bring significant benefits to their economies and citizens.

Moreover, the evidence suggests that such activities allow developing countries to better address domestic health concerns. That is because many of the research centres in developing countries are already focused on the development of therapeutic solutions to local diseases and conditions.

The paper also demonstrates that, while political debates that are currently taking place in international organisations tend to rely on the proposition that the global IP system does not work for developing countries, de facto IP-based technology transfer activities are already taking place in these countries.

From a more pragmatic point of view, it is important that developing countries review their IP policies with the aim of allowing public research bodies to own the IPRs arising from their work, as well as well to support these bodies efforts to become more professional in the management, commercialisation and exploitation of these rights.

Finally, it should be noted that the ability to engage in public-private technology transfer activities that are based on the commercialisation of IPRs are linked to the overall level of IP protection provided in a given country. Put simply, when the overall environment is supportive of the protection of IPRs this is also likely to have a positive effect on the rate and volume of technology transfer activities and vice versa.

As such, developing countries seeking to engage in technology transfer activities that are based on public private partnerships should do the following:

At the macro level – developing countries should:

- Not be afraid of implementing a robust IP system and should actually take steps to promote it
- Adopt a legislative framework that allows public research institutions to own the IPRs generated from their work (including patents)
- Provide the necessary degree of freedom for public research bodies to engage in technology transfer activities that are based on the commercialisation of IPRs via licensing agreements
- Allow public research bodies, as well as researchers, to receive most if not all of the income generated by the above activities (i.e. from royalties), as this will ultimately feed into future R&D

activities by these institutions, as well as providing a platform for growth for the economy as a whole

- Put in place National Innovation Strategies that take a comprehensive view of innovation and the myriad of ways this can be stimulated i.e. addressing IP issues, providing research funding and facilitating innovation networks
- Establish a system of government grants to support licensing activity
- Encourage mobility between the public and private sector

At the micro level - public research institutions

- Should consider technology transfer activities to be an inseparable part of their overall research activities
- Foster an entrepreneurial culture within academic institutions, aimed at supporting and incentivising its researchers to engage in technology transfer initiatives.
- Educate researchers and employees about the role and function of technology transfer and the commercialisation of IPRs
- Develop professional skills associated with technology transfer activities, mostly by establishing specialised technology transfer offices that employ professional and skilled staff
- Clearly define the legal and operational relationship between the public institution and its technology transfer office
- Create and implement guidelines and operations procedures for technology transfer activities taking place in institutions – from the researcher's lab, through to the technology transfer offices and on to successful licensing agreements
- Provide adequate financial incentives, including a share in royalties, to researchers and staff that are responsible for the knowledge and inventions underlining technology transfer activities