# ATDF JOURNAL VOLUME 3, ISSUE 3

INNOVATION;

TECHNOLOGY;

TRADE;

**DEVELOPMENT** 



"Intellectual property has the shelf life of a banana"

(Bill Gates)

### HIGHLIGHTS:

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- 2. Entrepreneurship Challenge Award Strictly for young people starting up, especially graduates.

Challenges of funding renewable natural resources research

Intellectual property clearinghouses as an institutional response

A role for intellectual property in Africa?

Facilitating Trade in Drugs: An account of the WTO's agreement

Is Intellectual Property a Catalyst for Development?

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Chisokone Market, Zambia. Where the future mingles harmoniously with the past.

(Source: Konde, ATDF)

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Edited by Anatole Krattiger et al

# CHALLENGES OF FUNDING RENEWABLE NATURAL RESOURCES RESEARCH AND EDUCATION IN SUB-SAHARAN AFRICA

### August B Temu, ICRAF, Nairobi

### **Abstract**

The purpose of this paper is to encourage an intellectual debate. I have deliberately avoided the common rhetoric and poverty statistics that have recently come to characterize or accompany any statement on Africa. For so long, the rhetoric that Africa is poor and therefore incapable of spawning its own development has dominated communication and information systems that they could become "facts" in the minds of some people. If this is not nipped in the bud, especially for the youth of Africa, it will cost the continent dearly in terms of future development. The only way we can sustain development in Africa is to recognize and engage our own intellectual and physical strengths for that purpose, while tapping into our natural capital. It is argued that natural resource education, research and innovation should be funded from the very resources that we are seeking to improve. Thus the starting point is an analysis of the values we should assign to research and education.

### Valuing research and education

Investing in research and education is predicated upon an appreciation of the value of knowledge. Research is a tool for producing knowledge, which can be a public or a non-public good depending on the circumstances. So there must be a quest for knowledge for research to be supported. Knowledge is generally a neutral product which can be used to the benefit or detriment of society. Unfortunately, not all knowledge from research can be applied freely. Depending on the purpose of research and the objectives of the researcher, the knowledge generated can be put into two main categories as elaborated in the Table 1, adapted from Kolliker (2004).

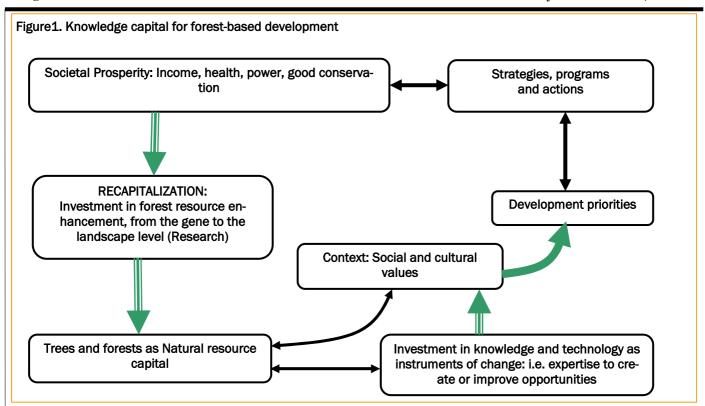
Non rival knowledge is like research methods. The meth-

ods can be used by anyone without being diminished. However, they can be protected by patents or intellectual property rights and thereby be restricted in use to only a few individuals or institutions. Such exclusion defines the product as a *club good*; otherwise it would be a public good. Rival knowledge or good is one that is diminished by use, such as the discovery of a use for a non-renewable natural resource. Again, depending on rights and the availability of such knowledge, it can be classified as a private or a common pool resource.

Knowledge generated from publicly funded research is not necessarily a 'public good'. In other words, the "public-ness" of a research product is not an inherent characteristic of the product itself, but depends on the producer and the purpose for which it is produced. What we can learn from Table 1 is that research has to be set up in a manner that produces a clear output, whose ownership and use can be defined by persons or the institutions involved, often called the stakeholders. Thus, research must be seen as a business that generates useful products or services, which, in terms of usage, can be restricted or made public as desired. This reasoning is important for us to determine who should invest in renewable natural resources research and why.

The general purpose of research is to raise the overall amount of knowledge known about a particular subject or object, so it feeds well into educational and societal needs. In Figure 1, a conceptual model is presented, where research is part and parcel of resource development, management and utilisation. Any renewable natural resource would be valueless if it is not viewed in the context of society's social, cultural and economic needs. Research helps us to relate the physical condition of the resource with these societal values in order to articulate and prioritize strategies and interventions that bring prosperity. Again, research is necessary for us to de-

Type of good	Limits in availability	Qualification
Non-rival	Non-excludable	Public good
(i.e. not diminished by use,	(everyone can access and use it)	
e.g. research methods)	Excludable	Club good
	(e.g. through IPR or patent)	
Rival	Non-excludable	Common pool resource
(i.e. diminished by use, e.g. use for a non-renewable mineral)	(everyone can access and use it)	
	Excludable	Private good
	(e.g. through IPR or patent)	



velop recapitalization strategies that sustain both the natural resource and its contribution to prosperity.

Investing in research is similar and complementary to investing in education. The former generates knowledge whilst the latter is a tool for sharing knowledge. In an ideal situation, the two are mutually supporting. Education influences change in society, and likewise, society influences the content of education.

Good education raises the level of knowledge in specific areas, enabling society to better analyze, make choices and take appropriate actions. Likewise, the experiences of society influence institutions of learning as well as the learning experiences by putting into context what happens when certain knowledge is applied in a particular circumstance. So both education and society continue to shape each other, achieving a dynamic synergy.

This understanding makes the case for substantive investment in renewable natural resources research and education. A critical question is: How well are our research and education efforts in natural resources linked and mutually reinforcing? From available experience, it would appear that natural resources research and education are designed and managed independently. They sometimes compete for resources. Institutions of learning have great responsibility in generating, collating and sharing knowledge, yet currently they do little more than sharing knowledge, and even that, largely with students and not communities or industry.

A recent survey of forestry education in Africa and Southeast Asia (Temu et al 2005) concluded that there is an urgent need for foresters to be competent in:

linking tree and forest management to actions and strategies to achieving social and economic development goals,

managing tree and forest resources in a broader context of sustainable natural resources and environmental conservation,

innovating in the wider areas of agriculture, forestry and renewable natural resources

stimulating entrepreneurship in community and private forestry, and

strengthening linkages and synergy among natural resource sectors and between them and agriculture.

In other words, the technical substance of forestry education must be contextualized in the African situation, solving African problems and fitting the social, cultural and economic settings of Africa, while at the same time being sensitive to global society and environmental concerns. This should be true for education in other renewable natural resources.

### Investing in research

Currently in SSA the responsibility for research on lands, forestry, wildlife and fisheries is almost exclusively in the public domain. Private sector research initiatives are quite restricted both in scope and in space to where it makes business sense. This leads to the debate on whether research in renewable natural resources really requires special attention. The easiest response is to refer to the key role played by natural resources in the livelihoods of our people, and the current threats to the

natural resources. An even stronger argument though is to show what research is able to deliver. We can also argue for research by stating the cost of not doing it in a specific area. St. Paulia, a beautiful violet flower from the mountains of East Africa became a multi-million Euro business in Europe, completely eluding the attention of local researchers. So funding and participating in natural resource research is indeed very important. Research on St Paulia was funded by UK government (Peter Wood 2006 – personal communication).

There is a need to make natural resources in SSA work better for development, through effective research. To leverage local funding and participation in natural resource research, we have to demonstrate that renewable natural resources research really works for development. This should create the demand for research.

But some past research investments have produced disappointing results. Here is an example. In one country, research on timber utilization was carried out for over 40 years. The main focus was to investigate the potential utility of indigenous tree species, by determining their fibre characteristics and strength properties. Quite a few scientific publications were produced, but they stopped short of one critical result - helping the development of mechanisms to make better use of the timbers. In other words, they generated knowledge but could not move it into use. After 40 years of funding by government and development partners, the research support was scaled down so much that today it is practically only symbolic in terms of size and activities. So after so many years of public investment, it was still unclear what exactly the country was getting out of it, because there was an underlying assumption that the private sector would take up and use the research findings. That did not happen. The inability of research institutions to transform research results to practical applications for development is one of our main weaknesses. But this is also linked to problem diagnosis and setting the objectives of our research. All too often the end users of research results and other stakeholders are not involved.

Most renewable natural resources in SSA are under public responsibility. In such a situation, governments would be expected to generate or at least create conditions for other stakeholders to support research that generates the knowledge needed to improve benefits from our renewable natural resources. This is not happening at the expected scale, ostensibly because we are unable to generate research funds. I would argue that our natural resources can generate the funds needed for research. Nothing stops us from using our own natural resources for this purpose.

It is clear that the Consultative Group for International Agricultural Research (CGIAR) centres are able to secure funds for natural resources research because of two main advantages: First they have the critical mass of scientific knowledge and skills needed to address the research problems and second, they have the needed management and accountability capacity to deliver on their research commitments. So why is this not true for national research institutions in SSA? Literature searches on the subject show a large volume of criticisms on governments, research funding institutions and the African academia as the main culprits for failures in research in general. We can focus on what we can do to leverage and sustain funding for renewable natural resources research, by considering the following approaches:

- building on available and locally contextualized knowledge in order to maintain relevance
- ⇒ improving institutional frameworks for research
- ⇒ strengthening human capital for research
- rationalising research capacity and strengthening integration of research institutes and universities, and
- enhancing coordination and regional cooperation.
- ⇒ All these ideas are quite familiar, yet they are far from being implemented.

## Building on available and locally contextualized knowledge

Africa has biological wonders: The Namibian desert plant (Welwitschia mirabilis) that grows only two leaves and can live for over 1000 years supporting a myriad of other life forms as it switches between C3 and C4 states; the giant frog Canrana goliath in Congo which can produce several kilogrammes of meat; the rare mammalian frog in Tanzania that has intrigued scientists; and so many organisms macro- and microscopic in our rich biota remain only partially untapped to benefit Africans (Mshigeni et al 2000). Africa is quite rich, but Africans The abundance of natural resources (renewable and non-renewable) as exemplified in DRC, Angola, Sierra Leone, Sudan, Gabon, Nigeria, Liberia and most of the countries in Sub-Saharan Africa (in terms of biota) is intriguing and by far supersedes many other countries in the world that are developed or classed as transitional economies. However, our management of natural resources proves beyond doubt the adage that "possession of natural resources is in itself only an indicator of the potential for development, but does not guarantee development". And so it has remained for Africa. Serious research is needed to expand the knowledge available today and unleash the potential for improving the well-being of people. There is no shortage of exciting areas of research! But for us, exciting research must also make exciting economics!

There are many examples of traditional African scientific innovations. The extraction of preservatives from *Commiphora myrrha* that were used for mummification of

dead bodies is well known but poorly appreciated traditional African science. The preparation of "old man's tea" from the bark of Prunus Africana as prophylaxis against prostrate cancer received global attention only recently, and is currently exploited by France, importing the tree bark from Africa to extract the cancer preventing ingredients. The business they generate is based on ancient African research findings! The fields of human and animal nutrition and medicine provide thousands of examples of this kind. What is worrisome is what this generation is doing, or stated more appropriately, not doing to improve and use such knowledge. Let us steer away from 'ethno-altruism' as expounded by Lettmayer (2000), in which traditional values and approaches can be blindly glorified over foreign ones. Sinclair and Joshi (2000) explain how traditional knowledge can selectively be captured and utilised in research. Various methods exist for doing this effectively. The claim often made that we do not have enough funds to support research is inaccurate. Our greatest weaknesses today emanate much more from our own attitudinal orientation and ineffective institutional establishments, including organization, governance and integrity. There is a huge wealth on knowledge (both indigenous and external) that is poorly utilized despite strong evidence that it could play a role in driving Africa out of poverty. The starting point is to understand the demand for research.

### Is there an established demand for renewable natural resources research?

The majority of SSA's rural population relies directly on agricultural production and direct extraction from natural resources to sustain livelihoods. The export trade is dominated by direct extraction and sale of natural resources and some primary processing of agricultural produce, much of it in the hands of private institutions. Thus, the region's development is heavily anchored on agriculture and natural resources. Enhancing science and technology through research in these fields is an essential lever for accelerating development in general and rural development in particular. Many ambitious commitments made by SSA countries and their development partners on raising the lot of the rural poor cannot be achieved because our investment in science and technology as the backbone for development is inadequate. So while there is a huge demand for research, scientists are not properly linked to it. There is little evidence that scientific innovation arising from our research has contributed in a significant way to development, and this may underline the reason for weak public funding for research.

Local communities have an enormous wealth of knowledge that requires some of fine tuning through research to contribute to real improvements of their lives. From the mortar that pounds the yams to the multistorey agroforestry farming systems that are so ecologically designed, we scientists have great opportunities to add value. My challenge to every one of us is to identify

just one item where his/her research and innovation can make a difference. The demand for research is large, but it is currently obscured by inadequacies in policy, institutional arrangements and, most of all, attitudes of scientists.

### Improving the institutional framework for research

Nyerere (1990) pointed out the weak institutional framework and investment in science and technology in The South. He counselled The South to enlarge its capacity and commitments in order to benefit effectively from science and technology (S & T). Apparently, this advice was well heeded by Asia but was largely ignored by Africa. Working S & T institutions with appropriate mandates and with long-term vision are only second to having the human capital This is currently appreciated by African leadership, and is the basis for NEPAD's efforts to promote institutions of excellence in Africa. This has involved the construction and equipping of laboratories as well as training of scientists. It has to be understood that excellence is attained or achieved, not constructed. It is imperative therefore that the "institutions of excellence" are conceptualized and promoted more in terms of programmes, intellectual leadership, and less in terms of physical infrastructure and facilities although these too are important. They would then be institutions for excellence.

A good institutional base is a fundamental requirement for research and education to thrive. Many aspects of RNR for instance forestry, soils, water and wildlife management cut across sectors. Actions taken in any of the sectors can have profound effects on the other resources. However, in many countries the sectors have separate and independent institutions in both research and education, and sometimes the communication among them is very limited. Thus beneficial synergies are foregone. Quite often we experience competition, duplication of efforts and diverging perspectives on specific approaches to RNR management. In such an environment, we are unlikely to excel.

Despite ecological similarities collaboration across countries is complicated by the high diversity of institutional structures and their parent ministries. An obvious cost in this institutional dispensation is the size of institutions. We have many small institutions whose capacity to work beyond their internal management processes is quite limited, let alone engaging in regional and international collaboration. We need multi-sectoral linkages that can improve efficiency. For this to happen it is necessary for those in academia to begin by overcoming our disciplinary barriers within departments and faculties and expand integrative education programmes (Temu 2004).

A good working environment: This is not a new idea. All of us are looking for better physical facilities, good ex-

posure, attractive salaries and benefits. Many reports lament the poor remuneration of academics that leads to the brain drain. While that is true, we also have internal brain drain, where scientists spend a disproportionate amount of time doing private activities and consultancies that very often do not even add to their skills. This 'internal brain drain' can be substantial. Many authors recommend increases in salaries and benefits, despite the persistent evidence that this rarely happens. If countries are not investing is research, why would they invest in researchers? Again, the problem lies in the fact that we have not been able to demonstrate that our research really pays off.

### Strengthening human capital for research

Human capital is central in any discussion of science, technology and development. As human beings, we are responsible for creating the right mindsets, policies, institutions (and institutional arrangements) and knowledge and innovations that improve and sustain our livelihoods. This is true at all scales, from the individual to the whole nation or humanity. Research is a very powerful tool for generating knowledge and innovation, the primary requirement for which is human capital. Education, training and exposure are essential elements that build the competence for research, as for many other competencies

High standards, reliable scientific skills and a sustained critical mass for research are crucial. Merger of sectors as proposed above can help, complemented by synergy of research with educational programmes. The great wealth of graduate students in our universities is yet to be tapped to implement national research programmes. This is a strategic issue which is easy to tackle but often overlooked.

We have some good work such as the identification in *Thaumatococus danieli* (Nigeria's sweet berry) of proteins that have 1600 times the sweetness of sucrose (Ogunseitan 1991). We can be proud of that. We also know of the identification and cultivation of red seaweeds in Zanzibar, the biological control of water hyacinth on Lake Victoria, and the new rice "Nerica" with Vitamin A by WARDA. But we know that African scientists contribute only 0.7% of global scientific publications, a disproportional contribution considering that Africa has about 11.5% of the global population. In the area of agriculture and natural resources we are slightly better off, with about 2% of all publications, but mostly from agriculture!

In 2003, The International foundation for Science (IFS) carried out studies in East Africa that clearly demonstrated that the average age of scientists at research institutes and universities is rising sharply, due to declining interest in research and academic jobs. To build up interest we must first demonstrate that science and

technology are being adequately exploited to drive development. In other words, we must attract local interest and investment in science and technology before expecting others to support us. Secondly, we must recognise and reward scientists and innovators appropriately and encourage them to move up the scientific ladder. Thirdly, we must create the right conditions for science and innovation to flourish. The best starting point is with research that relates directly to our social/cultural settings and especially with existing indigenous knowledge. Let us scientist incentivise the public by producing very useful products and innovations that will attract attention and support for our work.

### Rationalising research capacity and strengthening integration of research institutes and universities

A common practice all over the world is to divide our research programmes according to the standard scientific sub-disciplines. Thus soils research is seen as soil physics, soil chemistry, soil biology, biogeochemistry, soil carbon, and so on. Most problems requiring research solutions cut across these traditional sub-divisions. In forestry we have the traditional divisions of silviculture, engineering, wood technology, social science, economics and forest management. Quite often, research programmes are developed against these academic frameworks, and understandably, donors could not fund such programmes because they are drawn from structures that do not reflect the research problems or needs. With this approach, we are quite unclear on exactly what we are marketing to the funding agencies. Thus their reaction has been justified - choosing their own priorities and requiring us to frame projects within defined limits.

A cursory examination of current forestry research trends shows a downward spiral of hard science and emergence of a myriad of survey-based data largely focused on gender and participatory philosophies and practices. There is no doubt that these are important subjects. Our concerns are that they are done at the expenses of all other prime science topics; they rarely produce tangible results that can be extrapolated beyond the local survey area/community; and by investing such a large proportion of support in this area, donors skew (probably inadvertently) the balance of Africa's forest research agenda. The trend is palpable in other natural resource sectors and agriculture

Another crucial aspect is a new drive to demand that research projects demonstrate impact on livelihoods. Many strategic research areas are unlikely to produce results that have immediate impact on livelihoods, unless a project runs for a fairly long term. Most research projects are generally for small amounts of money (<US \$ 100K) and run for up to 3 years. There are challenges in making such projects respond to long term needs, so naturally they are crafted to address shorter-term needs. We therefore experience low cover-

age of certain areas as hydrology, land degradation, land use change, climate change and serious development of novel products and services from forests.

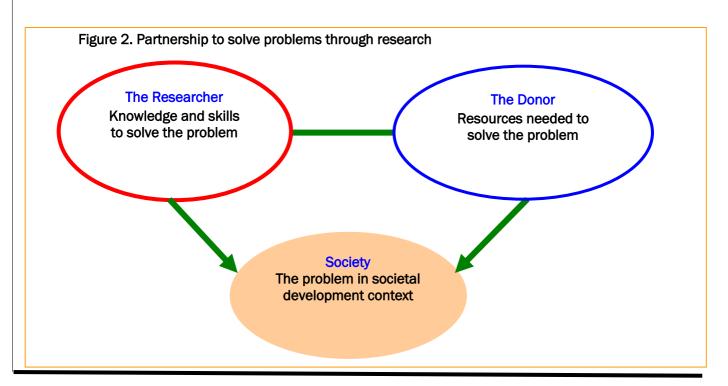
A stable (but not static), relevance research programme, with mechanisms to support dissemination of research findings is needed. It is fair to say that many national institutions have gone through participatory processes that led to the development of research programmes. However, the outcomes ought to be put into meaningful development context. For instance, it is helpful to express research programmes in the context of local and national poverty reduction strategies and Millennium Development goals (MDG). This helps us to demonstrate the contribution of the RNR sectors to real development, and that can attract local funding for research. Enabling scientists to work directly with communities and institutions that are experiencing the problems will improve context and eliminate the need to have additional personnel and structures for the dissemination of research findings. A good research strategy should be based on three key and interlinked domains: natural resource content, societal demand for products and services and ecosystem functionality (Hollier et al 2005).

A research funding organization is much like a coinvestor with the scientist. The funding agency has money and wants a solution to a specific problem. The scientist has knowledge and skills which can be used to resolve the problem, but s/he lacks the resources to carry out the research. Thus what we need is a research partnership, not a donor-recipient relationship. Unfortunately the latter has become so much the reality that scientists now accommodate donor demands, and are busy with project proposal writing protocols, funding restrictions and evaluations. They do not question the relevant or rationale of donor choices of research priorities, countries, institutions or individuals. All too often they accept donor conditions as givens, while the scientist practically cannot create conditions for the application on his/her knowledge and skills. This must be reviewed, and universities should lead that change, because they operate from a position of relatively higher freedom. What is needed is real partnership as depicted in Figure 2 and fair recognition of inputs by all parties, and not a one-sided dictation of conditions.

A fragmented approach to RNR research is a critical weakness in Africa. Research funding organizations develop their own research support strategies and programmes with very limited coordination. Due to inadequate local research support, our national research institutions, set aside their own research strategies and programmes, and bend over backwards to receive limited research support that diverts their time to issues It is hard to sell full prooutside their priorities. grammes to donors, who tend only to support projects that contribute to their own specific priorities. This approach scuttles the national research strategies and programmes and also undermines the scientific knowledge and skills of national scientists, as they often find themselves responding to international calls for research support in areas marginally related to their specific competencies. The result is - yes, we have RNR research taking place, but it is poorly articulated to provide the answers to the right questions.

### Enhancing coordination and regional cooperation

An aspect related to rationalization is the need to achieve some sort of harmony among the natural resource disciplines, improve collaboration across institutions and countries and improve collaborative bargaining. Agriculture has achieved funding success by form-



ing the sub-regional networks (ASARECA, CORAF and SADC-FANR) and a regional research network (FARA). They all have partnerships with the CGIAR system. RNR institutions are lamentably far behind in this approach. AFORNET and FORNESSA are good initiatives in forestry but are still in a nascent stage.

One of the ways we can promote regional cooperation in RNR education and research is through ecosystem-based assessment of education, training and research needs. From the start, we can recognize the main ecological settings such as dry lands, sub-humid, humid, mountain and coastal systems and these can be further categorised according to land use (agriculture, forestry, marine, wildlife conservation etc). Adding the sociopolitical and economic parameters would give us a sufficient base for putting together the cross-border research and education programmes that are collaborative and fundable as independent entities. Such an arrangement also has the potential to avert conflicts on natural resources. In short, we need better coordination and cooperation.

Byron and Turnbull (1998) pointed out some challenges in forestry research

Current forestry institutional structures are unsuitable for proper integration of disciplines

Forestry objectives are still primarily focused on public service, while policies have shifted to private and community arrangements. This causes confusion.

Current funding for forestry (education and research) is still weak

These observations are relevant to other areas of renewable natural resources and education.

### **CONCLUSIONS**

Research generates knowledge while education organizes and shares it, so the two are very closely linked. They should be treated as such in terms of policy and institutional arrangements. Supporting research is a reflection of a societal demand for knowledge. In renewable natural resources the demand is obscured by the inadequate policy, institutional arrangements and attitude of scientists. Current research suffers from among other problems, poor links with national development needs, and the lack of systematic and usable methods for qualitative assessment of natural resources; narrow focus of current projects and activities and strong dependency on external funding sources. Renewable natural resources in SSA are capable of funding research if the policy would allow it. What is needed is a clear vision of the benefits of research and serious commitment to fund and implement research from using a small portion of the renewable natural resources. The following recommendations are worth considering:

Renewable natural resources research policies and institutions should be re-designed to respond more directly to development needs such as addressing food and nutritional security, poverty and incomes, agricultural sustainability and conservation;

There is a need to create stronger vertical and lateral integration of disciplines and sectors to enhance synergy and efficiency;

Policies should be amended to encourage the use of renewable natural resources to fund research and education programmes:

A dedicated human resource development and sustenance is needed to achieve high standard of scientific and management skills needed (this includes improved working environment);

Effective mechanisms are needed to support dissemination of research findings and securing feedback from end users:

There is a need to promote eco-regional approaches as a way of achieving regional coordination as well as building adequate capacity for research investment and improving regional cooperation.

Globalization and opening up to private sector opportunities has hit the natural resources sector through intensified harvesting of raw materials, but not at all in research or education. This observation requires follow up. Finally, without attitudinal changes within the forestry and other natural resource sectors and serious efforts to sell research in development lexicon, it is highly unlikely that there will be a change in RNR research investment.

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# INTELLECTUAL PROPERTY CLEARINGHOUSES AS AN INSTITUTIONAL RESPONSE TO THE PRIVATIZATION OF INNOVATION IN AGRICULTURE

### Gregory D. Graff<sup>1,2</sup>, Karl Bergman<sup>3</sup>, Alan Bennett<sup>1,4,5</sup>, David Zilberman<sup>2</sup>

### **Abstract**

Intellectual property clearinghouse organizations such as the Public Intellectual Property Resource for Agriculture (PIPRA, Davis, California, USA) and the African Agricultural Technology Foundation (AATF, Nairobi, Kenya) have been created to help agricultural researchers navigate access to agricultural technologies protected under intellectual property rights.

### Introduction

For well over a hundred years, public-sector research programs at universities or government institutions around the world have been providing service of developing new crop varieties. Once developed, new crop varieties were typically released publicly; made available to seed companies, nurseries, and farmers without restrictions on use, whether for commercial agriculture or subsistence agriculture. In the last two decades however, the nature of crop variety innovation has changed dramatically in response to both the breakthroughs of biotechnology and legal innovations in the area of intellectual property (IP). While the United States has been at the lead in both respects, the resulting privatization of innovation in crop genetics has had global implications affecting and in fact constraining the technical options available to public sector crop development programs everywhere, including Africa.

Plant genetic engineering, pioneered in the 1980s, has led to new technical possibilities for altering the traits of crop plants in a controlled manner, but the technologies involved are very advanced and constantly evolving. Three distinct types of technologies emerged as essential to developing new biotech crops: genetic transformation techniques themselves, specific genes, and elite breeding materials or germplasm. The new paradigm of biotechnology introduced a technical ability to separate and recombine these three component technologies to create new crop varieties with new and powerful capabilities. Public sector researchers were often in the vanguard making the research breakthroughs that enabled plant genetic engineering.

In the United States in 1980 two landmark legal and legislative events occurred that would come to impact upon public sector agricultural research. First was the decision of the Supreme Court in *Diamond v. Chakrabarty* to allow the patenting of microorganisms that embodied man-made biotechnological inventions. The decision was extended in 1985 to cover plants, introducing new possibilities to exploit commercially the

emerging recombinant DNA technology in agriculture by patenting a new biotech crop variety itself. Second was the passing by the U.S. Congress of the Bayh-Dole Act (Public Law 96-517, 1980) to allow and encourage universities in the U.S. to patent and license newly invented technologies to the private sector. This legislation led to institutional policy shifts at many universities and the establishment of technology transfer offices (Graff, Heiman, and Zilberman, 2003). Outside of the U.S., while patenting of crop varieties is not widely practiced by other governments, the combined influences of international agreements, including the Trade Related Intellectual Property Rights Agreement (TRIPs) agreement of the WTO, bilateral trade agreements, and the Union for the Protection of New Plant Varieties (UPOV). have led to general strengthening of the IP environment for all of the technologies essential to the development of biotech crops. More recently other countries have been adopting laws and regulations that, like the Bayh-Dole Act, allow and encourage their universities to patent inventions.

Following Diamond v. Chakrabarty and the Bayh-Dole Act in the U.S. and similar policies in other countries. university-developed technologies have been increasingly protected by intellectual property rights in accordance with the new policies. Agriculture has been one of the fields-along with medicine and engineering-to be most affected. Some fundamental tools used for plant genetic engineering have been licensed by the universities to companies in the private sector under exclusive terms. While this has encouraged and been accompanied by an increasing level of private sector investment in crop variety development, one result for public sector researchers, however, is that once a technology is patented and exclusively licensed it is no longer available for the development and public release of any new biotech varieties by university based developers (Wright, 1998).

It is true that use of patented technologies further upstream in the research activities of universities continues to be allowed in most countries under formal "research exemptions". In U.S. patent law, there is not a formal research exemption, and university researchers using patented materials are operating in something of a legal grey area, under a *de facto* research exemption arising from the fact that there is simply no precedent for companies to sue universities for patent infringement. This *de facto* exemption has been circumscribed and narrowed in a recent decision by the U.S. Supreme Court in *Madey v. Duke University*.

During the mid 1990s the seed industry in the U.S., and to a lesser extent in Europe and Latin America, saw the entry of many larger chemical and pharmaceutical companies attracted by the potential of selling genetically engineered crops in combination with or in place of agricultural chemicals, their core line of business. Large agrochemical firms eventually acquired most of the smaller R&D companies and all of the major seed companies in the U.S., significantly consolidating the agricultural inputs industry (Graff, Rausser, and Small, 2003). This development towards larger companies was driven, in part, by the difficulties and high transaction costs of licensing technologies, combined with the valuable synergy effects of integrating the different component technologies (including plant transformation tools, genes, and plant germplasm materials) needed to develop biotech crop varieties.

Agricultural research today is increasingly characterized by incremental improvements of the existing transformation tools, trait genetics, or plant materials, with each advance yielding new and increasingly overlapping IP rights. In the current environment a robust corporate patent portfolio that spans all three areas of technology not only allows an optimization of technical synergy effects, but in some cases merely provides "freedom to operate" (FTO) in the marketplace. Freedom to operate is defined as owning or otherwise having access to rights to use the full range of technologies embodied in a product, minimizing or eliminating the risk of infringing patents held by others. The mergers in industry have resulted in a handful of large firms that control most of the vital IP.

The public sector has been left in stewardship of a highly fragmented IP-portfolio and an ever diminishing public domain. Today, at least in the U.S., neither the public domain nor the patent portfolio of any single public sector institution can offer all of the necessary key technologies to enable the development or commercial sale of a new transgenic crop variety. The upshot is a situation in which public sector actors and small entrepreneurs are restricted, lacking access to the full set of IP necessary to bring new crops to market. One highly publicized example of this problem was the development of "Golden Rice" (pro-vitamin A) which was constrained by 70 different patents or contractual obligations associated with material transfer agreements (Kryder, Krattiger, and Kowalski, 2000).

Yet, considered as a whole, public sector organizations in 2001 owned a large proportion of the industry's technology (24% of all agricultural biotechnology patents), more than any single firm. (Monsanto at 14% was the largest.) It was reasoned that this 24 percent of the industry's patents should contain variants of all or most of the key technologies needed to enable the development of new transgenic crops. The difficulty lay in coordinating access to all of those different technologies. Actors in the public sector and others restricted by lack of access to IP could thus benefit from collabora-

tion between universities and other public research institutions in the management of their collective IP to identify and bring together those technologies (Graff et al, 2003). This realization fueled the formation of PIPRA, the Public Intellectual Property Resource for Agriculture (Atkinson et al, 2003).

# 2. The formation of PIPRA as an intellectual property clearinghouse

PIPRA was established in 2004 as a coalition arising out of a dialogue among a dozen major universities and research institutes, with catalytic leadership and funding provided by the Rockefeller Foundation and the McKnight Foundation and expertly facilitated by the Meridian Institute. After a competitive review of proposals, the University of California, Davis was chosen as the host for PIPRA's headquarters. PIPRA currently has a staff of seven located at UC Davis. PIPRA can be found online at <a href="https://www.pipra.org">www.pipra.org</a>.

The organization is growing quickly—now consisting of over 40 member institutions from eleven countries, including several of the leading international research institutes of the CGIAR. When joining PIPRA, a member institution signs a Memorandum of Understanding whereby the institution agrees to cooperate with the other members on a number of issues. First they agree to help develop guidelines or "best practices" for licensing to encourage product development across as wide a range of applications as possible for the broader public benefit, practices such as retaining rights for research use and humanitarian use of a licensed technology. They also agree to contribute non-confidential in-house information to a common database that provides an overview of what agricultural technologies across all PIPRA member institutions portfolios are available or unencumbered. Finally, in the MOU they agree simply to explore the possibility of bundling certain technologies to facilitate commercial and/or humanitarian uses. (A copy of the MOU is online at <a href="http://www.pipra.org/docs/Memorandum%">http://www.pipra.org/docs/Memorandum%</a> 20of%20Understanding.doc.)

The fundamental mission of PIPRA is to make agricultural biotechnologies more readily accessible for the development and distribution of subsistence crops for humanitarian purposes in the developing world and neglected commercial specialty crops everywhere in the world.

### 3. The services provided by PIPRA

To fulfill that mission PIPRA's efforts are roughly divided into four general platforms: Information and Analysis, Educational Services and Outreach, Biotechnology Resources, and Collaborative IP Management.

### 3.1 IP information and analysis

One of the long-term aims of PIPRA is to provide freedom to operate (FTO) for public sector research and commercialization activities within the key technologies of agricultural biotechnology. In the short term, the organization works to reduce uncertainty concerning the IP status of

commonly used technologies, identifying where there may be FTO or how it might be achieved. This requires intensive study of the scope of existing IP claims and detailed comparison of what is available and what is not. Such analysis is routine in corporate patent divisions and law firms. It is not common in the public sector however. The rationale of PIPRA is to specialize in this work on behalf of the range of member institutions, undertaking the analysis of common tools of biotechnology, and making the resulting insights and recommendations known to the entire membership, and beyond.

The PIPRA patent database: PIPRA has launched a public database in collaboration with M-CAM, a company providing premier web-based products and services for patent data search and analysis. The PIPRA patent database contains the agricultural portion of the patent portfolio held by PIPRA member institutions and gives a clear picture of the availability of the technologies developed across the full set of PIPRA institutions. The database contains the patent text, patent status information (such as whether it is in application, in force, or expired), and licensing status (such as whether it is available for license, licensed exclusively, non-exclusively, all or some fields, and whether a sublicense is available). PIPRA has plans to expand this database to include entries on technologies which are (verifiably) in the public domain, in order to give a more complete overview of agricultural technologies that can be accessed and used.

Preliminary FTO research: PIPRA conducts preliminary searches of patent and non-patent art to support FTO analyses of important technologies, looking globally at the ownership situation. Identifying potentially relevant patents, mapping licensing information, and even making validity assessments are all part of this work. The end result is a set of reports containing recommendations for public sector researchers on how to proceed with research or commercialization activities, such as suggestions on strategies to "invent around" blocking patents, patents under which licenses can be obtained, and what technologies are in the public domain. While PIPRA engages in the background research, anything requiring legal analysis is referred on to an attorney. A number of law firms support PIPRA in this by providing FTO analyses on a pro bono basis.

Patent landscape analyses: The patent landscape analyses at PIPRA are mappings of the IP across broad sets of technology. These can vary in degree detail but generally do not go into the same depth as an FTO analysis. Rather, a patent landscape of a broad set of technologies, such as plant genes, would be part of or provide a starting point for FTO research on a narrower subset of technologies, such as plant promoter regulatory elements.

Industry and policy analyses: PIPRA conducts and publishes research on industry trends and structural shifts and also on developments in government policies, all with an eye to affects on IP in agricultural R&D.

### 3.2 IP management education and outreach

In order to facilitate public-private R&D partnerships and promote technology transfer to developing countries, PIPRA offers a number of educational services within IP management to researchers, administrators, technology transfer staff, sponsors, policy makers, industry, and farmers. These include:

IP management handbook: PIPRA is collaborating with its sister organization in the medical field, MIHR (www.mihr.org) also established through efforts of the Rockefeller Foundation, to put together an exhaustive handbook and accompanying web-based resource on IP management for policymakers and professionals in the developing world. PIPRA is working to improve IP management in agricultural R&D, and understanding the rules of the game are essential to being able to play. Lack of access to agricultural biotechnologies, especially in developing countries, often simply results from a lack of professional expertise in IP management in those countries, knowing how to access the technology. Lack of access can also result—even unintentionally—from overly broad terms of commercial licenses executed by universities and institutes in the North.

Research publications: Much of the work being done by PIPRA in FTO research, landscapes, as well as industry and policy analyses are being adapted (such as redacted to remove confidential information) for public access on the PIPRA website. Their publication is intended to allow the broad clientele at member institutions and others to benefit from the research and analyses done by PIPRA.

Professional training opportunities: PIPRA is seeking to educate IP professionals in the agricultural sciences by accepting short term interns to engage in the full range of work ongoing at PIPRA.

Short courses: Plans are in formation to formalize short courses on specific topics involving PIPRA's approach, IP analysis results, and recommended best practices.

### 3.3. Biotechnology resources

PIPRA is also working actively toward providing freedom to operate for neglected market applications of agricultural biotechnologies through the development of a suite of enabling biotechnologies for plant transformation.

Plant promoters: Laboratory based analysis is being carried out at PIPRA to discover where non-patented or accessible biotechnology components might be substituted for those with legal restrictions. PIPRA then integrates its systematic understanding of promoter effectiveness with



Intellectual property clearing houses may bring the benefits of modern agricultural technologies to African farmers at an affordable price

what it has learned about the IP status of the various promoters to come up with optimal recommendations for a variety of research contexts.

Plant transformation vectors: The first project underway involves vectors for the insertion of DNA into plant cells. This is a very important tool and one that is burdened with IPRs and to a large extent inaccessible for use outside of the major corporations. In order to avoid this bottleneck, PIPRA is attempting to develop a novel transformation vector in the PIPRA lab using technologies for which FTO has already been established, whether they are in the public domain or owned by a PIPRA member institutions and available for license. PIPRA may need to include one or two components that are proprietary to a commercial company, but the terms of any such agreement would be settled ahead of time, so as not to encumber the PIPRA vector system. PIPRA envisions making the vector widely available under a pooled nonexclusive license, with separate terms for research, humanitarian, and small-scale commercial uses.

This work requires a close collaboration between the lab, PIPRA staff performing IP searches, and supporting law firms doing the FTO analysis. If the project is successful, vectors, packaged with the license, will be distributed free of charge within the public sector and for humanitarian use. Private companies will pay a fee to use the vectors commercially. This degree of IP "self awareness" guiding research design is unique in the public sector.

### 3.4 Collaborative IP management

Reservation of rights in order to segment markets: PIPRA is also promoting among its member institutions a common licensing language that can be used to encourage and manage market segmentation. More precise licensing terms can be used to allow commercial licensing of technologies to firms to encourage them to invest in developing the technology for major commercial markets, while reserving rights in order to then license smaller firms to develop the technology for use in minor commercial markets such as specialty crops and, even more importantly, to allow non-market or humanitarian uses of the technology, such as in subsistence crops.

Greater precision in licensing terms aims to target the transfer of rights to those parties that are most likely to utilize the technology across a range of commercial and non-commercial contexts. PIPRA has participated in a consultative process with university attorneys and exter-

nal legal counsel to develop licensing language for retaining "humanitarian use rights". PIPRA member institutions are encouraged to use such language as part of their standard license agreements in agriculture. (PIPRA's proposed language for humanitarian use reservation of rights is online at <a href="http://www.pipra.org/docs/HumResLanguagePIPRA.doc">http://www.pipra.org/docs/HumResLanguagePIPRA.doc</a>.)

Bundling or pooling: The models for bundling or pooling IP being developed in PIPRA's transformation vector project can also be used in other areas. Current activities include development of a licensing model where rights over complementary technologies are pooled and can be accessed through a single non-exclusive license. Much of the effort here is put into discussion and negotiations with technology owners, including PIPRA's own member institutions, to find a model that preserves commercial interests while carving out space for public research and humanitarian uses.

It is important to point out that, while PIPRA already plays a role in identifying and defining the mutually-complementary technologies involved in IP coordination bottlenecks, PIPRA is still exploring models for bundling or pooling of technologies. One model being contemplated would be to take licenses to these technologies and then offer sublicenses. Another would be for PIPRA to assist in the set up and management of a pooled licensing arrangement signed directly between the owners of the technologies and the users. Arrangements for different technology pools indeed are likely to differ markedly depending on the nature of the technology involved, who owns the IP, in which countries the rights apply, and its commercial potential.

Exploring open source: PIPRA has likewise explored open source licensing models for biotechnology. In open source models, the owner (or owners) of a technology make it available for research and commercial use under a license where one of the basic terms is an obligation to license back to the owner(s) and/or other licensees (the "open source community") any improvements made on the technology. In biotechnology, the open source model has posed challenges in terms of finding an effective balance between the obligation to license improvements back to the open source community and any other obligations that might be in place to others with IP claims over parts of what is a typically involved in a complex R&D project. In addition, the cost of maintaining the open source commons based on a licensing of patent-protected technologies is significantly higher than in the classic case of open source based on licensing copyright-protected technologies like software. When a large investment is put into paying the fees to secure patent protection, it is often predicated on an expectation of commercializing the technology. Few are likely to be willing to cover the expense of patent fees, simply to "donate" the technology to the open source community. Indeed, for academic or public sector researchers in biotechnology, the lower cost and more likely option is simply to publish the improvement, thus leaving it to the public domain rather than to the open source commons.

Defensive publishing: Putting a technology into the public domain is, in fact, another IP management tool being researched and advocated by PIPRA. This is not always as straightforward as it sounds, however, given that many aspects of technologies as published may in fact be dominated, at least in part, by claims of existing or future patents. Still, in many cases it makes little sense to incur the costs of patenting a minor component technology when the prospects of licensing it as a standalone invention are small. Or, an inventor or their academic institution may simply choose to make their invention broadly accessible by publishing it instead of patenting it. In both cases, certain steps can and should be taken, with an eye on the patentability requirements established by patent law, to disclose as much as possible in terms of methods and possible applications. The intention is to make the publication as effective as possible as "prior art" to preclude encroachment by patent filings on improvements of the published technology or on similar technologies.

While the privatization of innovation has led to immense gains, there still exist many areas in which the social or humanitarian value of introducing an innovation may be high but potential market returns are almost non-existent. At present, campaigning for this shift in awareness and licensing practice is perhaps where PIPRA is having its greatest impact, preventing IP from creating future bottlenecks for agricultural R&D and crop variety development that is still clearly the mandate of public sector institutions.

### 4. Partnering for IP management in Africa

Economies in Africa continue to be highly dependant on their agricultural sectors. Subsistence or small scale agriculture still employs a majority of the working age population in many African countries. Agricultural innovation is therefore of high relevance to economic development and improvement to the human condition. When the needs of smallholder growers are analyzed with a critical eye, a number of viable solutions can be found that depend upon new agricultural technologies that are proprietary, registered under patents in some countries.

In most cases, questions of access to new technologies when considered from the African context are very different from those typically confronted in the U.S. or Europe. Most of the technologies that might be of interest in Africa have not been registered by their inventors under patents in African countries, and they are therefore by default in the African public domain.

An immediate legal issue arises only if the crop is to be exported to the U.S., Europe, or other country where patents may be in force. It is at the port or the border crossing that such traded commodities would come under the patent laws of those lands and thus might become infringing (Binenbaum et al, 2003). While this con-

straint does not, in principle, prevent the use of the technology in Africa, for African purposes, it does restrict the feasibility, in an increasingly globalized economy, of using technologies to produce crops that may at some point in time be traded. Also, practically speaking, proprietary technologies may not flow as readily through the research community to become an approach that might be experimented with in Africa's agricultural research institutions. Control of the technology may be maintained by the owners controlling access to biological materials, and the owners may be reluctant to release or transfer those materials for a variety of reasons often revolving around concerns over liability and stewardship.

In seeking to make the proprietary technologies owned by the PIPRA member institutions available for use in Africa, PIPRA has partnered with the African Agricultural Technology Foundation (AATF), hosted in Kenya on the campus of the International Livestock Research Institute (ILRI) in Nairobi to explore opportunities to provide royalty free licenses to African institutions (www.aatfafrica.org). The mission of the AATF is to identify innovation priorities based on an understanding of the real constraints confronting African farmers and facilitating access to any proprietary technologies that might be needed to create innovative solutions to overcome those constraints. Examples of technologies being developed through the facilitation of AATF include a maize variety able to overcome the choking weed striga because it is tolerant of imidazolinone herbicides, as well as a nutritionally biofortified sorghum.

While the AATF searches everywhere in the world for appropriate technologies, sourcing them from industry or from research institutes in both developed and developing countries, the PIPRA member institutions represent a wealth of technologies that may one day be used in Africa under a royalty-free humanitarian use license. The identification of opportunities, negotiations, and licenses can be facilitated through the partnership between PIPRA and AATF. While coming from a different corner of the world, a good example of the kinds of agreements that are feasible is a recent license signed by the AATF with Academia Sinica, a public research institute in Taiwan, for use of an anti-bacterial protein to combat banana leaf wilt (Academia Sinica, 2006).

### 5. Conclusions

In a world where knowledge and technology are both increasingly valuable and increasingly denominated as intellectual property assets, the role of IP clearing-houses, such as PIPRA and AATF, become crucial to the function of public sector institutions. They are navigating an often uncharted shoreline between the open seas of the public domain of knowledge and the fertile lands of proprietary technology.

The role of PIPRA might be best characterized as that of a "supply side" IP clearinghouse, primarily making the IP that is held by a group of inventing institutions more readily and broadly available for a range of commercial and non-commercial uses. The role of the AATF might be best characterized as a "demand side" IP clearinghouse, primarily facilitating use of IP by a group of applied research institutions seeking to be responsive to the needs of the end users within African agriculture, clearing the way on their behalf to use proprietary technologies. The ultimate goal of IP clearinghouse institutions is to help find an optimal balance between incentives that mobilize private investment in agricultural innovation and the effectiveness of public investment in agricultural innovation. They are an attempt to properly adjust the public-private mix in the engine of innovation that is driving today's economies and that has the power to transform the human condition.

### **Authors**

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### SIGNATORS OF PIPRA MEMORANDUM OF UNDERSTANDING

- 1. Agricultural Institute of Genetics, Vietnam
- 2. Agriculture and Agri-Food Canada
- 3. Arizona State University
- 4. <u>AVRDC The World Vegetable Center, Taiwan</u>
- 5. Boyce Thompson Institute
- 6. Cornell University
- 7. <u>CIMMYT International Maize and Wheat Improve-</u> ment Center, Mexico
- 8. CIP International Potato Center, Peru
- 9. <u>Donald Danforth Plant Science Center</u>
- 10. Fundacion Chile
- 11. Hanoi Agricultural University, Vietnam
- 12. Iowa State University
- 13. <u>IRRI International Rice Research</u> <u>Institute, Philippines</u>
- 14. Kansas State University
- 15. Michigan State University
- 16. North Carolina State University
- 17. Ohio State University
- 18. Oregon State University
- 19. Parco Tecnologico Padano, Italy
- 20. Purdue University
- 21. Rutgers University
- 22. Salk Institute for Biological Studies
- 23. St. Augustine University of Tanzania
- 24. The Samuel Roberts Noble Foundation
- 25. <u>University of Arizona</u>
- 26. University of Arkansas Division of Agriculture
- 27. <u>University of California, Berkeley</u>
- 28. <u>University of California, Davis</u>
- 29. <u>University of California, Riverside</u>
- 30. <u>University of Florida</u>
- 31. University of Georgia
- 32. <u>University of Kentucky</u>
- 33. University of Idaho
- 34. University of Missouri-Columbia
- 35. University of Saskatchewan, Canada
- 36. University of Tennessee
- 37. <u>University of Wisconsin (WARF)</u>
- 38. Virginia Tech
- 39. Washington State University

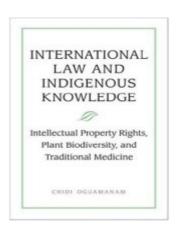
### **Featured Book**

# INTERNATIONAL LAW AND INDIGENOUS KNOWLEDGE: INTELLECTUAL PROPERTY, PLANT BIODIVERSITY AND TRADITIONAL MEDICINE Chidi Oguamanam

The suitability of mainstream forms of intellectual property rights to indigenous knowledge has recently been the subject of some debate. Efforts to reconcile the Western concept of intellectual property with indigenous knowledge have generally not taken into account the underlying epistemic schism between indigenous knowledge and Western scientific forms. The latter constitutes the main focus of intellectual property, especially the patent system, but as knowledge assumes increasing importance in indigenous quest for selfdetermination, cultural survival and economic empowerment, the gulf between indigenous and Western scientific knowledge assumes a new meaning. In this book, Chidi Oguamanam argues that the crisis of legitimacy that indigenous knowledge poses for the intellectual property system call for a rethinking of the intellectual property jurisprudence and its conceptual framework in a cross-cultural direction.

Dr. Oguamanam's study draws from interdisciplinary research in the social and medical sciences. It uses as its framework of analysis the legal doctrinal methodology, focusing on international legal and policy developments regarding the protection of indigenous knowledge, with emphasis on plant biodiversity as the mainstay or indigenous or traditional medical knowledge. He argues that despite the diverse historical experiences among indigenous peoples in the developed world and their counterparts in the Third World, the subject of knowledge protection constitutes a rallying point for their quest for self-determination and economic empowerment. Since every culture has knowledge protection mechanisms, modalities for protection of indigenous knowledge do not necessarily have to mirror those of conventional intellectual property.

One of the most in-depth studies in the area of indigenous knowledge and property rights to date, this work provides a thorough examination of the role of law and public policy in addressing the rift between Western



and non-Western knowledge systems and the crisis of legitimacy in the conventional intellectual property system.

\*Chidi Oguamanam is a professor in the Dalhousie Law School, Dalhousie University Halifax, Nova Scotia, Canada, where he teaches Advanced Intellectual Property Rights, Law and Technology. He served on the United Nations Convention on Biodiversity Ad Hoc Technical Expert Group on Genetic Use Restriction or terminator technologies. He researches and writes in the areas of biotechnology (medical and agricultural), including genetic modification and contamination, biodiversity conservation, international intellectual property law-making, globalization, food security, the protection of indigenous and local communities knowledge in international law and policy, biomedical ethics and public health policy, traditional or complementary and alternative medicine.

# KNOWLEDGE FOR DEVELOPMENT: A ROLE FOR INTELLECTUAL PROPERTY IN AFRICA?

### V. Konde, ATDF

### **Abstract**

Intellectual property rights (IPR) have become a subject of great public interest over the last decade or so. Some see IPR as necessary for promoting innovation, technology transfer, trade and investment, among others, in developing countries while others see such rules as a way of denying them access to technology and overpricing technology products such as medicines and improved seeds, among others. This overview looks at the potential and limits of using IPR as a tool for facilitating similar developments in Africa. It looks at recent trends in FDI flows, knowledge generation and protection abroad, and inter-firm and intra-firms technology transactions among regions.

### Introduction

"A good name is better than riches" is perhaps one of the best known quotes. Even though its origins may be contested, the quote underlines the importance and value of intangible assets in social or economic undertakings. Intangible assets comprise a large proportion of the total wealth of a country. As Friedrich List, a 19<sup>th</sup> Century German Economist noted: "The present state of the nations is the result of the accumulation of all discoveries, inventions, improvements, perfections and exertion of all generations which have lived before us: they form the intellectual capital of the present human race" [1].

It is, therefore, expected that those who have invested in the generation and accumulation of such intangible assets will have an interest in controlling its exploitation by others. This is particularly true if such knowledge assets constitute or play a major part in the competitive advantage of a firm or a country. Ensuring that those that invest in the generation of knowledge are rewarded accordingly is necessary to promote further development of knowledge.

However, others argue that societies that have accumulated knowledge have a responsibility to promote development by sharing it with those in need. President John F. Kennedy (US) said in 1962: "There is not enough money in all America to relieve the misery of the underdeveloped world in a giant and endless soup kitchen.... But there is enough know-how and knowledgeable people to help those nations help themselves" [2].

Balancing these two goals ([1] [2]) has been at the core of major policy debates on endogenous development over the past years. These debates tend to confirm the

suspicion that developed countries are happier building endless soup kitchens for the poor than let the poor have access to their prized knowledge and agree with List that those who have "attained the summit of greatness,... kicks away the ladder..to deprive [others] from climbing up. [3]

As with many other issues, some tend to paint IPR as either necessary or unnecessary but, as in many cases, a bit of both could be the right policy mix. This is particularly true as IPR policies function alongside other industrial policy tools that collectively promote knowledge generation and use.

It may also be important to understand why countries are adopting ever tighter IP rules. There are several reasons that may underline this trend:

- ⇒ Trade secrets are insufficient to protect today's inventions
- ⇒ Investment in innovation has increased in value and importance
- ⇒ Technology is easier to copy
- ⇒ Technology is key to competitiveness in trade
- ⇒ Technology is changing and spreading rapidly in the marketplace and [4]
- The shift from extraction-based to manufacturing/ service-based industries.

It is for these reasons that trade has been the central driver of stronger IP rules over the years.

As the number of products that embody some form of protected knowledge increases and competitiveness is increasingly determined by differences in manufacturing know-how, firms will choose to seek stronger protection to further enhance their ability to compete. Estimates suggest that the proportion of United States' exports that depend on some form of IP protection has increased from about 10% to above 50% in the last 50 years [5] and about 20% of the world manufactured exports were classified high-technology in 2004.

Therefore, it is not surprising that developed countries, whose firms are the major exporters of products that contain protected knowledge, are seeking a greater IP protection in developing countries. Developing countries, on the other hand, see it as an erosion of their right to access knowledge and learn to produce their own products. They consider it as a threat to their bid to develop, and in some cases, to survive.

However, the ability of a country to copy, imitate and learn from leading countries depends on its domestic technological capacity and human capital. There are indications that Africa's ability to use and generate new knowledge has declined. For example, between 2001 and 2005, only inventors from four out of the fifty three African countries obtained one or more patents from the United States Patents and Trademarks Office (USPTO), representing about 0.08% of the total non-resident patents granted during that period (See table 1). And that is 4 out of 53 countries.

Another way of looking at Africa's ability to use technology is to track payments for intangible assets. Africa's share of global royalty and licensing fee payments fell from 1.4% in 1998 to 0.6% in 2004. It also declined in absolute terms from \$840 million to \$765 million while globally payments doubled over the same period reaching \$120 billion. This gap in knowledge use is much wider if one considers that about \$382 million was paid by firms in South Africa, \$64 million by firms in Nigeria and \$50 million by firms in Kenya in 2004.

Such large knowledge gaps in knowledge use and generation casts some doubt on the extent to which most African countries could mould their IP legislations to promote innovation and development. This overview will use global trends in trade, investment and technology transfer to see areas where of IP could play a role in Africa's development.

### 2. Glance at IP trends.

The term intellectual property rights encompasses numerous exclusive legal rights awarded to inventors or creators by government for a given period of time and territory in which the use of the creations is controlled by the rights holders. The common ones include:

- ⇒ Patents for inventions only and usually for about 20 years
- ⇒ Utility model or industrial design rights for forms of appearance, style or design of an industrial object (e.g. furniture or textiles)
- ⇒ Trademark for a sign that distinguishes the product or service and whose protection may be indefinite.
- ⇒ Copyright for creative and artistic works (e.g. movies and paintings).
- ⇒ Trade secrets may be used to protect undisclosed commercial products or processes; it is illegal to disclose a trade secret.
- ⇒ Other forms of rights, among them; breeders, traditional knowledge or geographical indications.

In general, IP rules are designed to promote innovation and fair competition to facilitate economic growth. The first patent law, for instance, passed in Venice in 1474 was intended to protect inventions after their use were demonstrated. The law was passed at the time Venice was sought to promote manufacturing. Other measures developed within the same period included tax holidays for two years for skilled immigrant workers and controlling the migration of domestic skilled workers. [6]

Table 1. Patents granted to inventors in Africa between 2001 - 2005 by USPTO (by country of origin)

Country	Patent holder	Patents granted
Egypt	Individually	10
	Firms	0
Kenya	Individually	14
	Firms	9
Nigeria	Individually	8
	Firms	0
South	Individually	197
Africa	Firms	90
Total		328

Source: USPTO

Many developed countries still use their IP rules largely as a tool to promote industrial development and trade. They continuously review their IP rules to meet the changing needs of industry. For instance, in 2006, the United Kingdom Patent Office launched a consultative initiative with stakeholders on how the "inventive step in [its ] patents can [be used to] maximize innovation".. and "whether any aspect of the inventive step requirement should be modified." [7] It has also launched consultations on how to support innovation in the country and on the potential of representative action in terms of litigation costs, among others. [8]

Such reviews of IP rules are meant to strengthen the role of IP as a tool for economic development rather than for creating monopolies. [9] African countries seem to address their IP rules largely with a view to meet their obligations under the World Trade Organization (WTO), World Intellectual Property Organization (WIPO) and bilateral agreements. Moreover, the IP debate in Africa is largely not driven by industries in Africa but rather noncommercial interest groups addressing specific needs, such as, access to medicine and the rights of farmers to save seeds.

While firms are not the only stakeholders with interest in IP rules, they play an important role in enabling any IP regime to contribute to development. They also bear some of the costs associated with changes in IP. For example, the World Bank estimated that the full implementation of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would increase transfers of licensing fees to technology exporting countries by more than \$20 billion per year. [10] Almost all this increase would be bone by firms. Firms may pass on those costs to consumers through increases in unit prices. Such changes could affect decision to invest in R&D, access to new knowledge and alter competitiveness of products in the marketplace.

This overview will only focus on some of the broad assumptions of the impact of IPR on development. Some have argued that stronger IPR promotes innovation, investment and trade which are the major conduits for the transfer of advanced technologies. They also argue that

this may lead to increased production and exports over time, and improve the living standards of people. Many African countries have greater interests in many of these benefits of stronger protection of IPR, if they indeed occur.

### 2.1 IP and innovation.

IP is largely seen as an incentive to inventors. This assumption is based on the belief that a temporary monopoly use of the invention could enable inventors to recoup most of their investment. [11] Some of these profits or benefits may be ploughed back to stimulate additional innovation.

It is argued that the disclosure requirement, such as that in patents, play an important role in knowledge diffusion and promoting innovation. Such disclosure may stimulate interest in other areas beyond the original research. Without such rights, the knowledge embodied in many products will not be disclosed and, as a result, the technological insights it may stimulate will not occur.

IP may also serve as success benchmarks in some industries. In some markets and industries related to biotechnology and information technology, IP is used a measure of success because they primarily survive by continuously churning out new products and services. Strong IP rules may therefore be essential to stimulating innovation.

IP is also used as a bargaining chip in technology transfer and partnership deals. Firms or institutions may use some of their IP assets to gain access to other key IP assets owned by their competitors or pool their IP assets and form alliances or joint ventures. Such arrangements could accelerate commercialization of inventions and further development.

These assumptions are likely to hold true for some fields or industries and markets. For instance, nearly 90% of all the industrial technology alliances [12] involve European, American and Japanese firms and about 91% of such alliances were in three industries: automotive, biotechnology and information and communication technology in 2003. There is little evidence that strengthening IP regimes will facilitate alliances between the technology-developing ones and those without.

The extent to which current IP regimes stimulate or hinder innovation is a subject of great interest.[13] There is little argument that IP rules are needed but not everyone agrees on what should be covered and on the use of IP to create what has been termed "intellectual monopolies". For example, 'George Selden obtained a U.S. patent in 1895 for "putting a gasoline engine on a chassis to make a car". Thousands of dollars were paid in royalties - increasing costs and reducing production output. It was not until 1911 that Henry Ford and others challenged the validity of such a broad patent'. [14]

Similarly, patent thickets or de facto monopolies could be used to block or discourage others, in particular potential competitors, in a field of interest or stifle technological development. Peter Ringrose, Chief Scientists at Bristol-Myers is quoted saying: "there are more than 50 proteins possibly involved in cancer that the company [Bristol-Myers] was not working on because the patent holders either would not allow it or were demanding unreasonable royalties." [15]

When abused, IP may cause others not to practice their inventions until the blocking IPR expires or is invalidated. Similarly, demanding a high price for IPR increases the cost of innovation - hindering it rather than promoting. IP rules do provide some relief in cases where the IP owner is not willing to provide the technology on reasonable commercial terms and conditions, such as compulsory licensing. However, many potential users that may fail to obtain technology on reasonable and fair terms are unlikely to exploit protected technology using the flexibility provided by law for fear of paying the legal costs, for example those that may arise to prove that the terms were unreasonable.

Many African countries may have to tailor their IP regimes and support policies that promote firms and institutions capable of inventing new products and services derived from inventions. This may eventually enable them to enter into industrial technology alliances and to leverage their limited R&D expenditure. There are fears that the continent is remaining behind in innovation and IP alone is unlikely to help the content to innovate.

### 2.2 IP and technology transfer

The argument that IP facilitates technology transfer stems from two broad assumptions: 1. disclosure and 2. its impact on trade, FDI and licensing decisions. It is assumed that disclosure plays an important role in promoting diffusion of knowledge. The later role of IP in technology transfer stems from the assumption that the IP regime of a host country may influence the decision of a technology owner to export their technologies. A stronger intellectual property regime (i.e. legislation and enforcement) is thought to act as an incentive or source of comfort to technology exporters to transfer their technology without fear of losing control or revenue.

There is increasing doubts about the role IP disclosure requirements in patents play in facilitating technology transfer. Some inventions that were granted protection do not always contain new information that could be regarded as innovative or technology. In addition, detail of disclosure, whether the best mode of making the invention requirement is disclosed or not, does not necessarily represent how the invention will be used in industry (i.e. there is usually no requirement to update the mode).

In the second assumption, it is observed that firms have continued to prefer transferring technologies intra-firm. Roughly 70% of all royalty and licensing fee receipts by the major technology exporting countries (e.g. United

States and Japan) are intra-firm. In the case of the United States (accounting for half of all receipts), interfirm royalty and licensing fee receipts for industrial processes (or manufacturing know-how) as a proportion of the total has steadily declined from about 15% to about 11% between 1987 and 2004 (see figure 1a).

In the case of Africa, the trend is even more dramatic. Inter-firm payments as a proportion of the total of Africa's payment for intangible assets to the United States have declined from about 50% in the late 1980s to about 27% in 2004 (see figure 1b). However, Inter-firm payments for manufacturing know-how by Africa to the United States have fallen in absolute value from \$33 million to 1987 to \$20 million in 2004 and, has fallen as proportion of total payments, has fallen from 46% to 5% over the same period.

In many ways, the strengthening of IP rules has had little impact on the mode by which major firms transfer their technology at the global level.

The transfer of technology is often accompanied by contractual agreements that detail the nature of the technology, payment methods, period of use, liabilities, territories in which it could be deployed and how to deal with third-parties, among others. Other than sale or assignment of IP rights, most arrangements such as licensing, franchise and joint-venture, among others, include many other clauses that deal with knowledge disclosure to third parties, access to technology enhancements, use of inputs from other parties etc.

These clauses, often termed restrictive business practices, are also acceptable market mechanisms employed by firms to control the use of their technology or stay competitive, irrespective of the unique country-IP regulations. Earlier efforts to regulate the use of such practices through government screening of contractual

agreements [16] have largely been abandoned in favour of market-based approaches (see TRIPS Agreement Article 40). One could also include software and genetic use restrictive technologies among restrictive business practices, perhaps of a higher level.

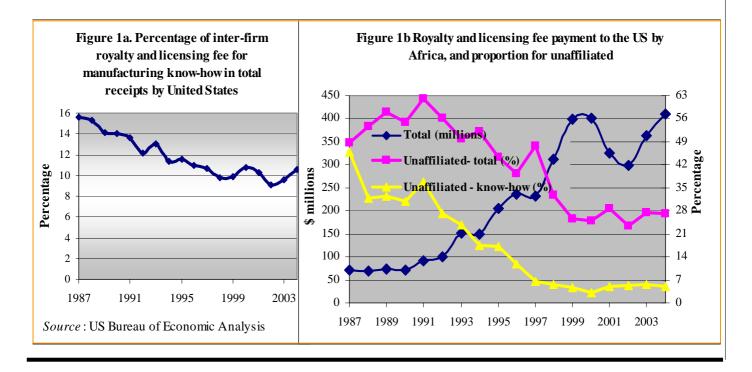
It is also often forgotten in the debate on IP and technology transfer that domestic firms import technologies to enhance their own performance. They are not necessary technology transfer agents for other firms. Other than public enterprises, most private firms are unlikely to share their imported technologies with competitors in the domestic market.

Overall, the strengthening of IP rules following the entry into force of the TRIPS Agreement do not seem to have been accompanied by increase in inter-firm transfers of manufacturing know-how and reduction in the use of restrictive business practices and/or government lists of dual-use products. It also remains unclear whether the increase in intra-firm royalty and licensing fee receipts by TNCs are due to improvements in national IPR regimes [17] or the growing trend in outsourcing manufacturing activities abroad.

### 2.3 IP and foreign direct investment

It is clear that protecting one's invention in today's knowledge economy is playing an increasing role in attracting investment needed to take the invention to market. As the Director of Nordisk put it:

"Anyone who has tried to create a biotech company knows just how important patents are. You learn this when you're studying, and again at your first job, and if you haven't done so before, you realise it the first time you meet potential investors." ....But patents are more than just important. They are crucial in deciding whether your invention has a com-



mercial future." [18]

However, the role IPR in stimulating foreign direct investment (FDI) remains unresolved. There are several observations that cast doubt on the role IPR plays in FDI flows. It has been observed that foreign firms rarely transfer all their technologies to their affiliates irrespective of the national IPR regime. If anything, investors are more likely to consider important factors such as market size, technological development, sophistication of consumers and economic and political stability in their decisions to transfer their technologies.

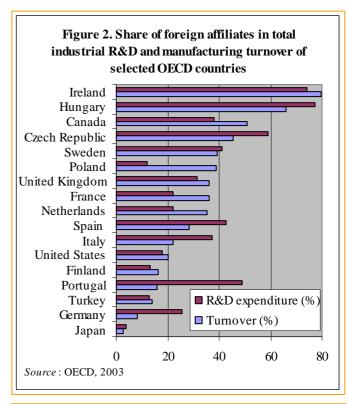
The second observation stems from the actual trends in flows of FDI over the last decades. It is difficult to explain using IPR arguments alone why Thailand attracted more FDI than the Republic of Korea throughout most of the 1990s and the 2000s. Similarly, countries such as China and Russia have continued to attract greater amount of FDI despite their perceived weak IPR regimes.

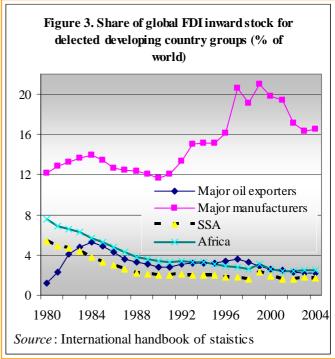
A third observation is based on the varying decisions of investors to spend a proportion of their sales on technology development. A survey among OECD countries revealed wide differences in the ratio of foreign affiliates' expenditure in national R&D in comparison to their proportional in sales turnover (see figure 2). Foreign firms' proportion in national R&D expenditure of Germany, Italy and Portugal is higher than their proportion in sales turnover. In a way, foreign affiliates prefer these countries for R&D performance than for manufacturing.

The above observation is also backed by the varying choice of firms to establish an R&D or manufacturing facility in a given country. Between September 2004 and October 2005, India attracted 146 R&D and 32 manufacturing investment projects while United States attracted 24 R&D and 69 manufacturing projects. Differences in national IP rules cannot adequately explain the decisions of investors to establish technology development or product manufacturing facilities in a country or another.

It is also observed that firms seek IP protection in strategic markets, such as China, European Union and United States, Inventors could undertake their innovation in a country with a weak IP regime but strategically seek protection in the potential markets for products or services where enforcement may be more effective. An increasing number of foreign affiliates are filing for nonresident patents in key markets. In the case of foreign affiliates in India, between 2001 and 2005, IBM has seen its annual patents granted by the USPTO increase from 8 to 26, Texas Instruments from 9 to 25 and General Electric 6 to 23, according to the USPTO database. A similar picture is emerging for foreign affiliates in China and Singapore as well. Domestic inventors too are seeking protection abroad where they are likely to export/sale their technologies or products.

Finally, UNCTAD's Inward FDI performance index,[19] which compares the countries' actual inward FDI flows to its potential to attract investment, for 2004, was topped by Azerbaijan followed by Belgium and Luxemburg, Brunei, Angola, Ireland and Gambia while South Africa and Kenya, ranked 126 and 127, respectively, out of 140 economies. [20] Perhaps other factors influence investment decisions much more than IP rules, otherwise countries such as South Africa and Kenya, perceived to have better IP regimes should score higher Angola or Gambia.





However, as other factors of interest to investors become more equal, IPR may become a major consideration especially in information technology and biotechnology. Furthermore, as African countries move up the technological ladder - from extraction-based industries to manufacturing ones, which attracts most of the global FDI and technology, IP may become an issue.

It is observed that developing countries that are major exporters of manufactures [21] attract more FDI than the top oil exporters or Africa (see figure.3). In the extraction-based industries such as mining, investors' main concerns are very simple and few: presence of natural resources, basic infrastructure, security and a government, or a resemblance of it that they could work with.

On the other hand, IP regulations could play a major role in domestic investment decisions. For instance, the infant African entertainment industry, e.g. music and video, is said to suffer from piracy, especially those in small economies. Although piracy is not the major factor slowing the development of the entertainment industry, it is assumed to be taking a large bite off the profits of an infant industry that is also exposed to competition from cheaper but high quality products from abroad. Since domestic investment tends to lead foreign investment, enforcing IP rules, such as copyrights in the case of the entertainment industry, could indirectly be a way of attracting domestic and foreign investment.

### 2.4 IP and trade

It is assumed that IP is critical in promoting trade in IP-intensive products and services. Some argue that producers are unlikely to export knowledge-intensive products to countries where IP rules do not protect the inventions embodied in the products. It is therefore, assumed that strengthening the IP regime would encourage trade and fair competition.

The argument that weak IPR protection will discourage export of knowledge-intensive products may be true if there are other players in the host economy capable of imitating or copying the technology or the mode of transfer would expose the technology to competitors likely to copy it. In addition, such copying or imitation has to attain an industrial scale to threaten the market share of the original exporter and thus discourage trade.

A survey by Lesser, conducted for WIPO, [22] revealed that most firms ranked product market potential first, followed by IPR enforcement and the cost of IP protections. The actual IP legislation was ranked lower. Most firms, other than producers of self-reproducing seeds (non-F-1 hybrids), indicated that they will export their products to countries with weak IP regimes.

The survey revealed that a firm will export to a given country if the perceived profits exceeding the cost of serving the market - taking into account the risk of not serving the market may increase the risk of losing out to

counterfeit products. In other words, if gaining some market share is profitable, it may be wiser to export than lose the market to imitators. Therefore, large markets attract ever growing volumes of high-tech exports irrespective of their IP legislation and enforcement.

Others see some copying as inevitable or as another ways of opening up new markets. As Charles Igwe, Executive Producer of The Big Picture Ltd (Nigeria), siad: "We're not worried about piracy. We realised that the only reason why people would make copies is that they can't easily get to the cities to buy more. We know that with every illegal copy you create a new market." [23]

While recognizing that IP is important in trade, Igwe also argues that it could also hinder growth of the industry. He argues the success of the Nigerian film industry - producing over 1000 movies a year and raking in about \$400 million in sales - largely depends on its ability to creatively and efficiently adapt. Some of its features include: 1. targeting home use due to lack of Cinemas or theatres, 2. distribution through social networks, 3. Keeping production costs low, 4. focus on African themes that speak directly to the public. [24] Any IP regulation has to recognize such differences if it has to save as a tool for development.

It should be noted that not all technologies are available for sale, irrespective if the IP regulation of the importing country. For instance, the Pakistani Physics Nobel laureate Abdus Salam recalled that 'Pakistan failed to buy the technology for the production of penicillin in 1955. A few chemists had to re-invent the process - and due to their inexperience - manufactured penicillin at 16 times the world market price.[25] The number of technologies than could not be easily bought range from simple enzymes and personal computers to that for producing vaccines and launching satellites into space (often falling under dual-use restrictions). IP does not seem to have loosened such technology export-restrictions.

There is a tendency to look at trade as exports by one country to another. In reality, firms decide to sell or buy from other firms at home or abroad. It is observed that many firms prefer to transfer their technologies within their network of firms and, to some extent, partners. It has been shown that most United States TNCs imported their high-tech intermediate inputs from affiliates abroad. In a way, intra-firm trade is higher in high-technology intermediate inputs than in other categories of inputs. [26]

Many African countries are do not far offer the market size China or Russia present to many exporters. Therefore, lowering the costs of doing business, including offering good IP protection has to be considered to promote exports of technology-products into their markets.

Domestic firms, too, are unlikely to import products into a market where cheaper copies are sold and thus under-

mine their competitiveness unless they are subsidized or shielded from such competition (e.g. government contracts for medicines or enforcement of IP). Therefore, a case for strengthening IP regulations could be made to protect domestic producers while maintaining space to permit learning.

IP regulations may be tailored, for example, to allow greater latitude for R&D and learning at home (e.g. to includes initial sales) while largely permitting imports of original products in certain sectors of interest. For example, some developed countries' legislations allow generic drugs manufacturers to test and submit for approval and registration of their generic drugs before the patent expires. For many African countries, an extension to allow them to stock pile or distribute the generic medicine may be necessary for a smooth transition, given the small size of domestic drug producers.

The purchasing power of consumers may also have to be considered. A situation such as that witnessed in the health sectors where millions of people who cannot afford medicines die even when legal flexibilities exist to produce cheaper versions has led to the distorted view that IP protection merely serves as an exploitative tool of TNCs. In many African countries, more government intervention or brokering of technology deals in areas of interest should be used to take advantage of the flexibilities.

### 2.5 IP and enforcement of product standards

Although IP is often seen in terms of innovation and trade, it also plays a role in maintaining and assuring the quality of product and service standards. The enforcement of trademarks and copyrights in particular, play a role in ensuring that products do not sound or look so alike that it confuses customers. If the confusing products are of good quality or performance, among other properties, the issue is largely violation of IP and competition rules.

However, if the products that appears like the genuine one is of poor quality or performance, it may be dangerous or risky to use. A recent paper highlighted a few examples from Africa:

"During the 1995 meningitis epidemic in Niger, the authorities received a donation of 88,000 Pasteur Merieux and SmithKline Beecham vaccines from neighbouring Nigeria. The drugs were found to be counterfeit, with no traces of active product. Some 60,000 people were inoculated with the fake vaccines.

The recent discovery of counterfeit antiretrovirals (stavudine-lamivudine-nevirapine and lamivudine-zidovudine) in central Africa raises the prospect of a disastrous setback in the treatment of AIDS in sub-Saharan Africa, unless vigorous action is taken now". [27]

### Chisokone market, Kitwe, Zambia.



The market sits in the heart of Zambia's second largest city, next to modern shopping outlets. Its a one-stop shopping outfit for carpenters, pupils, patients, welders, trackers and do-in-yourself enthusiasts.

Any room for IP?

The problem is not restricted to developing countries. In March, 2006, the European Commission issued a warning (IP/06/375) that several websites were selling *Rimonabant* - a treatment for obesity and smoking cessation - before it was approved for use in the European Union. In 2004, three men were jailed in the United Kingdom for running an illegal facility that could produce up to half-a-million tablets a day and appeared to be part of an international operation that produced counterfeit diazepam, steroids and Viagra.

It is possible that counterfeiters establish illegal production, distribution and marketing systems that are protected by corrupt officers and other criminal elements. [28] For instance, In Nigeria, where about half of all the drugs on the market were counterfeits in the late 1990s, early efforts to control counterfeiting were met with stiff resistance. Some of buildings of the national food and drug authority torched and the director almost killed in an assignation attempt. [29] A strict enforcement of IP rules and, registration and approval systems of products or services could help fight such a scourge.

IP rights, especially trademarks, could help stem the flow of fake products in the market. Trademarks are also a more useful tool in educating the public, tax authorities and marketing chains identify fake products than patents and copyrights. Such IP rights may also enables injured individuals to claim damages in the case the products cause harm or do not perform.

However, one has to underscore that in some cases, such illegal products fill a vacuum created by both IP and

non-IP measures. For instance, many lives could be lost in Africa if anti-malarial drugs required a prescription or were sold only in legal pharmacies for two simple reasons: 1. Few people have access to health centre or imitations of one, let alone access to qualified doctors and laboratories capable of diagnosing malaria and 2. Malaria infection rates are high - in some areas, infections could reach up to 1 in 3. In such cases, the makeshift stalls selling anti-malarial tablets become life-savers.

A similar debate has raged in Africa on the effect of second-hand clothes and used cars on ailing infant industries. Any fight against counterfeiting in Africa has to include empowerment and capacity-building initiatives, not only to prosecute illegal vendors, but to develop the technological and industrial bases as well as key infrastructure for delivery of decent services to the public.

### 3. Moving up the technological ladder

There are some who argue that for many African countries IP is not the major issue until they develop some capacity to use current knowledge. [30] For example, Taiwan is thought to have largely used older machines imported from advanced countries and focused on re-engineering non-proprietary product technologies in its early stages of development and conducted little research up to the 1970s. [31]

A recent report indicates that Taiwan had a limited budget and research personnel scattered in various institutions, more like Africa today. To solve this problem, it established the Industrial Technology Research Institute (ITRI) in 1973 with about 450 employees. [32] By 2000, ITRI had 6100 employees of which 900 had PhDs and 3600

had bachelor's or master's degrees. Government provides ITRI with contracts to develop generic technologies that are then transferred to private sector under non-exclusive arrangements.

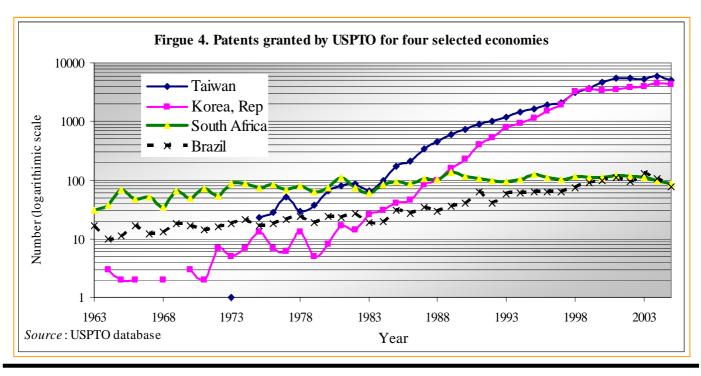
Korea is another country that has made major technological leaps in the recent years. Korea seems to have targeted process rather than product technologies. Korea imported industrial processing technologies (i.e. manufacturing know-how) that it then used to produce or deliver its research output to market. For example, in the car industry, Korea first learnt how to assemble and mass produce foreign models of cars before moving to increasing local content, and engine and vehicle designing. Like Taiwan, most research is designed, financed and conducted with significant private sector participation.

It is thought that Taiwan and Korea placed a great emphasis on:

- ⇒ human capital development
- ⇒ Importing or acquiring foreign technology from developed countries
- ⇒ Building indigenous science and technology capabilities and
- ⇒ Perfecting the conversion of research output into commercial products and services.

It may partly explain why these two countries have emerged as major technological powerhouses, over taking established ones such as Brazil and South Africa (see figure 4). Today, they are among countries that are calling for strengthened IP rules, separating them from countries such as Brazil, India and South Africa which still need more space for learning.

Most African countries' technological prowess is well below that of South Africa. They have to focus on build-



ing their technological capabilities and industrial base. Africa is remaining behind other developing regions not only in patent counts but also in scientific publications (see figure 5). It is the only region whose science and engineering article counts fell between 1988 and 2001.

At first glance one will call for increased R&D expenditure to enable the continent to catch-up. However, increasing R&D budgets without clearly defined targets could lead to what have been termed 'Solow Paradox', 'Productivity Puzzle' or 'European Disease' – a situation where increased investment leads to major scientific breakthroughs that is not necessarily commercialized or result in increased productivity. [33] Africa already displays some of such failure where even the little research outputs seems not to be commercialized.

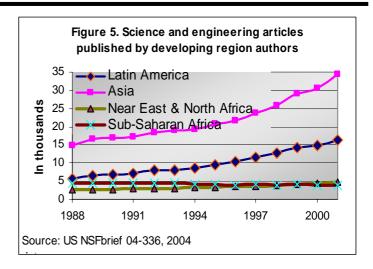
However, if African countries are serious about scientific and technological development of their countries or to use IP for national development, they may have ask their "co-operating partners" or donors to deliver most of their aid in form of technologies in areas of interest. Countries could use part of the aid to pay for technology licenses in areas such as health, energy and agriculture. They could also utilize some of such resource to import skills, and refurbish and/or refocus their public research institutions to become technology delivery vehicles to emerging firms. In return, developed countries will be meeting their obligations under the TRIPS Agreement (Articles 7, 66 and 67).

Of course, their sensitive areas such as health and agriculture where IP could become a challenge in meeting development targets. Countries could expand their bills of rights or strengthen their competition laws accordingly to meet food security and health needs. Recent cases in South Africa and Brazil highlight the importance of public interest or pressure in such negotiations.

### Concluding remarks.

IP has to be considered in its rightful place as a tool for rewarding inventors, protecting knowledge assets and promoting innovation. It could therefore be used to promote development of industries and give value to domestic knowledge (e.g. herbal medicines and traditional designs). In this case, IP tools could be used to give commercial value to natural resources and promote creativity.

Awareness and enforcement of some of the often forgotten IPR components, such as utility models, trademarks and copyrights, could play an important role in promoting fair competition and industrial development. In particular, trademarks are important in protection of technology or non-technology based products, increasing market penetration and extending the protection beyond patent life. For example, aspirin continued to earn Bayer some money a century after the patent expired.



The extent to which IP could be used as a tool for industrial development in Africa will depend on how IP rules are allowed to interact with other industrial and economic policies essential for building a viable technological base.. In this case, deliberate government policies to stimulate investment in R&D and human capital development in public and private institutions will be required. As of now, some African countries treat R&D expenditure by firms in their tax policies in the same way as expenditure on luxury cars. Incentives, such as those offered to attract FDI (e.g. tax holidays and duty free imports of machinery) may be needed to stimulate investment in R&D.

The ability of many African countries to use their IP rules to promote trade, investment and technology transfer is limited. For instance, Egypt is the only African country among the 48 countries the United States Trade Representative has designated as Priority Watch List, Watch List or Section 306 monitoring countries with respect to IPR infringements, in the 2006 report. The absence of almost all African countries from this list which includes countries such as Brazil, Canada and India, either suggests African countries do not have the capacity to exploit technology or their IP legislation and enforcement is excellent. The former is likely to be true.

Africa's greatest challenges is perhaps balancing the interest of its trade partners that are calling for ever stronger IP rules with its needs to develop industries that will compete in global trade in future. Meeting these conflicting needs may require an investment in diplomacy skills to negotiate for space to learn and develop a sound technological base while guaranteeing some fair market to its trade partners.

The former may prove challenging but not impossible. African countries could develop international R&D collaborations with developed countries in a specific industry or technology. They could also use some of their bilateral aid packages, aid for trade and, for some, debt savings to subsidies specific technology transfers or transactions. And where they hit a block, they could mobilize pressure groups, such as NGOs, to accelerate the process. Such measures could offset any costs associated with IP while meeting their WTO obligations.

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# FACILITATING TRADE IN DRUGS: AN ACCOUNT OF THE WTO'S AGREEMENT ON PATENTS AND PUBLIC HEALTH

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### Abstract:

This paper tells the story of the controversial 30 August 2003 decision of the World Trade Organization (WTO) General Council on intellectual property (IP) rules and flexibility for addressing public health emergencies. It provides a brief history on multilateral agreements governing intellectual property and international trade, as well as outlines the emergence of the IP agreement within the WTO. Then, it describes how WTO members clashed over IP issues related to the HIV/AIDS pandemic, explains the essence of their disagreement and chronicles how they attempted to strike an accord that balances the objectives of commerce and health.

### Introduction

An ambulance pulls up outside the WTO building. An African woman emerges, hooked up to an emergency intravenous drip of generic medicine. But suited trade delegates from the US, Canada, the European Union and Switzerland, egged on by drug company lobbyists whispering in their ears, "Cut the tube that leads to her arm". She protests holding out the WTO's "Doha Declaration" she was told would guarantee her access to affordable medicines. But drug company lobbyists remind the trade delegates: "She doesn't have the right disease. She doesn't come from a poor enough country. She can't prove she won't sell the drug to a rich tourist. She hasn't got the proper authorization." [1]

Staged by Oxfam in November 2002, the stunt dramatized concerns that negotiations on the WTO's intellectual property agreement threatened to undermine important legal flexibilities guaranteed in the previous round of negotiations and further restrict access to medical treatment for some of the world's most poverty and disease-stricken people. While it may seem alarming that a commercial instrument, such as patent protection, could impede access to lifesaving medicines, attempts to balance the interests of producers and consumers of patented medicines created a political morass that left players on virtually all sides frustrated, angry, and worried about the future.

### Where did the fight about IP begin?

The impetus for the Intellectual Property (IP) fight was the long-standing challenge of simultaneously encouraging innovation and making cutting-edge information, ideas, and products readily available to those who need them. To achieve these ends, governments created IP

protection. IP is a creation of the mind - it is ideas that have value in the marketplace. Since the costs of generating new ideas are largely upfront costs, once an idea has been generated, the cost of sharing it is virtually zero. IP would be accessible to consumers at no cost, absent a system for designating rights to the generators of IP. For this reason, IP protection awards monopoly rights to the generators of IP, for some specified period of time, as a means of preserving the economic incentive to invest in research and development. At the same time, IP protection provides universal access to new ideas (either through the requirement that inventers disclose information about their invention when they apply to governments for protection or through the distribution of the final product) so that researchers and innovators may build on the latest knowledge and information and, ideally further human progress.

At the international level, IP protection began in 1883 with the Paris Convention, the first major treaty that granted national treatment - or the same protection for the nationals of other states as they provide to their own nationals - for industrial property, such as inventions, trademarks, and industrial designs. The Paris Convention was followed by the Berne Convention in 1886, which provided protection for literary and artistic works, such as novels, plays, musical works, drawings, paintings, and sculptures. Over time, the administrative arrangements for these treaties merged and ultimately became the World Intellectual Property Organization (WIPO) in 1967. Seven years later, the United Nations formally recognized the WIPO as "a specialized agency and as being responsible for taking appropriate action in accordance with its basic instruments, treaties and agreements." [2]

For all intents and purposes, WIPO became the global governing body responsible for encouraging the development and protection of intellectual property. Its activities centered on developing new norms and standards for intellectual property protection and encouraging states to conform to them. [3] However, countries were not obliged to sign the WIPO administered treaties and WIPO lacked enforcement capacity. This shortcoming in IP protection fueled the drive of major IP producers to explore avenues for more effective and consistent protection

### Enter the WTO.

In 1995, the burgeoning global economy brought with it an overhaul of the multilateral trading system and adoption of IP protection by the WTO. The original system of international trade was born out of the Bretton Woods Agreement, an agreement aimed at promoting economic cooperation following the Second World War, by establishing the World Bank, the International Monetary Fund and an International Trade Organization (ITO). The trade framework that ultimately emerged was narrower in scope than the plan for the ITO, which would have covered rules on employment, commodities, investments, restrictive business practices, and services. It became known as the General Agreement on Tariffs and Trade (GATT), entered into force in 1948 and focused mostly on reducing tariffs on goods. [4] The GATT facilitated decision making between contracting parties through a series of negotiations known as "trade rounds." There were seven rounds leading up to the round that established the WTO, which lasted from 1986 to 1994 and became known as the Uruguay Round.

On January 1, 1995, the WTO came into existence and revamped the multilateral trading system in several respects. First, it provided protection for IP, in response to the growing threats of piracy and patent infringement, particularly with the proliferation of trade in high technologies. Second, it covered trade in services, including those relating to transportation, communications, and finance. Third, it created a process known as a "single undertaking," which departed from the GATT tradition of structuring negotiations around unilateral concessions, where contracting parties could pick and choose which agreements to sign. Instead, the Uruguay Round negotiations took place on all trade issues simultaneously, so that concessions made in one area could further negotiations in another, ultimately leading to a single package of agreements on which countries could vote up or down. Fourth, the WTO overhauled the dispute settlement mechanism in the GATT by creating more detailed rules and procedures and the possibility of compensating for injury through retaliation. [5]

The changes to the multilateral trading system were farreaching and controversial. Whereas the GATT consisted of 23 contracting parties, the newly-formed WTO began with 123 members (now 149), representing a much greater diversity of interests and capacities to engage in world trade. Even though not all members participated in negotiations equally, for reasons such as a lack of staff resources or access to exclusive meetings for only the most powerful, all members voted on a single package of agreements. In the end, many developing countries felt as if they had been forced to adopt a new trade agreement which tipped in favor of the more powerful, industrialized members for two reasons. First, it seemed to disproportionately benefit the domestic industries of more industrialized countries, as they have historically been the primary creators of IP and have more highly developed services industries. Second, the agreement required changes in domestic laws, which some developing countries lacked the technical capacity to implement.

In 2001, discussions about launching a new round of negotiations illuminated discontentment with the Uru-

guay Round agreement. For example, Indian Commerce Minister, Murasoli Maran, opposed launching a new round because he noted that, "imbalances will become worse and intolerable" and that "developing countries... already paid the price by agreeing to some of the contentious issues in the Uruguay Round of trade negotiations." [6] The Prime Minister of Malaysia, Datuk Seri Dr Mahathir Mohamed concurred when he stated that "developing countries were already disadvantaged by the imbalances contained in the Uruguay Round agreements." [7]

### What did the TRIPS actually do?

The WTO's Agreement on Trade Related Aspects of Intellectual Property (TRIPS) established minimum standards for intellectual property protection relating to copyrights. trademarks, geographical indications, industrial designs, patents, layout designs, trade secrets, and anticompetitive practices in contractual licenses. [8] Unlike IP protection in the WIPO, which lacked enforcement capacity, the TRIPS agreement had teeth for two reasons. First, the TRIPS agreement required that all members adopt procedures and remedies in their domestic laws, guaranteeing that individuals could seek enforcement of IP protection in judicial and administrative settings. [9] Second, the TRIPS agreement was backed by the newlybolstered dispute settlement mechanism in the WTO, which provided members an avenue for recourse when other members failed to conform to the provisions of the agreement. In contrast, the WIPO could neither force members to sign agreements, nor could it enforce the agreements that members elected to sign.

Like other changes that accompanied the establishment of the WTO, the TRIPS agreement underscored the divide between developed and developing countries. Developed countries, making up the vast majority of net exporters of IP, sought a far-reaching agreement that forced developing countries to adopt and enforce existing international IP conventions. On the other hand, developing countries, comprised largely of net importers of IP, worried that IP protection would strengthen the monopoly power of multinational corporations and ultimately result in higher prices for many products in their countries. [10]

Developing countries were joined in criticizing the TRIPS agreement by some members of the academic community. London School of Economics scholar, Dr. Razeen Sally argued that the effect of the TRIPS "is to close, not open, markets" and that "strong patent protection in particular increases prices and transfers rents from poorer developing countries to multinational enterprises headquartered in the West." [11] He was joined by Colombia Economist Jadish Bhagwati, who stated that "intellectual property protection is not a 'trade' issue; the WTO ought to be about lowering trade barriers and tackling market access problems." [12]

### Enter the HIV/AIDS pandemic.

Soon after the Uruguay Round, a political battle over the implications of bringing IP protection in the WTO began to germinate around the issue of access to medicines, most notably antiretroviral drugs (ARVs). During this period, 36.1 million people worldwide were living with HIV/AIDS. [13] Of these, 90 percent were in developing countries and 75 percent were in sub-Saharan Africa. [14] The international community was stepping up efforts to deal with the pandemic, through instruments such as the Millennium Development Goals, [15] the UN Declaration of Commitment on HIV/AIDS, [16] the Joint United Nations Program on HIV/AIDS (UNAIDS), [17] and the International Partnership against AIDS in Africa (IPAA). [18]

At the country level, governments began developing laws to make medicines more accessible to victims of disease. However, the pharmaceutical industry began to question the legality of some of the domestic laws in light of the newly-adopted TRIPS agreement. In 1998, the Pharmaceutical Manufacturers Association, comprised of thirty-nine pharmaceutical companies, filed a suit against Nelson Mandela and the South African government to block implementation of the South African Medicines Act. [19] The Act was aimed at making drugs more affordable by offering patients generic medicines and empowering the government to import medicines from other countries in cases where they were available for purchase at lower prices. [20]

At the time of the case, more than 4.5 million people in South Africa were infected with HIV/AIDS and most lacked access to treatment. Numerous NGOs, including Médicins Sans Frontières (MSF), Treatment Action Campaign (TAC), Health GAP Coalition, Third World Network (TWN), Oxfam, and Consumer Project on Technology (CPTech), mobilized by circulating petitions, staging protests, and writing letters. Rumor has it, even Mike Moore, then-Director-General of the WTO, rebuffed the pharmaceutical industry representatives asking them why they did not bother to sue Gandhi and Jesus too. [21] Three years later, the pharmaceutical companies negotiated a settlement with the South African government and withdrew the case.

Brazil also had a confrontation over a national law relating to access to medicines. In 1996, Brazil passed a law to further its policy of providing universal distribution of HIV/AIDS drugs to its estimated 600,000 residents infected with HIV/AIDS. [22] The law permitted the government, under certain conditions, to authorize domestic production of medicines without the permission of the patent holder. The US government filed a complaint in the WTO, backed by the pharmaceutical industry. In the wake of political pressure exerted by many of the same NGOs that were active in the South Africa case, and failure to effect a change in the Brazilian law through the WTO dispute settlement mechanism, the US withdrew its complaint in July 2001. [23]

### TRIPS and public health in the new round.

The persistence of HIV/AIDS, paired with legal battles over the domestic laws of South Africa and Brazil, made TRIPS and public health a major issue when the WTO launched the next round of negotiations in Doha, Qatar in November 2001. The overriding problem was that the TRIPS agreement did not clearly delineate countries' options for simultaneously addressing public health crises and satisfying its obligations to protect IP. Consequently, one central objective for negotiations was to resolve the ambiguity in the TRIPS agreement.

At the Doha Ministerial Conference, WTO members responded to the need for clarification by endorsing the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration "recognized the gravity of public health problems afflicting many developing countries and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics" and stressed the need for an agreement "supportive of WTO members' right to protect public health and . . . promote access to medicines for all." [24] It delegated responsibility for resolving the ambiguity to the TRIPS Council, the WTO body which administers the TRIPS agreement. Specifically, it instructed the Council to "find an expeditious solution" and report to the General Council before the end of 2002. [25]

### The crux of the problem.

As with many international agreements, the TRIPS agreement was reached through "constructive ambiguity," leaving certain provisions open to various interpretations for purposes of achieving consensus. In the debate on TRIPS and public health, much of the disagreement focused on a particular legal instrument, known as "compulsory licensing." A compulsory license is authorization by a government to produce a patented product without the consent of the patent holder. [26] Compulsory licensing is unpopular with patent holders because it can threaten the monopoly rights afforded to them by IP protection. Article 31 of TRIPS set restrictive conditions under which a country can issue a compulsory license. Specifically, it provides that in "situations of national emergency or other circumstances of extreme urgency," countries can issue a compulsory license to manufacturers for the production of pharmaceuticals. [27] It also set forth a series of conditions for countries issuing a compulsory license, including obligations to notify the patent holder, outline the scope and duration of manufacturing operations, and provide an appropriate level of compensation to the patent holder.

However, Article 31 limited compulsory licensing to production for a country's domestic market, as section (f) says that "any such use shall be authorized predominately for the supply of the domestic market of the Member authorizing such use." [28] As a result, countries lacking the capacity to produce pharmaceuticals domestically could not take advantage of the compul-

sory license provisions under the TRIPS agreement. They were left with four options. First, they could continue to purchase medicines from the patent holder, though they were cost-prohibitive for many countries and the very problem the TRIPS and public health negotiations were attempting to address. Second, they could attempt to import medicines from countries where the patent holder sold them at lower prices, a practice known as parallel importing, which was also wrought with legal controversy. [29] Third, in the short-run, they could issue a compulsory license to a foreign manufacturer, in a country where pharmaceuticals were not yet protected by patents. Countries that had not yet adopted patent laws were not constrained by the provisions of the TRIPS agreement. [30] However, eventually all WTO members would be required to comply with the TRIPS agreement. Fourth, arguably, they could import medicines from a country that had patent protection, providing the amount did not exceed that which was produced predominately for the supply of the domestic market. Yet, under any of these scenarios, there was neither a guarantee that these countries could supply other markets, in addition to their own, nor supply medicines at an affordable price.

### How did the TRIPS Council attempt to solve the problem?

The Doha Declaration on the TRIPS Agreement and Public Health included two instructions for the WTO body responsible for administering the TRIPS Agreement, the TRIPS Council. First, the Declaration directed the TRIPS Council to extend the deadline by which Least Developed Countries (LDCs) were required to implement IP protection on pharmaceuticals until 2016. LDCs are among the fifty least developed countries in the world and are designated as such by the United Nations; thirty-two of these belong to the WTO, many of which lacked the capacity to manufacture pharmaceuticals. [31] On June 27, 2002, the Council issued the extension, preserving the option for LDCs to import, and in some cases produce, generic pharmaceuticals without the permission of patent holders.

Second, the Declaration mandated that the TRIPS Council design a plan to expand access to medicines for countries without domestic manufacturing capacity. However, finding a solution required that the Council consider several issues, including:

1. **Price** - The overall objective of the Doha Declaration on the TRIPS Agreement and Public Health was to improve access to medicines. While several obstacles impede access, such as infrastructure for the delivery of medicines and availability of qualified health personnel, price is the obstacle that IP protection rules influence. Since IP protection awards monopoly rights to patent holders, it affects the number of suppliers in the market, the level of competition for business, and ultimately price. Hence, the WTO could encourage lower drug

prices by modifying provisions of the TRIPS agreement to provide exceptions to monopoly rights.

Since compulsory licensing was permitted under the TRIPS agreement, it was one instrument that could help make medicines more affordable. It promised to increase competition by allowing countries with manufacturing capacity to authorize additional suppliers to enter the market. It encouraged competition and in some cases, enabled countries to obtain price reductions with patent holders by threatening to issue a compulsory license. In the end, the major challenge for the TRIPS Council was to extend the compulsory licensing mechanism to countries lacking manufacturing capacity.

2. Capacity - The Doha Declaration on the TRIPS Agreement and Public Health sought a solution for "WTO members with insufficient or no manufacturing capacity." [32] However, it was unclear what constituted "manufacturing capacity." As members endeavored to define "capacity," they considered a number of different factors, including, countries' respective levels of economic development, monetary values of drugs and medicines, and histories of discovery and marketing of chemical entities. [33] The debate was further complicated because only a handful of countries produced the active components in a medicines that are responsible for their effect. This fact begged the question - should those countries, which import active ingredients for pharmaceutical production also be deemed to have manufacturing capacity? [34]

Even if the WTO settled on a definition for manufacturing capacity and created a system for assessing whether member countries had adequate capacity, another challenge still remained - while some countries might have the capacity to produce certain medicines, it did not necessarily mean they could produce any and all medicines, in light of technological and economic constraints. Several NGOs, including CPTech, Oxfam, MSF, and Health Action International (HAI), raised this issue in a letter addressed to delegates of the WTO. The letter highlighted a statement by a WTO dispute settlement body, in a related case, which acknowledged that "smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale." [35]

3. Scope of Diseases – The Doha Declaration on the TRIPS agreement and public health specifically recognized "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Naturally, countries with a large pharmaceutical industry, and the pharmaceutical companies themselves, sought to limit the conditions under which countries could circumvent patent protection, particularly by curtailing the flexibility provided by

the "other epidemics" clause of the Declaration. As one company warned, "extensive use of these exceptions/ flexibilities...would quickly negate the intellectual property-related incentives that are needed to develop the next generation of pharmaceutical therapies." [36]

On first glance, it seems that the Declaration targeted a select group of the world's most pressing health challenges. However, in legal terms, it was unclear which diseases qualified as "other epidemics." The US worried that this clause could be used for breaking patents on "any drugs for any disease, including 'lifestyle' drugs for erectile dysfunction, baldness, or obesity." [37] While at one level it seemed ridiculous that countries would use flexibilities under the TRIPS in this way, newspaper articles attest to attempts to provide local generic manufacturers with permission to produce Viagra, without the permission of the patent holder, in Egypt and China. [38]

At the same, developing countries viewed attempts to narrow the scope of diseases, as reopening an issue that had already been settled in negotiations over the language of the Declaration. According to a representative from Brazil, "it was not in the purview of the Council to re-examine what had been agreed upon in the Declaration." [39] Moreover, developing countries feared losing the right to define for themselves what constitutes a public health emergency and the flexibility needed to respond to unforeseen health challenges. As the South African Ambassador later noted, "it is neither practicable, nor desirable to predict the pharmaceutical product needs of the members desiring to protect the public health." [40]

4. Coverage - The Doha Declaration on the TRIPS agreement and public health was a response to "public health problems afflicting many developing and leastdeveloped countries," particularly those with "insufficient or no manufacturing capacities in the pharmaceutical sector." [41] To ensure that the Declaration facilitated access to medicines for the intended countries, the Council considered limiting the scope of countries that could utilize a solution. One method for accomplishing this objective was to target countries identified in the WTO as developing and least developed. However, developing countries comprised about two-thirds of the membership in the WTO and included a diverse range of income levels, some of which might be more likely targets for additional flexibilities under the TRIPS agreement and some of which might not. [42] In contrast, LDCs were among the needlest countries in the world and were designated as LDCs by the United Nations. [43] Since the Council's first action was to delay implementation of the agreement for LDCs, the remaining challenge was to decide which developing countries the solution should target and how they should be targeted.



The Doha declaration and IP issues: Access to drugs. A temporary solution or permanent fix?

### Towards forging agreement.

In 2002, the Chair of the TRIPS Council, Ambassador Eduardo Perez Motta (Mexico), engaged in a process commonly used in the WTO to facilitate agreement. He held numerous small meetings and consultations with members and then proposed a compromise in the form of a draft text. In December, he circulated the draft text, which garnered wide support on several points. It proposed to waive the TRIPS requirement that compulsory licensing be used predominately for the domestic market. The waiver would allow countries to import generic medicines from foreign manufacturers under a compulsory license. In addition, the draft proposed safeguards against abuse and the diversion of products to unintended markets. These would require, among other things, that members using the waiver: (1) specify the names and expected quantities of products; (2) confirm that the importing member has insufficient manufacturing capacity; (3) utilize special labeling, marketing or packaging to distinguish products from the rest; and, (4) post details about the conditions of the compulsory license on a specified website.[44]

Yet, many countries were skeptical about the text. While there was broad consensus on the major provisions, several developed and developing countries remained uncomfortable with the details of the draft. For example, developing countries contended that the safeguards were too onerous. In particular, a group of African countries argued that provisions, which required special labeling and markings for medicines produced under compulsory licenses, would "further increase production and compliance costs" and ultimately compromise the effectiveness of the solution. [45] Some developed countries considered the draft overly broad, particularly with respect to the scope of diseases. A representative from Canada noted that "members still needed to distinguish between those [diseases] that were epidemics and those that were not." [46] Nevertheless, all members were willing to support the draft text except for one- the US, which walked away from negotiations at midnight on December 20, 2002. In her statement before the Council, the US representative explained that "her delegation was willing to join the consensus on all parts of the draft except the scope of diseases." [47]

Rumors among some insiders suggest that key officials in the Office of United States Trade Representative (USTR), which manages trade issues on behalf of the President, supported the draft text. Yet, political pressure from pharmaceutical industry executives on the White House led to the USTR's rejection of the proposed agreement. While the rumors cannot be corroborated, the pharmaceutical industry clearly exercised considerable power. In December 2002, the industry had recently contributed \$60 million for Republican campaigns in the mid-term election, allowing the more conservative party to expand their majority in the House of Representatives and regain control of the Senate. [48]

### Breaking the deadlock.

Director-General Supachai Panitchpakdi proposed that the TRIPS Council overcome the deadlock on the scope of diseases and reach an agreement by February 11, 2003. [49] To this end, the US, the EU, and Japan each brought new policy initiatives to the WTO at the start of the new year. The US proposed a moratorium on WTO challenges to poor countries for using compulsory licensing in response to "HIV/AIDS, Malaria or Tuberculosis or other infectious epidemics of comparable scale and gravity." [50] The moratorium was intended to serve as an interim solution, allowing LDCs and lower-income developing countries to authorize foreignbased generic manufactures to produce patented medicines for a narrow set of diseases. [51] However, the EU delegation considered the moratorium a "facesaving exercise," which had "limited substantive value" because it did not provide the legal footing for generic producers to export medicines. More specifically, the EU suggested that even if WTO members joined the moratorium, it lacked "the legal backup at the domestic level" for generic producers to sell medicines to needy countries. [52]

Instead, the EU proposed to add a footnote to the TRIPS agreement, specifying that it apply to a more flexible definition of at least 22 infectious diseases, including HIV/AIDS, Tuberculosis, Malaria, Measles, Influenza, and Meningitis. In addition, the EU proposed that the World Health Organization serve in an advisory role to the WTO on the scope of diseases. [53] According to a representative of the EU, the proposal was not designed "to restrict the scope of the Declaration, but to preserve it" and that the only difference between the draft text and the EU proposal was that "for those public health problems not appearing on the list, the WHO could be called upon, in case of any doubt, to give its opinion." [54] Japan offered a proposal similar to the EU proposal, calling for application of the TRIPS and public health agreement to 22 epidemics. [55]

The TRIPS Council missed the February 11<sup>th</sup> deadline for an agreement, in spite of the new policy initiatives, as well as the efforts of the TRIPS Council Chair, Ambassador Motta. The Chair had been working to forge an agreement by leaving the draft text from December

2002 intact, while crafting an interpretive statement to accompany the agreement, known as a Chair's statement, which "recognized the importance of patent protection as incentive for drugs development while reaffirming the rights of governments to protect public health." [56]

However, before Ambassador Motta's could complete negotiations on the statement, his term as Chair expired and Ambassador Vanu Gopala Menon (Singapore) took over. The new Chair built on the work carried out by his predecessor by also leaving the draft text intact and focusing on a Chair's statement. To help devise the statement, he convened a small group of representatives from the five countries of the US, Brazil, India, Kenya and South Africa. These countries were particularly relevant to the discussion either for their pharmaceutical manufacturing industry or the widespread suffering from diseases in their respective countries. More specifically, the US was home to the largest pharmaceutical company in the world, Pfizer, and comprised a market valued at some \$200 billion a year and growing. [57] Furthermore, since the US was the only member to reject the December 2002 draft text, breaking the deadlock was largely a matter of finding agreement between the US and everyone else. Brazil's aggressive HIV/AIDS program engendered large-scale domestic production of generic medicines- it involved government manufacturing of ARVs for distribution, free of charge, to HIV/AIDS victims. [58] In addition, the US and Brazil had previously engaged in a legal battle over Brazil's HIV/AIDS program. India was one of the largest generic drug producers in the world, with an industry valued at £2.7 billion. [59] Manufacturers of patented medicines had long complained about India's lax enforcement of IP protection. Kenya had firsthand experience with the devastation of AIDS, as more than 2 million of its adults and children lived with AIDS and the disease claimed approximately 600 lives or more per day. [60] Its Ambassador to the WTO, Amina Mohamed, often spoke on behalf of a group of African countries in the WTO, known as the African Group, which were also dealing with the far-reaching impacts of the AIDS pandemic. [61] South Africa was also home to tremendous suffering from HIV/AIDS, as 4.7 million of its population of 40 million was HIV-positive. [62] In addition, the relationship between the government and pharmaceutical companies was combative, as evidenced by the legal dispute over the importation of medicines. [63]

By the Spring of 2003, the context for discussing TRIPS and public health began to change. Members became more concerned about unforeseen health emergencies when Severe Acute Respiratory Syndrome (SARS), a respiratory illness, emerged in Asia. It spread to 8098 people in 26 countries in just a matter of months, causing 774 deaths, as well as major disruptions in travel and health services. [64] According to a representative from Kenya, in light of SARS, "an urgent solution was needed." [65]

In May 2003, the World Health Assembly also acknowledged the need for a solution to the TRIPS and public health issue in the wake of SARS. The Assembly resolved that "in order to tackle new public health problems with international impact, such as the emergence of SARS, access to new medicines with potential therapeutic effect and to health innovations and discoveries should be universally available without discrimination." [66] Furthermore, it urged members to: (1) reaffirm that public health interests are paramount in both pharmaceutical and health policies; (2) consider adapting legislation to use the full flexibilities of the TRIPS agreement; (3) continue to work towards a reaching a solution on the TRIPS agreement and public health; and, (4) establish conditions to spur the development of new medicines for diseases affecting developing countries. [67]

In the same month, a group of more than 70 countries from the African, Caribbean and Pacific Group of States (ACP), issued a letter to the TRIPS Council, criticizing the US for blocking the adoption of the draft text in December 2002 and stressing the need for an agreement. [68] In addition, the letter requested "that the issue of TRIPS and public health be addressed satisfactorily" before the next ministerial conference and "that all WTO stakeholders be mobilized to ensure urgent and adequate resolution to the issue." [69]

In June 2003, in Cairo, the WTO held a mini-ministerial meeting, which is an informal meeting of trade ministers, held prior to a formal ministerial meeting to promote consensus-building on various trade topics. During the meeting, the US abandoned its endeavor to limit the scope of diseases. According to then-US Trade Representative, Robert Zoellick, the US changed its position because the scope of disease was no longer an issue with the pharmaceutical industry. [70] According to one report, The USTR managed to "convince its industry to give up its demand on reducing the coverage of disease." [71] As a result, Ambassador Menon began to plan for brokering an agreement. He indicated that US seemed comfortable with the draft text. but wanted more assurances that the agreement would not be misused. [72] At this point, he would begin working to incorporate assurances in the Chair's statement

### What about everyone else?

Members of civil society and WTO members, who were not privy to the meetings of the five countries negotiating the Chair's text, began to worry when they realized that an agreement was forthcoming. Because they were excluded from meetings, they tried to figure out what exactly was being negotiated. Trade representatives sought information from their colleagues. Some NGO's were permitted by the Secretariat to enter the WTO and speak with representatives coming and going from meetings. One representative later noted that civil society exerted considerable influence by asking questions, lobbying representatives, and reporting on negotiations. For example, NGO's, such as CPTech and

TWN, remained in the halls of WTO at all hours of negotiations, speaking with representatives, and providing detailed updates on negotiations on their websites.

In August, the US, Brazil, India, Kenya, and South Africa completed their draft of the Chair's statement and released it for other members to review. It purported to outline the "shared understanding of Members regarding the decision . . . and the way in which it [would] be interpreted and implemented." [73] Moreover, it specified the following: (1) the decision should be used in the pursuit of public health rather than for commercial objectives; (2) all reasonable measures should be taken to prevent diversions from the markets for which the products were intended; (3) Members should seek to resolve any issues arising from the decision "expeditiously and amicably;" (4) information relating to the implementation of the decision should be brought to the TRIPS Council in its annual review; and (5) twenty-three developed countries agreed not to import pharmaceuticals under the agreement. [74]

When the civil society received copies of the draft statement, several groups announced their concern. MSF suggested that, "rather than allowing the poorest countries to make effective use of compulsory licensing, this text seeks to throw up as many obstacles and discouragements as possible, and opens the system up to constant political intimidation from powerful members." [75] Oxfam said that "the statement contained 'burdensome conditions' on top of what was already a restrictive text, and was unlikely to benefit the developing countries it was designed to help." [76] Civil society was joined in their opposition to the proposed statement by some representatives, but it didn't seem that there was much they could do to stop its approval, as it was quickly garnering the support of trade ministers and high-ranking officials in the country's capitals.

### One last-ditch attempt.

The TRIPS Council was expected to adopt the agreement on August 28, 2003. Concerned that the proposed agreement was bad for developing countries, a staff member of one NGO pleaded with a like-minded representative from the Philippines not to give up on "the good fight." The representative indicated he would try to find a way to address the impending course of events.

On August 28th, when the TRIPS Council took up the agreement, the representative from the Philippines raised his microphone, requesting to be recognized. He read a statement, indicating that while the Philippines would support the agreement, the Chair's statement did not, in fact, outline a shared understanding of the membership. His country had a different understanding of the agreement, which he proceeded to delineate for the Council. [77] Among other things, he noted that:

The Chair's statement indicated that members should take all reasonable measures to prevent product diversion, but many developing countries were ill-equipped to fully take responsibility for trade diversion. His country understood that the obligation of developing countries was on a "best-endeavor basis."

While the Chair's statement indicated that the Agreement should not be used as an instrument for pursuing industrial or commercial policy objectives, the Philippines understood that a policy designed to circumvent patent rights or monopolistic-rights was inherently an instrument of industrial policy.

His country understood that special packaging and coloring requirements, aimed at safeguarding products against trade diversion, threatened to increase costs, and make the system more difficult to use for both importing and exporting members.

After he read the statement, consensus began to unravel and the Council meeting was adjourned. As it turned out, other developing countries also had questions about the Chair's text. It took two days of political haggling and unseen pressuring, for proponents to rebuild the consensus. On August 30, the Philippines retracted its statement and the WTO passed the agreement. It consisted of a waiver, which was exactly the same waiver the WTO considered in December 2002. It permitted countries to import pharmaceuticals manufactured under compulsory licenses and contained several safeguard provisions for patent holders. Also, the agreement contained the Chair's statement and the commitment by 23 countries not to use the system for importing medicines. While the WTO celebrated the agreement, wide disagreement remained over whether it balanced effectively the interests of IP protection and public health.

In December 2005, WTO members made the agreement of 30 August 2003 an amendment to the TRIPS agreement requiring parties intending to import or export medicines manufactured under compulsory licenses to notify the TRIPS Council, which makes the notifications publicly available on the WTO website. This amendment will be formalized when two-thirds of the Members ratify it. To date, three countries have ratified the amendment: the US. Switzerland, and El Salvador.

### **Author declaration**

This case study was written by Gina Vea, Programme Officer of Intellectual Property at the International Centre for Trade and Sustainable Development. This paper was written before taking up the current position and does not reflect the views of the organization. It benefited greatly from the input from colleagues at the Terry Sanford Institute of Public Policy at Duke University

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# IS INTELLECTUAL PROPERTY A CATALYST FOR DEVELOPMENT? - THE CASE OF BIOTECHNOLOGY SECTOR IN MALAYSIA AND SINGAPORE.

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#### **Abstract**

Intellectual property protection is often regarded as a catalyst for endogenous development and developing countries are being encouraged to a have proper intellectual property system that also includes patents registration. There is however a controversy whether a patent system will effectively encourage domestic firms to innovate and contribute to local economic development or whether it just benefits foreign investors and their off-shore production. Malaysia and Singapore are two countries in Southeast Asian committed to promote biotechnology as a catalyst for future economic growth. The two countries may be different in many ways but their approaches to stimulate technological innovation by means of a strong intellectual property system are quite similar. The article shows that patent systems are now increasingly being used by local firms in Malaysia and Singapore, yet foreign firms continue to have by far the largest share of patents.

#### Introduction

Intellectual property is said to be a catalyst for economic development. Take the patent system for example. The granting of patents originated in Europe in the 15<sup>th</sup> century where European economies issued letters of patent to local and foreign inventors to attract them to invest in their particular country. Patents were granted as monopoly rights to foreign and local investors in return for them bringing in their technology. The system was used to protect the trade of glassmaking in Venice, the industry of silk-making in Lyons and the glassmaking, weaving and shipbuilding in the early period of the Industrial Revolution in England.

The most famous and probably the first written law on patent was the Venetian Patent Law of March 19, 1474 [1]. It confirms the early recognition of the importance of foreign experts in bringing knowledge and investment to "benefit to the State". The Venetian Patent Law granted patent protection for 10 years. The Law also prohibited any form of infringement in any territory and not just in Venice [2]. The law was introduced to attract inventors and investors to Venice to generate new economic activities. At the time the law was introduced, Venice already had a glass-making industry which was monopolised by guilds. The guilds had their own rules which were restrictive thus restricting innovations.

The short lesson from history shows that patents were being used to attract foreign direct investments and spur local innovation that would eventually lead to higher economic growth. This article will argue that developing countries, such as, Malaysia and Singapore realised that intellectual property protection such as patents should be used to achieve both - attract foreign direct investments and encourage local companies to

innovate. In a knowledge-based economy where intangible assets such as intellectual capital become increasingly important, the state increasingly plays the role of a mid-wife that facilitates birth of a home-grown technology industry.

Successful participation in the knowledge economy decreases the reliance on labour intensive activities and will encourage higher value-added production. In countries, such as, Malaysia and Singapore, continuing dependence on labour intensive activities will not ensure future economic growth as they stands in direct competitions with other economies in the region that offer cheaper labour costs. As they are more affluent, the two countries are also facing a shortage of skilled labour that comes along with the shift to a more knowledge-based economy which uses more skilled human resources.

Despite having access to one of the largest biodiversity resources in the world, both Malaysia and Singapore are still lagging behind in local R&D, thus stifling the growth of home-grown technology. It cannot be said that this is because of the patent system. However, it can be argued that the focus of the economy has been on other sectors, such as, infrastructure development. As there is growing competition from neighbouring countries offering cheaper labour costs, Malaysia and Singapore have to move on to high technology activities. The move to high technology activities requires R&D and higher spending on R&D.

The low amount of R&D spending per capita is a serious issue that must be addressed by the relevant countries. A critical determinant of the availability and accessibility of biotechnology innovations in developing countries is the countries' own national capacity in biotechnology research. National research capacity increases the ability to invent new technologies, to import and adapt agricultural technologies, to ensure that the public goods aspects of research are addressed and to appropriately regulate technologies [3].

Research capacity depends on wide portfolio - physical, human, and financial resources that facilitate the effective use of research. Research capacity is not limited to undertaking research projects, but encompasses engagement with a broader innovation system, including specifying, accessing, interpreting and applying research [4]. It also involves a spectrum of key elements and activities, including defining objectives and priorities in an identified sector; developing and implementing clear policy strategies for the identified sector and designing appropriate biosafety regulations; developing R&D management capacity; facilitating transfer of technologies, knowledge and skills to the private sector; and promoting international collaboration and technology transfer [5].

A common problem of high technology investment in Malaysia and Singapore is the fact that most are owned by foreign companies. This is because the two countries are at the early stage of the transition from low level manufacturing based economy into high technology based economy. Thus there is a dependency on foreign direct investment to bring in new technologies and to facilitate transfer of technology to the domestic sector, owned by Malaysians and Singaporeans. The transfer of technology will allow domestic players to learn from the new technologies and this will result in spin offs from the foreign owned companies.

There is no doubt that both countries are well known for their manufacturing prowess based on foreign investment and imported technologies. However, they have yet to be recognized as centres of world-class excellence in science and technology and research and development [6]. With the exception of Singapore, public spending on R&D averages less than 0.3 % of domestic income in the region, which is below the 2.5-3 % range in Japan and Korea [7]. Singapore has been successful in raising R&D expenditures to 1.8 % of domestic income [8]. Malaysia has little R&D expertise in general, not only in biotechnology. The present government's R&D expenditure is only 0.5 % of GDP. According to the numbers of the Knowledge-based Economy Master plan, the figure is even lower at 0.39 %. The Government is aiming to increase R&D spending in the field of science and technology to at least 1.5 % of the GDP by 2010 [9].

#### The use of biotechnology in Malaysia

Towards the later part of the 20<sup>th</sup> century and at the turn of the 21<sup>st</sup> century, Malaysia and Singapore have put more focus on biotechnology as a catalyst for the future economic growth. Although the focus is the same, the approach may be different.

Malaysia, which is ranked by the United Nations Environmental Programme (UNEP) as 14th in the megadiversity countries, [10] will use this natural asset as a basis for the biotechnology R&D and commercialisation. Malaysia has the natural resources that are useful in R&D and the necessary motivation to develop a biotechnology industry. Yet, to make biotechnology an engine of economic growth, it also needs to invest in its human capital and the acquisition and attraction of new knowledge and technologies from abroad.

Malaysia has an important agricultural sector, which accounts for 12% of the GDP [11]. In the new Asian knowledge economy that is also slowing trickling down into the agricultural sector, Malaysia competes with its neighbours as well as China and India in exporting to the Asia Pacific region. Malaysia has produced a National Biotechnology Policy, which was launched on 28th April 2005. As the current Chairman of the Organisation Islamic Conference, Malaysia has a strong economic influence in the Moslem World and it intends to expand its markets in Middle East. Malaysia's leadership on

"Halal" food is also recognized in the Organization of Islam Conferences [12].

The National Biotechnology Policy is to give impetus to developing the biotechnology sector into a new economic engine enhancing prosperity and wellness of the nation by 2020. The policy encompasses 3 phases: capacity building (2005-2010), creating business out of science (2011-2015), and turning Malaysia into global player (2016-2020). The policy document does not explain in detail what activities will take place in each phase.

To implement the policy, Malaysia has created Malaysian Biotechnology Corporation to oversee the implementation of the policies and initiatives. The Corporation will be a dedicated and professional one-stop agency responsible for developing the country's biotechnology industry. It is overseen by an Implementation Council and advised by an International Advisory Panel, both under the leadership of the Prime Minister of Malaysia. The Malaysian Biotechnology Corporation will coordinate biotechnology initiatives from all relevant government ministries, but will come under the purview of the Ministry of Science, Technology and Innovation. It will also work closely with relevant ministries to enhance biotech R&D and to help improve the regulatory environment.

The activities for the first phase (2005-2010) are best explained by the 9th Malaysia Plan (2006-2010) in particular, Chapter 6 of that Plan. The 9th Malaysia Plan states that 'The Ninth Plan will focus on implementing the NBP to develop Malaysia's niches in agriculture biotechnology, healthcare related biotechnology, industrial biotechnology and bioinformatics. In this regard, the promotion of foreign and domestic investments and close collaboration with foreign entities to access new technology, expertise and markets will be intensified.'[13]

Among the strategies employed by Malaysia are:

- transforming and enhancing value creation in the agriculture sector through biotechnology;
- ⇒ capitalising on the strengths of biodiversity to commercialise discoveries in health-related products and position Malaysia in the growing bio-generics market;
- ⇒ nurturing growth opportunities in industrial bioprocessing and bio-manufacturing;
- ⇒ leveraging on the convergence of technologies to grow the nascent bioinformatics industry;
- creating an enabling environment with supportive institutional, regulatory and financial framework to facilitate the build up of a strong and diversified biotechnology industry;
- enhancing human capital development to meet national needs; and
- establishing R&D centres of excellence and accelerating technology development, diffusion and commercialisation.

With the promotion of biotechnology as the growth

sector, Malaysia hopes to create 100 companies with about 280,000 jobs and contribute towards 5 % of GDP by 2015 [14]. This is comparable to the contribution of some 50 medium-sized Malaysian companies in 2002 [15]. This is a modest target, considering that the sector will take about another 14 years to achieve its target. To achieve the target, Malaysia plans to conduct research and academic development activities in seven areas: molecular biology, plant biotechnology, animal biotechnology, medical biotechnology, environmental and industrial biotechnology, and bio-pharmacy and food biotechnology.

A local patent system is expected to assist and benefit local inventors and investors in their efforts to realise the potential of biotechnology. Malaysia signed the Convention on Biodiversity (CBD) on 12<sup>th</sup> June 1992 and ratified the same on 24<sup>th</sup> June 1994 [16]. As a country rich in biodiversity, Malaysia offers vast opportunities for bio-prospectors to make use of these natural resources and convert them into new products [17].

Genetic resources have long been a source of important raw materials in agriculture and medicine. They have continually provided the basis for both the improvement of agricultural crops and for traditional plant-based medicines. About 75% of the world population relies on traditional plant-based medicine for its primary healthcare [18]. It has been reported that 33% of drug products in the highly industrialized countries are derived directly from plants; most of these are tropical plants growing in equatorial countries such as Malaysia.

The rapid advancement in science and biotechnology has increased the potential uses of genetic resources and hence their actual and potential economic value, prompting a surge of interest in these resources and stimulating trade [19]. The growing biotechnology industry currently utilises genetic resources to develop new and improved drugs, crop varieties, industrial techniques and a myriad of other commodities. Its combined annual global market value was estimated to lie roughly between US\$500 billion and US\$800 billion in 1999 [20].

This is a combined value derived from the following sectors: pharmaceutical, botanical medicines, major crops, horticulture, crop protection products, and applications of biotechnology in fields other then healthcare and agriculture and cosmetics and personal care products. The global market value of drugs derived from genetic resources is estimated to be US\$ 75-150 billion per year. The annual total value of sectors associated with the global seeds market, not limited to seeds using genetic diversity, is estimated at around US\$ 45 billion, while the total output from the world's agro-ecosystem is equivalent to US\$ 1.3 trillion per year [21].

A major issue for national implementation is the need to achieve a balance between controlling access to genetic resources and facilitating it. Malaysia will be concerned as to how it can capture a share of the benefits generated from genetic resources, and simultaneously tackle the unauthorised use of its genetic resources [22]

Prospectors from other countries must also protect local people and traditional knowledge, from misuse or piracy. Bio-piracy is still an unresolved issue, as developed countries are reluctant to curb it through rules in the international fora. For example, they have not adopted rules on the disclosure of origin of biological materials claimed in patent applications.

The European Union intended to introduce a rule to disclose the origin of genetic material used in patented inventions. An obligation of this type was incorporated in the draft of the European Union Directive relating to patents on biotechnology, as recommended by the European Parliament in July 1997, but was removed from the final text. However, Recital 27 of the Directive mentions an obligation to provide information as to geographical origin of biological material where this is known, without prejudice to patent validity.

Brazil, a leading mega-biodiversity country, has made several proposals to the WTO TRIPs Council, WIPO and the CBD to introduce provisions requiring disclosure of sources of genetic materials. Brazil is of the view that patent applicants for inventions relating to biological materials and/or associated traditional knowledge, under the existing relevant international treaties, should be required, as a condition for acquiring patent rights, to disclose: (i) the source and country of origin of the biological resources and associated traditional knowledge used in the invention; (ii) evidence of their compliance with prior informed consent under the relevant national regime; and (iii) evidence of their compliance with fair and equitable benefit sharing under the relevant national regime.[23]

Between 30<sup>th</sup> January and 3<sup>rd</sup> February 2006, the CBD, at the Ad Hoc Open Ended Working Group on Access and Benefit Sharing in Granada, discussed the draft International Regime on Access and Benefit-Sharing. Among the scopes of the regime is the plan to introduce a fair and equitable sharing of the monetary and nonmonetary benefits arising out the utilization of genetic resources, and associated traditional knowledge in the context of mutually agreed terms. The draft proposes that:

- a. The regime applies to all genetic resources and associated traditional knowledge, innovations and practices and benefits arising from the utilization of such resources. However, it will not apply to the plant genetic resources that subject to the International Treaty on Plant Genetic Resources for Food and Agricultures. It is also proposed that conditions for access to genetic resources shall be dependent upon or related to benefit sharing arrangements;
- b. Access procedures shall be clear, simple and transparent and provide legal certainty to different kinds

of users and providers of genetic resources with a view to the effective implementation of article 15, of the CBD:

- Parties or Countries of origin providing genetic resources, may establish measures requiring that access to such genetic resources shall be subject to prior informed consent; and
- d. Mutually agreed terms for access to and specific uses of genetic resources may include conditions for transfer of such genetic resources to third parties, subject to national legislation of countries of origin.

It is also proposed that in accordance with article 8(j) of the CBD:

- Parties may consider developing, adopting and/or recognizing, as appropriate, international, national and local sui generis systems for the protection of traditional knowledge, innovations and practices associated to genetic resources;
- b. Parties to recognize and protect the rights, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities and ensure the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices; and
- c. Parties should comply with the prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with article 8(j) of the Convention on Biological Diversity, subject to national legislation of the country where these communities are located.

The draft proposal also foresees the establishment of an international certificate of origin/source/legal provenance of genetic resources to be issued by the provider country or country of origin. The issues are still being discussed at the CBD and they are not expected to be resolved in the near future.

However, the need to address bio-piracy, which normally refers to foreign entities, should not prevent the possible use of biodiversity, in a sustainable manner. [24] Thus, there are rules which allow bio prospecting by foreign entities by collaborating with local concerns. For example, in the Malaysian state of Sarawak, foreign bio prospectors may collaborate with local institutions to conduct such activities.

Under Section 23 of the Sarawak Biodiversity Centre Ordinance 1997.

'no person is allowed, without a permit issued by the council and subject to such terms and conditions as may be stipulated in such a permit, to collect or take any plant or any part of a plant found on any State Land, protected forest, forest reserve or communal forest or collect any biological resources as may be specified by the Council for the purpose of any scientific study or experiment or for medicinal or pharmaceutical research or development.'

A permit is also required for ethno biological research.

Under Rule 3 of Sarawak Biodiversity Centre Regulation 1997, only the following persons are eligible for such permits to conduct bio prospecting in the state:

- a. Malaysian citizen who is either of Sarawak origin or permanently resident in Sarawak; or
- A corporation or body corporate established under any written law in Malaysia or educational institution registered with the Ministry of Education, Malaysia; or
- A corporation or educational institutions incorporated under the laws of foreign country with the experience, expertise knowledge and facilities to undertake research on the biological resources of the State; or
- d. Any person who has special qualifications or expertise in any particular field of research relevant to the biological resources of the State.

However, a person under paragraph (c) and (d) above must have sponsors who are Malaysian citizens of Sarawak origin, or permanently resident in Sarawak, or an institution or a corporation incorporated or registered in Sarawak. Such a sponsor shall undertake to the Council that he will comply with the provisions of the Ordinance, the Regulations, and the conditions of the permit.

The Regulation also prohibit any collection of biological resources for research or commercial purposes from any state land, national park, nature reserve, wildlife sanctuary, forest reserve, protected forest or communal forest or any marine and aquatic areas without permit. It also prohibits such biological resources from being exported for research and commercial purposes without permit.

Under Rule 14 of the Regulation, the Sarawak Government may impose a condition that the State Government have the rights to patents and intellectual property to any discovery resulting from the research undertaken and, where appropriate, the rights to share such rights with other parties to the research agreement; and the rights to license any patent or intellectual property referred to above and the entitlement to benefits derived there from. The State may also require that the bio prospectors arrange for programmes or make arrangements for the transfer of technology, skills and knowledge derived from any research covered by such agreement, including the training of scientists from the state and their participation in such research.

In Malaysia, traditional Malay, Chinese and Indian systems of medicine are practised. Cross-cultural utilization of traditional systems of medicine is also popular. In Malaysia, the market for traditional medicine is estimated to be RM 1 billion to RM 2 billion annually, which is larger than the market for modern medicine [25].

#### The use of biotechnology in Singapore

Singapore focuses on different sectors of biotechnology, such as, allowing stem cell research, pharmaceuticals and medicinal products. As seen from Table 1 below, despite the challenges posed by the financial crisis in the late 1990s and other unfavourable global factors, Malaysia and Singapore largely remain on track in terms of economic growth and charted a 4.4 % and 5.4 % growth rate respectively in 2005.

Malaysia's economy is expected to grow by another 6 % in 2006. Table 1 below also shows that there is a big per capita income gap between Malaysia and Singapore. The per capita income in Malaysia is around US\$9,857 compared to Singapore's per capita income of US\$24,853. This could explain the difference in the R&D spending in Malaysia and Singapore. Singapore being a small country with a small population may concentrate on a specialised field. Malaysia, with 13 different states and a population of nearly 26 million people will have spend more on other areas, such as, poverty eradication and infrastructure development.

Since there is an income gap and the gap in R&D spending between the two countries, both countries focus on different areas in the biotechnology sector. Malaysia originally plans to focus on areas that can use its biodiversity as an attraction for investors, whereas Singapore concentrates on biomedical manufacturing. However, as mentioned above, Malaysia is also interested to venture into certain areas that can be considered the niche of Singapore, such as bio-manufacturing. It is expected that Malaysia and Singapore will be able to foster strategic partnership in the future. [26]

The Economic Development Board of Singapore (EDB) is responsible for the country's biotechnology development policy. The EDB aims to make the country a world-class hub attracting 15 top biotech or pharmaceutical companies by 2010. One of its projects is an infrastructure project called "Biopolis", an 18 million square foot biomedical sciences hub, housing public research institutes, corporate R&D centres and start-ups. The EDB first developed the R&D infrastructure as well human resource training and technology facilities. A gradual shift towards the promotion of biotechnology investments is part of the second stage [27]. The National Biotechnology Program Unit was established in 1988.

The EDB's priority is to develop pharmaceuticals and diagnostic toolkits of high commercial value. Recent initiatives by the EDB emphasize biomedical research geared toward commercializing and promoting a start-up formation to make Singapore a regulatory haven for stem cell research [28]. Singapore has also established the Biomedical Research Council and a Biomedical Grid, a high-security network enabling biomedical research information to be shared and distributed between interested parties within the 'grid'.

Table 1 - Economic growth in Malaysia and Singapore.

Country	GDP growth rate (constant prices)	GDP per capita, (current prices)	
	Percent	US\$	US\$ PPP
Malaysia	4.4	4,625	9,857
	Q3 2005	2004	2004
Singapore	5.4	25,207	24,853
	Q3 2005	2004	2004

Source: ASEAN Secretariat

Singapore has attracted some pharmaceutical giants. Eli Lilly is spending US\$ 140 million on research over five years and Novartis is spending US\$119 million over five to ten years from 2002 [29]. With the help of various incentives to attract R&D from foreign investors, Singapore has managed to produce various innovations like urine-powered batteries [30] and body parts produced from stem cells. [31] In view of the competition, Singapore plans to spend S\$12 billion over the next five years as compared to S\$5 billion dollars between 2001 and 2005 [32]

In addition, Singapore offers grants for start up companies [33]. There are several other initiatives, such as, US \$ 600 million to attract leading international companies to conduct R&D in the form of a Biomedical Science Investment Fund. In addition, Singapore Biolnnovations (SBI) has investment commitments of US\$ 21 billion for 13 new companies. SBI invested in three European, five Asian and fifteen US based companies. Singapore also has a policy to develop a manpower requirement [34].

Although Singapore does not have many natural resources for certain bio-based R&D, its position in the centre of Southeast Asia, close to Malaysia and Indonesia, which are rich in such natural genetic resources, allows Singapore to remain competitive and take full use of such an advantage. The availability of funds also attracts investors to the country.

The statistics from the government are very encouraging [35]: The Biomedical Sciences industry's manufacturing output grew to S\$15.8 billion in 2004, a 33.2% increase over 2003. Pharmaceuticals contributed S\$13.9 billion or 88% to the total manufacturing output, with employment expanding by 7.4% compared to 2003. Value-added also showed a robust 48% growth to reach S\$10.1 billion. Employment grew by a healthy 6.7% to 9,225 in 2004. Medical Technology enjoyed a 6.0% growth in manufacturing output to reach S\$1.9 billion in 2004. The latest figures show that the Biomedical Sciences industry's manufacturing output grew to S\$18 billion in 2005, a 9.8% increase over 2004. Pharmaceuticals accounted again for 88% of the total while Medical Technology enjoyed a strong 10.6% growth to reach S\$2.1 billion in output. Employment also expanded by a healthy 8.6% to cross the 10,000 mark. Of the 10,200 jobs in the BMS manufacturing sector, 62% are in Medical Technology [36]

#### Patents and Biotechnology in Malaysia and Singapore

It is commendable that the two neighbouring countries. which are also the two most dynamic economies in the ASEAN region, have managed to resort to high technology to generate economic growth. However, the issue is whether the emphasis on this high technology such as biotechnology is to the benefit or to the detriment of the local (home-grown) scientific communities. Are the local scientific community able to use the patent system in the same way as foreigners? Or, are the patent systems in the two countries more for the benefit of foreign investors? The other issue is whether the local scientific community will be able to take advantage of the foreign patents by engaging in various collaborations for mutual benefits, such as, to achieve technology transfer to local experts. These issues require further research to find the ways to allow the local scientific continue to fully benefit from the patent system.

Nevertheless, patent is not a licence to commercial success. Many patented products or process are not commercialised. There are other factors that affect a failure or a success of a patented product or process. At the same time, commercialisation also depends on the intention of the patent owners. Some patent owners apply for patents to protect future research rather than seek commercialisation. Commercialisation of patented products or process depends on other factors, such as, marketing skills, viability of the products or process to meet market and consumer demand and expectation, viability of production, and the ability to translate the technology into commercially viable process. At the same time, some products such as pharmaceuticals require regulatory approvals from relevant authorities. The regulatory process can take much time and incur huge expenses.

In Malaysia, many researches are conducted at public universities, as the universities have access to expertise and grants. However, the results of the research, even if patented may not result in commercialisation. According to a study by Amran Md. Rasli, an associate professor at University Teknologi Malaysia, anticipated commercialisation activities of the university failed due, in part, to the lack of connectivity between the industry and academia. One of the contributing factors to the failure is that commercialisation of R&D has not been traditionally a high priority of university research.[37]

Another factor that leads to lower commercialisation in Malaysia is the fact that most researches are funded by the Government. Recent assessment by the Ministry of Science, Technology and Innovation (MOSTI) indicated that most academia research and development (R&D) activities are funded by the ministry and other governmental agencies with only 0.68% university R&D funding coming from the industry as compared to the more advanced countries, such as, Canada (11.8%), Germa-

ny (7.5%), UK (6.2%) and the USA (5.5%). Countries such as Canada, Britain, Australia and Germany exhibit strong university-industry linkage. [38] Md. Rasli also finds that one key reason for poor university-industry linkage in Malaysian, especially in the life sciences sector, is the lack of industry receptors due to the limited state of development of this industry in Malaysia. The Malaysian industrial sector 'prefers' to be labour intensive and not invest into R&D in technology to gain competitive advantage. As such, Md. Rasli states that Malaysia's commercialisation effort to date has been quite modest with low number of patents indicated by 8.8 patent applications per population million as compared to Australia (546), USA (623) and South Korea (1,561). Further, compounding the situation is the fact that, the commercialisation movement has not resulted in any significant licensing revenue for the Malaysian universities. No R&D output from Malaysian universities has been commercialised yet on a national scale. Only 5.1 % of 5,232 R & D projects implemented during  $7^{th}$  and 8th Malaysia Plans were considered as having commercialisation potential.[39]

Thus, one of the ways to promote commercialization is to encourage joint ventures or collaborations between local and foreign firms. Foreign firms may need the market and access to natural resources and at the same time local firms need access to the technology. Patents and the numbers of patents filed do not give the accurate picture of the situation. For example, certain foreign companies might have licensed out their patent to a domestic firm, or they are in a joint-venture and the registration largely driven by the interests of the experienced foreign firm. A joint-venture agreement/ partnership also enables the domestic firm to get full access to the protected knowledge of the foreign firm. Moreover, the equation is too simple because young Malaysian companies cannot churn out as many patents as foreign companies who are in business for many decades, and have expertise in getting patents for even minor innovations. Malaysian companies may use patents to attract investment, but foreign companies use patents to broaden their war arsenal in case they are sued by another company for patent infringement.

Both Malaysia and Singapore are members of the World Trade Organisation ("WTO"). Both countries are also signatories of the Paris Convention for the Protection of Industrial Property 1883 ("Paris Convention") and the Washington Patent Cooperation Treaty 1970 ("PCT"). Being WTO members, both countries have to comply with the requirement of the Trade Related Intellectual Property Rights (TRIPs) Agreement. There is no doubt that both countries' patent laws are in compliance with TRIPs provisions. The main issue here is whether the existence and the implementation of the patent laws will benefit local innovations?

One of the ways to overcome this challenge is by the relevant country to introduce a *sui generis* system for certain innovation, such as, petty patent. Malaysia's Patent Act 1983 provides for utility innovation model,

generally known as utility model. Utility model may be defined as a second tier patent system, offering a cheap, no-examination protection regime for technical inventions which would not usually fulfil the strict patentability criteria. [40] The important factors identified by Suthersanen in relation to utility model are: utility model protection is accorded, cheaply and quickly, to inventions or innovations, many of which cannot gain protection under the patent regime.

Suthersanen identifies three traits common to all the national "utility model" laws from a global perspective: all utility model laws confer exclusive rights on the proprietor of the right (as opposed to an anti-copying right); novelty is a criterion in all utility model systems, though the standard of novelty varies widely; registration is a requirement but usually there is no substantive examination of applications; and most utility model laws protect the technical character of the invention, as opposed to the ornamental function or the appearance of the product. [41]

Simultaneously, the country may introduce sui generis registration system for traditional knowledge-based activities, as provided for under the CBD and discussed above. In this way, traditional knowledge-based activities may get protection in the form of proper registration and obtain rights, similar, to those obtained by patent holders.

#### The patent - dilemma with patents

Supporters of the patenting system argue that the rationale for a patent is to provide a long-term advantage to society as a whole by rewarding the development of new inventions. The counter argument is that the knowledge from the patents is not free and thus, the public may not fully benefit from the information provided in the patent disclosures. However, many innovations are not patented and remain trade secrets, meaning that a majority of new knowledge are not shared with the public.

It is also argued that patent promotes the advancement of technology and protects the inventor. The investors are rewarded by receiving exclusives over the inventions, which leads to financial rewards for their labour. Patent holders (most of which are the employers of the inventors) have the right to sell, transfer. assign or license the patented invention for free or for revenue. It is also argued that if there is no patent, individual inventors would not be encouraged to invent new products or share their inventions with the public. To obtain a patent, the inventor must eventually disclose to the public how to make and use the invention in the best way the inventor knows. The counter argument here is that inventors' motivation for obtaining a patent is for monetary gain rather than to share to knowledge with the public. The sharing of knowledge is by default of the system.

The Malaysian Patents Act 1983 and the Singaporean Patents Act 1995 provide that there are three elements to be satisfied before a patent is granted i.e. it must be new; involve inventive steps; and the invention must be

industrially applicable. There are slight differences in the wordings of the laws.

Under the Malaysian Patent Act, an invention is patentable if it is new, involves an inventive step and is industrially applicable. [42] In Singapore a patentable invention is one that: (a) is new; (b) involves an inventive step; and (c) is capable of industrial application. [43]

The Malaysian Patents Act excludes from patentability discoveries- scientific theories, plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living microorganisms, micro-biological processes and the products of such micro-organism processes and methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body other than to products used in any such methods. [44] This has direct implications for biotechnology. Singapore's patent law is more biotechnology friendly as it does not provide for such exclusion.

Countries such as Malaysia and Singapore are however wondering whether their patent systems are really used to reward development of new local and home grown inventions or whether they merely serve foreign patents to stake out their intellectual property rights area in the country? Does this mean foreign patent protection hinder local innovations? These two questions need further study so that not only Malaysia and Singapore will benefit from the answers but also other developing countries. This is because if local patents systems are just acting as mere agents to protect the interests of foreign inventions at the expense of local inventions, then there must be a rethink of the whole system, with a focus on how local inventions should be able to benefit more from the system.

Table 2 shows that, in Malaysia, between 1986 and 2006 there have been 82,008 foreign patent applications and only 4,603 local applications. Local applications are only about 5% of the total applications. Of the patents granted, local patents make up only 2.3%. The figure also shows that only 578 out of 4,603 or 12.5 % applications filed by locals are granted. The ratio for the foreign applications is higher, at about 30% of the total applications.

One of the possible explanations for this situation is that the majority of foreign applications are priority applications, meaning that their applications are based on approved patents issued elsewhere. The Malaysian Patent Office will normally approve patents already granted by the European Patent Office (EPO) or those meeting EPO standards. The lower ratio of approvals issued to local applications also explains the standard of advice they get from local practitioners. In Malaysia, there are about 150 patent agents and the majority of them are lawyers without technical or scientific background. This means that the advice they can offer to their clients are based on the interpretation of the law rather than assisting client with the scientific technicalities of the application.

Table 2: Patents Application in Malaysia

Year	Patent applications		ıs	Patents granted		
	Local	Foreign	Total	Local	Foreign	Total
1986	29	233	262	-	-	-
1987	71	3,195	3,266	-	-	-
1988	73	1,547	1,620	-	6	6
1989	84	1,803	1,887	11	121	132
1990	92	2,213	2,305	20	498	518
1991	106	2,321	2,427	29	1,021	1,050
1992	151	2,259	2,410	10	1,124	1,134
1993	198	2,684	2,882	14	1,270	1,284
1994	223	3,364	3,587	21	1,608	1,629
1995	185	3,992	4,177	29	1,724	1,753
1996	221	5,354	5,575	79	1,722	1,801
1997	179	6,273	6,452	52	737	789
1998	193	5,770	5,963	21	545	566
1999	218	5,621	5,839	39	682	721
2000	206	6,021	6,227	24	381	405
2001	271	5,663	5,934	18	1,452	1,470
2002	322	4,615	4,937	32	1,460	1,492
2003	376	4,686	5,056	31	1,547	1,578
2004	522	4,920	5,442	24	2,323	2,347
2005	522	5,764	6,286	37	2,471	2,508
2006	361	3,710	4,071	87	4,162	4,249
Total	4,603	82,008	86,605	578	24,854	25,432

Source: Malaysian Intellectual Property Corporation.

A check with the patent statistics in Malaysia and Singapore fails to reveal how many of those patents are biotechnology-based invention. Patent offices in both countries do not reveal how many patents are still in force. At the same time, there is no clear figure of how many patents are commercialised. Probably the Government should commission a study to find out how many of these patents are commercialised. The study is important to ascertain the effectiveness of patent system and its contribution to the local economy.

Table 3 above shows number of patent applications filed in Singapore from 1990 to 2005. Singapore has 96251 patent applications by way of registration, direct national filings, and PCT applications entering national phase. The figures from 1990 to 1995 in the second column refer to the re-registration application or priority application under the Paris Convention. The figures are applicable to those applications before the introduction of the new Patents Act 1995, which enforce the PCT into Singapore.

The third column refers to PCT applications in Singapore which designates Singapore as the applicable country where the patents will be enforced. Thus,

Table 3: Patent Applications in Singapore 1990 to 2005

Year	Re Registration Applications	Direct National Filings and PCT Applications entering natio- nal phase	Total
1990	1028	-	1028
1991	1104	-	1104
1992	1354	-	1354
1993	1426	-	1426
1994	1818	-	1818
1995	2329	2412	4741
1996	2802	12357	1515 9
1997	2140	6048	8188
1998	-	6367	6367
1999	-	6679	6679
2000	-	7720	7720
2001	-	8133	8133
2002	-	8070	8070
2003	-	7908	7908
2004	-	7951	7951
2005	-	8605	8605

Source: Intellectual Property Office of Singapore

these figures refer to foreign applications. Compared to Malaysian figures in Table 2 above, Singapore received more foreign applications than Malaysia. However, Malaysia has not implemented the PCT and all foreign reregistration applications will have to go through priority application procedure under the Paris Convention.

As shown in Table 4 above, local applications in Singapore between 1995 and 2005 is 4844. This is about 6% of the total applications filed as shown in Table 2 above. This shows that, although Singapore is seen as more advanced in the biotechnology field as compared to Malaysia, Singapore also suffers from serious local patents deficit even when compared to Malaysia. It is unfortunate that the Intellectual Property Office of Singapore does not produce the numbers of patents approved to facilitate comparison of the figures of Singapore's approved patents with the figures in Malaysia.

#### **Policy Reforms**

Malaysia has taken few policy measures to address the problems of lack of local innovations. For example, one of the main thrusts of the National Biotechnology Policy is to develop an effective legislative and regulatory framework [45]. Under this thrust, Malaysia seeks to create an ena-

Table 4. Local Applications in Singapore

Year	No. of applications
1995	145
1996	224
1997	288
1998	311
1999	374
2000	516
2001	523
2002	624
2003	626
2004	641
2005	572

Source: Intellectual Property Office of Singapore, as of February 2006.

bling environment through continuous reviews of the country's regulatory framework and procedures in line with global standards and best practices [46].

Under the 9th Malaysia Plan 2006-2010, Malaysia recognises the importance of a good regulatory environment in developing the biotechnology industry. One of the thrusts is the creation of regulatory framework to facilitate the build up of a strong and diversified biotechnology industry [47]. As stated in the 9th Malaysia Plan, Malaysia intends to improve the intellectual property (IP) policy and management framework. The main objectives of the IP plan are:

- to conduct a comparative study on the best practices of IP policy and management;
- ⇒ to identify areas for the improvement in IP regulations and processes;
- to introduce guidelines on IP sharing for researchers in public research institutions and in business collaborations as well as for local and foreign ventures;
- ⇒ to establish a referral centre that offers technical advice on issues such as IP and regulatory compliance;
- ⇒ to conduct capacity building and awareness programmes to encourage researchers to patent their findings and products;
- to develop a comprehensive IP guide and management manual; and
- ⇒ to develop an adequate IP-related human resource base including patent specialists, technology evaluators, lawyers and examiners.

Singapore has also introduced measures to increase

patent applications in the country. The EDB introduced the Patent Application Fund-Plus Scheme in 2002. This fund is to partially fund patent application costs. According to the EDB, up to 2006, this fund has supported a total of 348 applications, of which 209 are Singapore based businesses and 139 individual inventors.

#### Conclusion

The above discussion shows that they are more foreign applicants (including resident foreigners) and foreign granted patents in Malaysia and Singapore than locals. It is expected that this trend will continue in their near future.

The existence of foreign patents may have negative effects on local innovations if the patent claims are broad. However, the patent system alone should not be the main reason for lack of innovation. There are many other factors that affect innovations, such as, availability of fund for R&D, existence of capable human capital, an environment conducive for research, and, existence of suitable facilities.

There has to be a rethink of how the two countries address the issues relating to..... In addition to capacity building, grants of patent application funds and awareness programmes, local patents offices in the two countries may have to look at the possibility of revamping substantive provisions in their patent laws. One such provision is on research exemptions. There should be wider exemptions given to the local scientific community to conduct research in areas which may otherwise be in breach of existing patents.

Under Section 37 of the Malaysian Patents Act 1983, the rights under the patent do not extend to acts done only for scientific research. This is a broad research exemption. Nevertheless, this has to be explained to the scientific community. In Singapore, Section 66 (2) of Singapore's Patent Act 1995 provides for an exemption for experimental purposes relating to the subject-matter of the invention. The wordings between the Malaysian and the Singaporean provisions are different. Malaysia refers to scientific research and Singapore refers to experimental purposes. It is suggested that Malaysia's research exemption is wider than the Singapore's exemption.

Research exemption is important to encourage R&D and innovation within this biotechnology field. Without research exemptions or clear authorisation, activities falling within the scope of the patent owner's rights infringe on the patent holders' rights. Consequently, patent legislation in many countries states that research and/or experimentation on a patented invention is not an infringement of the patent holders' rights. This experimental use exception attempts to balance the interests of patent holders in commercialising their inventions with those of society in fostering further research. [48] This is because access to basic or platform technology such as DNA sequences, cell lines, plants and animals at reasonable cost is crucial to research.

Malaysia and Singapore may have to learn from the experience of more developed countries. For example in the United States, although the US Patent Act does not provide for statutory research exemption, the Waxman Hatch Act of 1984 provides exemptions to experiments carried out on drugs or medical devices for the purpose of obtaining Food and Drug Administration approval.

In Madey v. Duke University [49] the Court of Appeals of the Federal Circuit that Duke University did not qualify for exemption because its use of the patented invention (a free electron laser) fell within normal "business" activities of the university, such as fulfilling government grants. Accordingly, in the US the research activities may not be shielded from patent infringement liability.

In Canada, the current Canadian experimental use exception is vague and dates from a 1971 decision of the Supreme Court of Canada in Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp. [50] decided in the context of research aimed at sustaining a compulsory licence. This situation was not remedied through the introduction of section 55.2 into the Patent Act. That section sets out a specific experimental use exception applicable only to regulated inventions such as pharmaceuticals.

The Canadian Biotechnology Advisory Committee (CBAC) recommends that the Patent Act should be amended to include an exemption from claims of infringement for research on a patented invention, as well as for certain research using a patented invention: [51]

It is not an infringement of a patent to use a patented process or product:

- (a) privately and on a non-commercial scale or for a non-commercial purpose, provided that such purpose does not significantly prejudice the economic interests in the patent of its owner; and
- (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or to create a new (i.e., not incorporating the patented invention) product or process.

Most European countries have modelled their statutory provisions on Article 27 of the Community Patent Convention, even though it is not yet in force, the relevant portion reads: The rights conferred by a Community patent shall not extend to: (a) acts done privately and for non-commercial purposes; and (b) acts done for experimental purposes relating to the subject-matter of the patented invention.

The second part of the provision is similar to the provision in section 66(2) of the Singapore's Patent Act 1995.

The TRIPs Agreement provides exceptions to exclusive rights under certain conditions. It provides that

'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'[52]

Correa and Yusuf suggest that the following exceptions may be provided for within the scope of article 30: acts done privately and on a non-commercial scale, or for a non-commercial purpose; use of the invention for research; experimentation on the invention to test it or improve on it; use of the invention for teaching purposes; preparation of medicines under individual prescriptions; prior use; and experiments made for the purposes of seeking regulatory approval for marketing of a product after the expiration of the patent, [53]

In Switzerland, Thumm reports that there are asking for a broad research exemption, which is considered to be a more efficient strategy to resolve problems to those technologies of public interest. They also have asked for clarification for the "experimental use" exemption. [54]

Any reforms that the Governments of Singapore and Malaysia introduce may take into account several factors, such as, the need to attract and maintain foreign investments and at the same time the desire to encourage local domestic innovations.

The continued reliance on foreign technologies and foreign direct investment may have negative effects on the economy in the future as foreign companies may be more attracted to new markets which offer better returns for their investment.

Therefore, it is of crucial importance that governments in developing countries assist local innovators in all their efforts to file a patent. However, states cannot ensure the successful commercialization of the patent and for that purpose, foreign companies may still be of some importance (e.g. the local patent holder could license out the technology to a company (foreign or local) that has all the resources to commercialize it. The revenues from the royalty fees could then be reinvested into local private R&D in order to eventually obtain new patents. These would be genuine knowledge firms and they are likely to emerge also in countries such as Malaysia and Singapore, if the governments encourage such a development.

#### About the author

Sufian Jusoh is the author of the book 'Biotechnology Law and Regulations – The ASEAN Perspective,' (London, Cameron May, 2006). I am grateful to Victor Konde, Philipp Aerni and Intan Murnira Ramli for their useful inputs, comments and support. All errors and omissions are mine.

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## ATDF CORNER:

# LEARNING TO WALK; ATDF REGISTERED IN GENEVA, EXPANDING IN ZAMBIA AND A BIG THANK YOU!

Africa Technology development Forum (ATDF) was conceived in 2003 as virtual centre dedicated to facilitating information exchange related to technology and development of Africa. Over the past three years, ATDF has slowly transformed itself from simply providing a website space for technology, trade and innovation stories to becoming a publication entity. The usage of the ATDF website has continued to grow, with traffic so far tripling that of last year.

The ATDF Journal, this issue being the 9<sup>th</sup>, was conceived as a newsletter for short stories but quickly assumed a life of its own to become a full-fledged ATDF quarterly publication in the second issue as authors have continued to demand more space. It is our hope that Journal will continue to save authors in Africa and abroad seeking to contribute to the technological development of the continent.

Yet, over the years, several requests to practice what ATDF preaches have grown even louder and have pushed ATDF to work even harder. We acknowledge ATDF still needs to improve its services as well as make a real difference on the ground by pro-actively promoting entrepreneurship and technology use in Africa. To this effect ATDF has taken two modest steps:

## ATDF was officially registered as an international NGO in Geneva, Switzerland.

ATDF will seek to use the Geneva base to provide young African scientists and those with interest in African issues to:

- ⇒ Familiarize themselves with international issues likely to affect Africa's technological development
- ⇒ Negotiating strategies of developed and developing countries
- ⇒ Interact with other scientists and
- ⇒ Mobilize and work with African representatives to the United Nations and WTO as well as use the concentration of embassies to establish networks with home institutions.

However, we still looking for support to enable ATDF meet these broad goals. So far, ATDF has been one of the most cost-effective organization dependant largely on the goodwill of its broad base of editors, advisors, members of the steering committee, authors and well-wishers to implement its programs at near-voluntary costs.

ATDF is registering a corporate entity, ATDF Business Hub, in Zambia . The Hub will be responsible for investing and promoting entrepreneurship, initially in Zambia and later on in other countries. In brief, the Hub is designed to mobilize young creative minds in Zambia that have excellent business ideas but lack the financial support and the necessary network to succeed as entrepreneurs. The ATDF business hub is offering an annual competitive award for two to three technically and commercially viable business projects. The winners will be allowed to use ATDF business resources and take advantage of the ATDF business network while ATDF will take up interests in the projects to help them succeed. It will particularly encourage young people in universities, research institutes and industries to participate.

The Hub will also offer two to three smaller awards for great business ideas from university and colleges students (see page 51).

ATDF is indebted to Syngenta Foundation for providing the initial support that enabled ATDF develop its business strategy and to Dr. Ernst Thomke who has kindly provided the financial investment for the Hub. The ATDF Business Hub is fortunate to have the financial and intellectual support of Dr. Ernst Thomke, inventor of the Swatch concept and probably one of the most successful Swiss high-tech entrepreneurs.

The Hub consists of a board of advisors, experienced Zambia business executives, directors of research institution and senior government advisers and one international expert. It also has a board of directors that will be assisted but Dr. Ernst Thomke.

ATDF is also scouting for financial support to enable the Hub expand to other African countries, produce an annual print versions of most read (or editors choice) articles of the ATDF Journal and expand the use and content of its several e-centers.

Finally and more importantly, ATDF wish to thank all those who have supported or planning to support any of its activities. A special thank to our team of editors, advisors, web-manager, authors, critics and readers. We count on your continued support to enable ATDF made a modest contribution towards the development of Africa.

## Zambia Entrepreneurship Award 2007 (up to US\$ 50,000!)

# Unleashing the power of entrepreneurship: Investing in ideas! See details

The Zambian Entrepreneurship Award is designed to promote Zambian men and women, especially those below the age of 45, who have innovative business ideas and the necessary discipline and skills to convert their ideas into a successful company that creates new products, services and employment for the Zambian people. The business projects can range from low-tech innovations in areas such as the agricultural, mining, services and manufacturing sector to high-tech innovations in IT and biotech, among others. Small start-up firms seeking technical and financial support may also apply.

The winner of the award is expected to:

- establish a Zambian company that converts the business idea into real products and services (with the base of the company in Zambia)
- ⇒ dedicate 100% of his/her time to the company
- ⇒ have either have Zambian citizenship, be a resident of Zambia

#### **Application Form**

Please complete chapter 1 in the form and submit all the necessary information of your business project description, evaluation and realisation (chapter 2 and 3).

Send in the documents in a double copy to:

<u>Info@atdforum.org</u>: In the subject enter "Entreprenuership Award) or ATDF business hub, P.O.

Box 31484, Lusaka

Deadline for Submissions: 31. January 2007

#### Chapter 1: Personal Information of the Applicant

Name:

Contact address:

Phone/Mobile:

Date of Birth:

Current occupation and position (students indicate year of study):

Primary motivation to become an independent entrepreneur:

-----maximum 1 page-----

#### **Chapter 2: Project**

- 1. Title/ Description of the Project:
- a. Summarize your project idea in maximally 20 lines (mandatory) and some documents you think are necessary to illustrate the idea (optional)
- 2. Evaluation of your project (use maximally 6 lines to answer each question)

- a. Why do you think your project will meet an essential demand in Zambia?
- b. How and where do you see your product on the market?
- c. How do you assess the economic potential of your project? (please add information about expected variable and fixed costs of the company over time as well as the expected sales price of your product and the calculated revenues. This could be arranged in the form of a business plan that also includes the budget of the first year)
- d. Number of employees in the short and long run (1-2 and 3-5 years).
- e. Please outline the different stages of the realisation of the project
- f. How do you intend to secure the initial and future financing of your project?
- g. Do you have, or intend to apply for, patent, trademark or copyright protection?

——maximum 7 pages———

#### 3. Project Realisation

- a. What type of company do you want to register and where will it be located?
- b. Do you have some other institutions or people that support you financially (names/amount)
- c. Would you agree if the ATDF Business Hub would participate in your company with a share of 10-30% of the initial capital stock?

——maximum 1 page———

4. Enclosures

#### Mandatory:

- a. CV and passport photo
- b. Copy of a Zambian residence certificate

**Optional:** 

a. List of references

Date/Location:

Signature:

——maximum 1 page———

This application will be submitted to the board of directors and the advisory board of the ADTF Business Hub.

The final selection for the business plan award will be taken after inviting the finalists to make a presentation in Lusaka.

For more information on how to support, participate or compete, send an email to <a href="mailto:info@atdforum.org">info@atdforum.org</a>.

## ATDF CORNER

# ENTREPRENEURSHIP CHALLENGE AWARD 2007 UP TO \$3000 FOR WINNING IDEAS! See details

They say "development is about improving the quality of people's lives and expanding their ability to shape their own futures." The ATDF Business Hub realises that many potential entrepreneurs face "confusing questions" that often deflates the initial inspirational rush. Some of these questions include: How good or original is the idea and whether it will work or sell and who will support it! The Hub will seek to harvest and nurture these ideas before they are discarded.

The Entreprenuership Challenge award will be provided to selected innovative business concepts. It will provide a modest financial investment for further refinement, pilot and market research and a network of accomplished entrepreneurs in technology-intensive and highly competitive sectors. This award is designed for candidates below the age of 40.

#### Preliminary application for support:

In no more than 1100 words, provide your name(s) and contact address(es) [team applications are highly encouraged but not necessarily favoured], affiliation and describe your idea in simple English. Please, indicate if the idea is yours or belongs to a firm or institution. Please, indicate if there are individuals or teams you wish not to see your application. Devote more than 60% of the space to describe your idea and its potential.

#### **Crucial dates**

- ⇒ 2007 January 31st: Deadline for receiving project proposals
- ⇒ **2007 May 31st**: Deadline for full-length proposals
- ⇒ 2007 August 30: The first investments will be made to selected individuals/teams/firms.

<u>Title:</u>	Title of idea, your name(s), address/contacts, and one statement of the idea)
	DO NOT PUT ANY INFORMATION THAT YOU CONSIDER CONFIDENTIAL.
	(Information in this space may appear on our website)
Abstract:	Briefly make the good case why your idea is needed as clearly as possible (in about 120 words)
	about 120 words)
<u>Details:</u>	Describe you idea, use and target in more details (in about 350 words)
<u>Market</u>	Describe the potential users, buyers, gaps it will fill and size. Will you need suppliers and do you know their interests? Do you have any competitors and why
	will customers choose their products/services over theirs? ( about 400 words)
Benefit	How will your product generate economic and social values? What will your idea contribute to society? (in about 100 words)
Personal interest	Why do you want to develop this idea and not any others of your ideas? (100 words)

#### **Featured Book**

## INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES

(Edited by Anatole Krattiger, Richard T. Mahoney, Lita Nelsen, Jennifer A. Thomson, Alan B. Bennett, Kanikaram Satyanarayana, Gregory D. Graff, Carlos Fernandez, Stanley P. Kowalski.

#### Sharing the Art of IP Management!

To be published in Spring 2007, the Handbook is prepared for policy makers, leaders of public sector research establishments, technolo-gy transfer professionals, licensing executives, and scientists, this book offers information and strategies for utilizing the power of both IP and the public domain. It illustrates how IP can be judiciously leveraged to forge stronger partnerships and usher in a new age of collaboration and sharing.

The book puts aside ideological debates to focus on pragmatic considerations and prac-tical opportunities. Written by practitioners in the field, its ~135 chapters are a compre-hensive resource on current IP management issues and approaches. While the authors always keep their eye on the big picture, the Handbook eschews general proclamations. Instead, it puts forward thoughtful dialogue aimed at real-world problems faced by those who want to put IP to work for the public sector and public interest.

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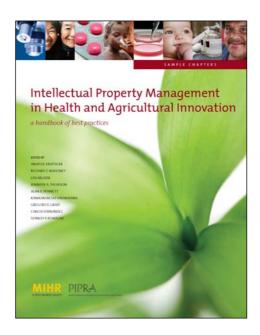
IP and Innovation in Health and Agriculture; The Tool Box; "Global Access" Licensing Practices; The Ins and Outs of Contracts; IP Policies, Strategies and Management Valuation, Commercialization and Spinouts; Special Cases (including Genomics, Bioprospecting and Building Networks); National, Institutional and Topical Case Studies and more.

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"At the dawn of the 21st century the world created an unprecedented wave of public-private partnerships...



For such investments to bear fruit as public goods it is paramount to manage IP with the public interest in mind. This handbook provides expert guidance to do just that and will assist in developing new capabilities in low- and middle-income countries." –Ariel Pablos-Mendez, Director, Knowledge Management and Sharing, WHO

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"This Handbook— which really transcends the category of handbooks altogether—is a must read for anyone who deals with IP. It provides the reader with lots of valuable insights for better licensing practices and much, much more." —Pramilla Senanayake, FRCOG-Chair, Global Forum for Health Research, MIHR and the Concept Foundation

"[This] Handbook is an important step toward new trans-national networks... involving multiple partners in both North and South—donors and doers alike— who still believe in the power of innovation to address the needs of the poor." – From the Foreword of Sir Gordon Conway KCMG DL FRS Chief Scientific Adviser, DFID, IJK

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