Intellectual Property Protection and Biotechnology: Issues and Processes for African Consensus

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Contents

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Executive Summary

Intellectual property (IP) is the creation of the human mind—the intangible intellect that can translate into tangible products. Intellectual property rights (IPR) protect the use of these human creations. The major elements or forms of intellectual property rights today include patents, utility models, industrial designs, trademarks and service marks, geographical indications and layout of integrated circuits, copyright, and plant breeder' rights. Intellectual property protection can be traced as far back as 1474 when the first patent statute was established in Venice followed by the monopoly statutes of England of 1624. Since then most countries, including countries have developed some form of intellectual property law to provide exclusive rights to inventors over their inventions for a limited period of time.

This paper addresses the impact of IPR on biotechnology development and utilization in Africa. It focuses on current debate on access to technology, highlighting controversies and concerns existing globally and identifying Africa's stand on these issues. The paper synthesises deliberations of international fora responsible for creating policies relating to IP and its applications. A summary of key areas on IPR and biotechnology requiring further dialogue in Africa is outlined.

Most countries in sub-Saharan Africa have IP laws developed to varying degrees. Regional organisations such as the African Regional Industrial Property Organisation (ARIPO) and the African Regional Intellectual Property Organisation (OAPI) provide harmonisation of IP laws for their respective member countries and one involved in capacity building and registration of intellectual property rights. The broad consensus on the economic debate on IPR is that the economic interests involved are significant. There are indicators that strong patent regime may lead to increased global trade, attract more Foreign Direct Investment (FDI) for host countries, lead to increased licensing of technologies and possibly contribute to more local production through FDI. High standards of IPR are required to provide adequate incentives to firms and researchers to innovate, and recoup the cost of R&D and at the same time give a boost to the economy.

However, evidence on the response of R&D investments in developing countries to changes in IPR protection remains scarce. It has also been found that the contribution of IPR to economic growth increases with the openness of the economy. Agricultural research in developing countries has traditionally been carried out by the public sector. The introduction of protection for plant varieties is expected to foster the privatization of agricultural research. The reaction of national or international research centers to this trend is likely to have important economic implications. As innovators claim IPR over plant varieties, the policy of free germplasm exchange among research centers will have to be adapted. A possible danger in this context is the adoption of cumbersome bureaucratic procedures for germplasm exchanges in response to the introduction of IPR. With increasing investment of resources in research and development (R&D) in Africa's national research systems, policy makers and research managers have an opportunity to become more sophisticated in their approaches.

The most traditional argument for protecting IPR in developing countries is the risk of piracy, which makes technology owners less willing to transfer proprietary knowledge to countries with weak IPR regimes. Perhaps the most straightforward use of a legal tool is the increased use of Material Transfer Agreements (MTAs) for exchange of genetic materials, particularly for research. It is sometimes argued that a strong IPR regime in a country will encourage the inflow of Foreign Direct Investment (FDI). A 1996 UNCTAD study found that the major determinants of technology transfer include the costs of making such transfers, which depend on local technological capability. This capability refers to factors such as skill availability, technology supply structures, and R&D capacity, enterprise-level competence and institutional and other supporting technological infrastructures. Compliance with the minimum standards of the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement will be perceived as a threshold indicator, since it will influence the perception of foreign investors about the relative attractiveness of competing investment locations. In the case of Africa, empirical analysis is needed on the economic implications of the policy options available to the continent under the international IPR agreements such as TRIPs, to supplement the recent work in the developed countries.

Under the TRIPS agreement, African countries will require significant reforms in their IPR regimes and minimum standards of protection, and they will gradually be strengthened worldwide. The task ahead for African countries is to transform their IPR regimes into effective instruments to promote innovation. Given the institutional and financial constraints facing African countries, technical assistance from developed countries and multilateral institutions may play a positive role in this process. The question of enforcement is likely to become a major area of contention in the years to come. Provisions of the TRIPs Agreement allow for WTO member countries to patent some categories of life forms and living processes. Article 27.3(b) of the TRIPs Agreement and its implementation is bound to open the door to a flood of patents on life forms, including genetically modified plants, animals and their parts, and other naturally occurring biological resources. Patenting of life forms has raised ethical, environmental and developmental concerns in developing countries. For Africa, fears are that due to IPRs, only a handful of rightholders will control the production and marketing of seeds and farm inputs resulting in unreasonable pricing beyond the reach of the average African farmer and making African farmer increasingly becoming dependant for the supply of seed and farm inputs. Strict IPR protection may slow the pace of innovation in Africa and increase the knowledge gap between the developed countries and African continent. The recent establishment of African Agricultural Technology Foundation (AATF), which is owned and managed by Africans, is designed to acquire proprietary technology at low or no cost for research in Africa. Its establishment emanates from the dire need for Africa to address chronic hunger and disease on the continent through drought and disease resistant crops and improved animal husbandry.

In Africa, public research institutions are weak and biotechnology has potential to boost Africa's agricultural productivity, healthcare and environment in a sustainable way. Biotechnology research is capital- and knowledge-intensive. Without targeted support there is risk that the technology will bypass Africa's resource poor farmers. Research capacity in Africa is limited, and African countries may have to import the technology in order to use it. Technology development should in reality result in reduction of prices medicine. However, cost of patenting drugs became unaffordable to the majority of the public in Africa.

Africa has great commercial potential of its biodiversity, which should be sustainably exploited for socio-economic development of the continent. Therefore, the commercialisation of potentially useful plants and animals remains a viable option of reducing poverty in Africa. The emergence of biotechnology has brought with it highly controversial ethical issues. In the 1980s

the traditional IPR system, which was meant to protect inventions in mechanical, chemical and electrical fields was extended to the protection of biotechnology inventions. This shift of patenting new forms of life has generated intense debate at national, regional and international levels.

The traditional knowledge systems on which communities have depended for their survival for hundreds of years are key elements in the economic, social and cultural lives of traditional and modern societies. These systems have made use of diverse biological and genetic resources for food and medicines, passing on their know-how from generation to generation in a sustainable manner. Increased awareness of the value of biodiversity and the need for its conservation and sustainable use in agriculture and healthcare has of biodiversity and biotechnological inventions. Misappropriation of local communities' resources also adversely affects conservation and sustainable use of biodiversity. Africa being an important and rich centre of origin in terms of biodiversity, it is important that property regimes address transboundary issues. This is of relevance with respect to life forms, which occur in common across boundaries. In spite of the presence of IP policies in most African countries, clear guidelines on repatriation of genetic material are lacking. This has led to losses of valuable organisms, animals and plants from the African region to more developed countries, in such examples as Tuli cattle breed from Central Africa and Masai sheep in Kenya.

In recent years there has been increasing public interest in the subject of IPR and its relationship with sustainable development, including the environment and human development. This issue has been the subject of debate in international fora such as TRIPs, WIPO, CBD and FAO.

The problem facing the future of traditional knowledge is the misappropriation of this knowledge from local communities. Examples of patent cases involving misappropriation of traditional knowledge and genetic resources that have been cited in recent times are the neem, turmeric, and basmati rice of India and hoodia cactus of the San of Karahari Desert. Controlled Bioprospecting conducted under mutually agreed terms and compensation arrangements could be of benefit to African countries. Therefore legal frameworks governing access to and benefit sharing of genetic resources are of urgent need if destruction to biodiversity and loss of valuable plant and animal species in Africa is to be stopped.

The mechanisms for recognition and protection of innovations derived from traditional knowledge systems must be established at national, regional and global levels. Increasing activity is taking place internationally where intellectual property is being defined in various fora for the utilization and protection of genetic resources and traditional knowledge.

The TRIPs Agreement sets minimum standards for the protection and enforcement of IPRs, including biological inventions, under Article 27.3(b) of the Agreement. The issue of patents on life forms is a current topic of debate worldwide. Several factors have led to the emergence of this debate, namely: (1) advances in the field of biological sciences, (2) increasing abilities to isolate and manipulate genes, (3) rapid development of genetic engineering, bioprospecting, and the problem of biopiracy of traditional knowledge.

The growing demand for biological or genetic resources, due to their demand in biotechnology, pharmaceutical, cosmetics, agriculture and other industries, has resulted in increased bioprospecting activities in developing countries. The aspects of Article 27.3(b) of the TRIPs Agreement have practical consequences in Africa, because almost all developing countries including Africa excluded living organisms from patentability in their domestic legislation before the TRIPs Agreement came into force in 1995.

Traditional knowledge, innovations and practices have contributed significantly to the present body of knowledge in science, agriculture, medicine and environmental conservation. There has been little recognition and protection of this body of knowledge. The lack of legal recognition and protection has lead to a situation where custodians of knowledge and innovations derived from traditional knowledge systems are not rewarded for contributions rendered. Since 1999, discussions on this situation have gained momentum internationally with greater gains and concern for protection of traditional knowledge and folklore in developing countries. At the Doha Ministerial Conference of 2001, WTO members agreed to exercise the relationship between the CBD and the production of traditional knowledge and folklore previous to the in 2000, the WIPO general assembly agreed to establish an Intergovernmental Committee IGC on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. On going deliberation are expected to determine the future directions of these discussions for conclusive outcomes.

International Treaty on Plant Genetic Resources for Food Agriculture (ITPGRFA). ITPGRFA was adopted in Rome in November 2001 and came into force in June 2004. This is a multilateral system for access for food and agriculture to 35 crop genera and 29 forage species and also associated benefit sharing and under article 9 of ITPGRFA encourages countries to take steps to protect and promote Farmers Rights including protection of their TK and the right to participate in benefit sharing and in national decision-making.

In conclusion, three key issues for African consensus on IPR and Biotechnology are:

1. Access to technology for increased crop yields and fortification in order to fight hunger, starvation and malnutrition in Africa.
2. Access to pharmaceuticals at affordable cost to fight human and animal diseases prevalent in Africa and to acquire technologies for countries in Africa to manufacture drugs for key diseases such as HIV/AIDS and for orphans diseases which are no longer adequately produced in developed in developing countries.
3. Development of capacity for IP management and policy institutionalisation in Africa.

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1. INTRODUCTION

Intellectual property is the creation of the human mind the intangible intellect that can translate into tangible products. Intellectual property rights (IPRs) are legal rights governing the use of such creations. IP has been divided broadly into two categories, namely industrial property and copyright. Industrial property includes inventions and identifying marks useful for industry and commerce. Copyright includes artistic, literary and musical works, computer programs and database among others. For some technologies, *sui generis*, or special, protection regimes do exist. Two such cases of *sui generis* are the layout designs of integrated circuits and plant breeders' rights (PBRs) for the protection of new plant varieties.

The elements or forms of industrial property rights today include patents, utility models, industrial designs, trademarks and service marks, geographical indications and layout of integrated circuits.

Intellectual property protection for inventions can be traced as far back as 1474 when the first patent statute was established in Venice followed by the monopoly statutes of England of 1624. Since then most countries, including countries have developed some form of intellectual property law to provide exclusive rights to inventors over their inventions for a limited period of time.

A patent is a legally enforceable right granted by the Government to an inventor for a limited period to exclude others from certain acts in relation to the new invention. A patent awards an inventor the right to prevent others from making, selling, importing, or using the protected invention without authorization for a fixed period of time, which is usually twenty years. In return, society requires disclosure of the technological information contained in the patent document to increase its application and public knowledge. Utility models are small incremental innovations requiring some design and development and are awarded a shorter period of protection ranging from three to ten years. Utility models are applicable for protecting innovations generated by small and medium enterprises. Industrial designs protect new or original aesthetic aspects of a functional article while Trademarks and service marks protect rights in a distinctive mark or name used to distinguish a product, service or firm. Their fundamental objective is to reduce consumer search costs and eliminate consumer confusion over the product quality and origin.

Geographical indications certify that products are made in a particular place and embody the quality or reputational characteristics of that location. Examples of such products are wines, spirits and foodstuffs. Copyright offers exclusive rights to the particular expression of the work for a period of time, typically the life of the creator plus 50 years. Copyright covers only expressions rather than ideas and therefore provides thinner protection than patents.

For some technologies, *sui generis* or special, protection regimes exist such as layout designs of integrated circuits which are more than literary expressions but whose inventive step is often minimal, suggesting a compromise between patent and copyright. Their protection period is 10 years and requires only originality in term of being the product of original intellectual efforts. Plant breeders' rights permit developers of new, distinctive, and genetically stable plant varieties

to prevent others from marketing and using the varieties without the authorization of the right holder within a fixed period say 15 to 25 years. Many countries limit these rights though exceptions permitting farmers to use the seeds for subsequent replanting and researchers to use the varieties for further breeding.

This paper addresses the impact of IPRs on biotechnology development and utilization in Africa. It also focuses on current debate on access to technology, highlighting controversies and concerns existing globally and identifying Africa's stand on these issues. The paper synthesises deliberations of international fora responsible for creating policies relating to IP and its applications. A summary of key areas on IPR and biotechnology requiring further dialogue in Africa is outlined.

Intellectual property is administered at national level, since laws governing IP ownership are statutory and thus issues can be contested in court. Most countries in sub-Saharan Africa have IP laws developed to varying degrees. Regional organisations such as African Regional Industrial Property Organisation (ARIPO) and African Regional Intellectual Property Organisation (OAPI) provide harmonization of IP laws for their respective member countries and are also involved in capacity building and registration of intellectual property.

2. SCOPE AND CRITERIA FOR IPRs PROTECTION:

The main elements of protection of each IPR are generally defined in terms of the subject matter that is to be protected or that can be excluded such as the preconditions for such protection; the rights accruing on protection and the permissible exceptions to these rights and the minimum duration of protection.

Generally, IPRs give creators exclusive rights over the use of their creations for a fixed duration of time. In some cases, however, IPRs are valid indefinitely, as long as the conditions for their protection continue to be met, as in the cases of trademarks, geographical indications, and trade secrets.

2.1 IPR and Research and Development: Creating Incentives

The broad consensus on the economic debate on IPRs is that the economic interests involved are significant. At some level nearly all legitimately traded goods and services operate under, patent, copyright, or trademark protection (Maskus, 1994). There are indicators that strong patent regime may lead to increased global trade, attract more Foreign Direct Investment (FDI) for host countries, lead to increased licensing of technologies and possibly contribute to more local production through FDI in developing countries. Strong IPRs may lead to pharmaceutical research and development (R&D) which could be more appropriate to the needs of developing countries and at the same time contribute to higher growth rates in these countries. Arguments put forward in favour of strong intellectual property rights are mainly to encourage inventors to invent new products and processes, which are an improvement over older technologies. By improving and maintaining high rates of inventiveness, intellectual property rights contribute to faster rates of technological change and thereby the rate of development of industries and countries.

By granting temporary exclusive rights to inventors, the state provides a reward for inventions. High standards of IPRs are required to provide adequate incentives to firms and researchers to innovate, and that such innovations give a boost to the economy. Therefore, IPRs constitute a

fair system of reward to innovators and to companies which have invested in research and development, and which may need to recoup their heavy expense. IPRs have impact on investment in R&D in both developed and developing countries. However, evidence on the response of R&D investments in developing countries to changes in IPR protection remains scarce. Although, there is growing appreciation for the role played by innovation in economic development in developed countries, IPRs protection has a marginally significant positive effect on economic growth in developing countries. It has also been found that the contribution of IPRs to economic growth increases with the openness of the economy. Agricultural research in developing countries has traditionally been carried out by the public sector and the introduction of protection for plant varieties is expected to foster the privatization of agricultural research. The reaction of national or international governmental research centers to this trend is likely to have important economic implications. As innovators claim IPRs over plant varieties, the policy of free germplasm exchange among research centers will have to be adapted (Barton and Siebeck 1994). A possible danger in this context is the adoption of cumbersome bureaucratic procedures for germplasm exchanges in response to the introduction of property rights.

2.2 IP as a Management tool in Research and Development

With the increasing investment of resources in research and development (R&D) in Africa's national research systems, management has an opportunity to become more sophisticated in their approach to the value of intellectual Property (IP) practice, as a management tool. Proper IP Management practice encourages scientists to report innovations, setting into place a system for knowledge transfer; puts procedures in place for active negotiation and follow-up of agreements, contracts and licenses, so as to be a responsible steward of resources; and, readies an institution for effective technology transfer planning that will enhance the probability that their institutional products will benefit a higher proportion of intended users. IP management is not the only way to accomplish many of these objectives. However, it is a methodology that emphasizes the practical application of research for developing innovations to address problems that need to be solved. It is important that African researchers learn to recognize and value their innovative contributions. Otherwise, no one else will.

How will African national research systems develop this capacity? Traditionally agricultural institutions have relied upon advice and training from organizations such as the CGIAR, instructors/workshops supported by international funding organizations such as USAID and/or efforts supported by philanthropic institutions such as the Rockefeller Foundation. And, on occasion, IP institutions such as the World Intellectual Property Organization (WIPO), the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and The International Union for the Protection of New Varieties of Plants (UPOV) have carried out training in IP practice, in partnership with local national IP Offices. Local IP/Copyright/Trademark offices will have experience in local IP practice, including a roster of patent agents/attorneys that can provide advice, based on their experience, and often copyright enforcement will be an area where local authorities have developed proficiency, as well. An untapped source of expertise is likely to be the local industrial community. Countries in East Africa are known to be industrial producers of a variety of processed food and agricultural products including textiles, foodstuffs, beverages (including beer), and processed grains and sugar. Many of these industries will have experience in trade secret protection, trademark use, and licensing or franchising. IP practice is best learned by doing.

2.3 Technology Transfer: The role of IPR

The most traditional argument for protecting IPRs in developing countries is the risk of piracy, which makes technology owners less willing to transfer proprietary knowledge to countries with weak IPR regimes. The survey done by Manfield (1994) found that US firms tend to regard intellectual property protection as being more important in decision making regarding the transfer of advanced technology than in investment decisions. Some analysts, however, remain skeptical about the relevance of this effect.

Subramanian (1990) points out that the north-south conflict occurs primarily in field in which imitation is possible, independently of technological transfer (for example, pharmaceutical and chemical products, and software). IPRs aid the process of technology transfer as they encourage foreign direct investment. Nogues (1993), in turn argues that the decision to license and transfer technology depends much more on the legal strength of the licensing agreement and, the adaptable capacity of the buyer to absorb technology than on the strength of the IPR regime. According, to Taylor 1993, firms in the north react to imitation by investing in "masking" technologies. For example, the encryption of software codes that increase the costs of imitation. It is important to note that the cooperation of the right holder and the user of the technology are fundamental in facilitating the technology transfer. On balance, IPR agreements should promote north-south technological transfers. Accordingly, the potential benefits of greater IPR protection are disputed to the extent that imitation is sound alternative for the formal transfer of technology.

Perhaps the most straightforward use of a legal tool is the increased use of Material Transfer Agreements (**MTA**s) to move materials around. Access will often be granted by an institution with ownership over germplasm, using such an agreement/contract/license. MTAs may have provisions that deal with IPR issues –such as, a requirement for the recipient to get an OK or agreement from the provider before any IPRs are sought over improvements associated with the use of the materials, or provisions that prohibit any IPRs being taken out over such improvements/innovations, or mandated ownership or licensing of any improvements of IPRs (E.g., automatic joint ownership). However, there is no requirement that an MTA must include provisions that deal with IPR-type issues.

Another impact associated with increased interest in access to germplasm, is the heightened interest in traditional knowledge of local plants with medicinal properties. There is a controversy in some countries, notably India, regarding the cataloguing of such information. Often this information is protected, as if a trade secret by communities, for religious, economic or other reasons. And, if traditional knowledge is put into the public domain, there is the danger that the information will be used without due attribution to the source, (--not to mention that it is unlikely that benefits will accrue to the originators of the information.) However a recent case from South Africa, involving the exploitation of the appetite suppressing qualities of the Hoodia cactus, present an intriguing story of exploitation that, through dogged pursuit, resulted in the possibility that an equitable share of the profits, if realized, will pass to the Khomani San community (Chennels, 2003).

2.4 Foreign Direct Investment (FDI)

It is sometimes argued that a strong IPRs regime in the country will encourage the inflow of Foreign Direct Investment (FDI), which in turn will bring about technology transfer to the host

country. However, according to an UNCTAD study on TRIPs and developing countries made this conclusion:
"*To date, there is little conclusive evidence that strengthened intellectual property protection would consistently expand the transfer of technology to developing countries. Key determinants of technology transfer (through FDI and through arm's-length licensing) include the costs of making such transfers, which depend on local technological capability. This capability refers to factors such as skill availability, technology supply structures, and R&D capacity, enterprise-level competence and institutional and other supporting technological infrastructures"* (UNCTAD 1996).

It is often argued that foreign firms avoid investing in countries with weak IPRs regimes (OECD 1989), but the magnitude of the impact of weak protection on FDI decisions is debatable. First, evidence based on surveys of foreign investors that identify IPRs as relevant variable for FDI decisions tend also to point out that other considerations- in essence, the overall investment in the country – are important (Frischtak 1989). In the metal and food industries, IPRs protection has marginal significance, but substantially significance in the case of biotechnology, pharmaceutical and chemical industries. Manfield (1994) also found that US FDI flows increase with perceived strength of the IPRs regimes in a particular country.

In conclusion, in a world of growing competition for FDI flows, future compliance with the minimum standards of the TRIPS agreement will be perceived as a threshold indicator, since it will influence the perception of foreign investors about the relative attractiveness of competing investment locations. In the case of Africa, empirical analysis is needed on the economic implications of the policy options available to the continent under the international IPRs agreements such as TRIPs, to supplement the recent work in the developed countries. Some observers have long felt that compulsory licensing at reasonable royalties do not necessary impede technological progress or lower the rate of innovation, yet there remains opposition, particularly by the research-based pharmaceutical industry, to the use of this policy instrument, as demonstrated, in the case of access to HIV/AIDS medicines in South Africa and Thailand.

Under the TRIPS agreement, African countries will require significant reforms in their IPR regimes and minimum standards of protection, will gradually be strengthened worldwide. Both developed and developing countries can explore positive-sum games in trade, foreign direct investment, and technological transfers as IPR protection is strengthened. As diffusing trade-related IPR frictions and preventing unilateral actions by major trading nations the task a head for African countries is to transform their IPR regimes into effective instruments to promote innovation. Given the institutional and financial constraints facing African countries, technical assistance from developed countries and multilateral institutions nay play a positive role in this process. The question of enforcement is likely to become a major area of contention in the years to come.

3. CURRENT ISSUES AND DEBATE IN AFRICA

Major concerns against strong IPRs especially in Africa are that strong IPRs regimes will confer monopoly rights to private research organizations and multinational corporations, which would increase the already high concentration of economic and technological power in a few corporations. Companies in developed countries hold over 97% of patents globally leaving 3% of the world patents held by inventors in developing countries. A survey of biotechnology patents showed that between 1990-1995, approximately 25,000 patents were granted throughout

the world, 37% originated in the US, 37% in Japan, and 19% in the European Union and the remaining 7% from the rest of the world, including developing countries. As a result of IPRs monopoly, the few multinational corporations can impose higher prices for products protected by IPRs and thus obtain monopoly profits at the expense of consumers as well as small and medium producers, especially those in Africa. Since the overwhelming share of patents are held by enterprises in the developed world, there is concern that strong IPRs will hinder the ability of African countries to attain new technologies. By strengthening IPRs in Africa, TRIPs Agreement gives opportunity to foreign firms to import technology at high prices rather than produce it in the host country, at the same time causing technology suppliers to raise their prices. These two factors may raise the cost and reduce the flow of technology to Africa.

Provisions of the TRIPs Agreement allow for WTO member countries to patent some categories of life forms and living processes. Article 27.3(b) of the TRIPs Agreement and its implementation is bound to open the door to a flood of patents on life forms, including genetically modified plants, animals and their parts, and other naturally occurring biological resources. Patenting of life forms would increase the profit opportunity for biotechnology firms from the commercialisation of genetically engineered crops and materials. A clear disadvantage is that increased acreage of GMOs would correspondingly reduce the acreage of traditional varieties whose wider range of diversity is ecologically advantageous, for agricultural production.

Patenting of life forms has raised ethical, environmental and developmental concerns in developing countries. For Africa, fears are that due to IPRs, only a handful of multinationals will control the production and marketing of seeds and farm inputs. This could cause unreasonable pricing beyond the reach of the average African farmer. Indeed prices of such inputs today are largely under the control of foreign multinationals, on whom African farmers are increasingly becoming dependant for the supply of seed and farm inputs.

Another trend is the occurrence of “reverse transfer of technology” in which knowledge derived from biological resources in poor countries is transferred to rich countries where it contributes to the economic and social development of these countries, while developing countries are minimally rewarded for their contribution. An example is the heat resistant bacteria strain found in Kenya’s hot springs and now patented by an American company and utilised for fabric discolouration in industry. Strong IPR regimes can discourage research and innovation by institutions in Africa. Where patents are held by foreign inventors and corporations, local R&D may be stifled due to monopoly rights and high costs. Therefore, strict IPRs protection may slow the pace of innovation in Africa and increase the knowledge gap between the developed countries and African continent. The recent establishment of African Agricultural Technology Foundation (AATF) which is owned and managed by Africans is designed to acquire proprietary technology at low cost or no cost for research in Africa. Its establishment emanates from the dire need for Africa to address chronic hunger and disease on the continent through drought and disease resistant crops and improved animal husbandry.

Firms and institutions in developed countries dominate the research in agricultural and pharmaceutical biotechnology and have extensive financial resources to equip their labs for research and IP protection. In Africa, public research institutions are weak and poorly funded and may thus be vulnerable to exploitation by foreign partners.

3.2 Intellectual Property and Biotechnology

IPRs are seen as a hindrance to Africa's access to technology and have become a sharp target for proponents against both the technology and the protection. Biotechnology has potential to boost Africa's agricultural productivity, healthcare and environment in a sustainable way. In the field of agriculture prospects are bright for Africa, where the need for new farm technologies is most pronounced.

Biotechnology advances, however, are predominantly taking place in the industrialized world. As we know, biotechnology research is capital- and knowledge intensive, and without targeted support there is risk that the technology will bypass the resource poor farmers in Africa. Research capacity in Africa is limited, and African countries may have to import the technology in order to use it. In most cases these technologies are also protected by intellectual property rights.

Controversies surrounding GM food arise more readily because food is a basic requirement which is in the domain of public good. This is different from medicine to which people have access as a matter of personal decision. Thus use of genetically engineered drugs and vaccines do not cause controversies in the same manner, as do GM foods. In the case of drugs the issue of concern is however that of cost. Technology development should in reality result into reduction of prices. However, cost of patenting causes drugs to became unaffordable to the majority of the public in Africa

Bio prospecting is the development of marketable products from biological resources. Africa has great commercial potential of its biodiversity, which should be sustainably exploited for socio-economic development of the continent. Therefore, the commercialisation of potential useful plants and animals remains a viable option of reducing poverty in Africa. The emergence of biotechnology has brought with it the highly controversial ethical issues of whether creations of genetically engineered organism constitute an invention, which is thereby patentable. While biotechnological and microbial processes, and plant varieties, are granted patent protection in some developed countries such as the US and Australia, the protection of new forms of life in particular has proved to be difficult and there are substantial variations among countries. In the 1980s the traditional IPRs system, which was meant to protect inventions in, physics, mechanical, chemical and electrical fields was extended to the protection of biotechnology inventions. This shift of patenting new forms of life has generated intense debate at national, regional and international fora.

The critics of patenting of life forms have argued that it is inappropriate to use the patent system to reward scientific work in the field of biological resources and processes, as living organisms are qualitatively different from non-living materials, and knowledge relating to biological processes and these biological material are not inventions.

Under the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement, member countries may exclude from patentability plants and animal and essentially biological processes for the production of plants and animals, but not microorganisms, biological and non-biological processes. Meanwhile, member countries of the TRIPs Agreement are required to apply some form of protection to plant varieties either by patents or an effective *sui generis* system or by combination of the two systems.

Article 27.3(b) of TRIPs states that members may exclude from patentability:

"plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

Note that the TRIPs Agreement does not mention whether or not genes should be patentable, whether derived from plants, human or animals. The issue raised by TRIPs is what constitutes an invention in relation to genetic material. For instance, should genetic material identified in nature be patentable on the ground that isolating and purifying it differentiates it from an unpatentable discovery. This is a matter for national legislation.
The only specific requirement, other than of microorganisms, is that plant varieties be protected.

In recent years there has been increasing public interest in the subject of IPRs and its relationship with sustainable development, including the environment and human development. This issue has been the subject of debate in international fora such as WTO, WIPO, CBD and FAO.

3.3 IPR, Traditional Knowledge (TK) and Biodiversity

Traditional Knowledge is a key element in the economic, social and cultural lives of traditional and modern societies. Communities have depended for their survival on traditional knowledge, practices and technologies for hundreds of years. They have made use of diverse biological and genetic resources for food and medicines, passing on their know-how from generation to generation in a sustainable manner. Increased awareness of the value of biodiversity and the need for its conservation and sustainable use in agriculture and healthcare has heightened the role and critical importance of this knowledge. Such knowledge is recognized today as a critical tool for development.

Local communities are increasingly becoming aware of their rights and the need to protect their knowledge. Misappropriation of local communities' resources also adversely affects conservation and sustainable use of biodiversity. The contribution of traditional knowledge to human development especially in the areas of food production and healthcare is of great importance to Africa.

Africa being an important and rich centre of origin in terms of biodiversity, it is important that property regimes address transboundary issues. This is of relevance with respect to life forms which occur in common across boundaries. In spite of the presence of IP policies in most African countries, clear guidelines on repatriation of genetic material is lacking. This has led to losses of valuable organisms, animals and plants from the African region to more developed countries. Many examples exists, such as the case of the Tuli cattle breed from central African whose highly productive abilities have made them attractive for repatriation of their germplasm to other developed countries without compensation to their original countries. Similarly valuable attributes of the Masai sheep with resistance to disease and acaricides have been targeted for repatriation. Most times, it is not easy to track down products pirated from their original countries, However, with new biotechnologies identification of pirated material is possible.

A greater interest in utilizing "nature's way of bioengineering" has set off a renewed fervour for access to plant germplasm. The hunt is on for natural products that can be used as source material for a wide variety of pharmaceutical products and for germplasm that can be used as a source of agronomic alleles that can be bred into domesticated plant varieties to enhance crop

germplasm for characteristics as varied as increased drought tolerance to enhanced nutrient content. What is the role/ impact of IPR in this domain of access to germplasm for research and development in Africa? What are the issues? Access to the germplasm itself; access to traditional knowledge used as a shortcut for picking likely candidates for further research, benefits that can be shared with the communities where plants are harvested or that have supplied useful information; leveraging access to germplasm as a way of transferring north-originated technology; utilizing products of this research to support local entrepreneurs, --to name a few. The impact of IPR in these areas is a very complex situation.

An increasing number of pharmaceutical companies freely access traditional knowledge for identification of plants for development of new medicines. Researchers screening plants for useful substances can cut down the time taken by getting information from traditional healers on which plants are effective for what ailment. Traditional healers in Africa have unknowingly made revelation of their skills without any gain from recipient prospectors. The problem facing the future of traditional knowledge is the misappropriation of this knowledge from local communities. Biopiracy is a topical issue for attention in Africa. Bioprospecting if controlled and conducted under mutually agreed terms and compensation arrangements, can be of benefit to African countries. Therefore legal frameworks governing access to and benefit sharing of genetic resources are of urgent need if destruction to biodiversity and loss of valuable plant and animal species in Africa is to be stopped.

Africa must borrow a leaf from countries such as India who have successfully challenged patents taken on knowledge previously recorded and utilised for centuries. In this respect, patents taken on Turmeric and neem tree products have successfully been contested and revoked. *(see appendix 1)*
And in the case of the San people of the Kalahari Desert, South Africa, use of the Hoodia cactus was known to stave off hunger. Patenting of the "sliming" agent by the South African Council for Scientific and Industrial Research (CSIR) was initially contested by the San tribe on the grounds of "biopiracy". However through negotiations, an agreement has been reached to share potential benefits amongst the concerned parties (see appendix II). This is probably the first case in Africa successfully concluded for mutual benefit of the parties concerned.

The mechanisms for recognition and protection of innovations derived from traditional knowledge systems must be established at national, regional and global levels. In Africa there is great danger that valuable trees and shrubs with medicinal and agricultural properties will become extinct if measures are not taken to monitor bioprospecting activities. In Kenya, the National Council of Science and Technology whose mandate is to oversee all research in the country does not have the required capacity for effective monitoring.

4. INTERNATIONAL DEBATE ON IPRs, BIOTECHNOLOGY AND BIODIVERSITY

Increasing activity is taking place internationally where intellectual property is being defined in various fora for the utilization and protection of biodiversity and biotechnological inventions. Intellectual property obtained by multinational corporations and other institutions may erode communities' rights and their traditional practices.

The relevant international fora and processes are:

- The Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement, 1994

- The Convention on Biological Diversity (CBD), 1992.
- The World Intellectual Property Organization (WIPO)
- The International Treaty on Plant Genetic Resources for Food and Agriculture, FAO, 2001.
- The International Union for the Protection of New Varieties of Plants (UPOV), 1978 and 1991 Acts.

4.1 Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement

Trade Related Aspects of Intellectual Property Rights (TRIPs) administered by the World Trade Organisation (WTO), stipulates that all signatories to the Agreement must conform to industrial country standards of patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuits and trade secrets. These supplement their obligations of the Paris, Berne, Rome and Washington Conventions in their respective fields.

The TRIPs Agreement which came into force in January 1995 strengthened the intellectual property protection on biotechnological inventions on product and processes. Under the Agreement, developing countries were required to extend the scope of patentability to microorganisms, microbiological processes, plant genetic material and techniques used for genetic transformation. Developing countries are obliged to implement Article 27.3(b) of the TRIPs Agreement, which requires WTO members to provide for the patenting of certain life forms and processes within their national laws.

Article 27.3(b) of TRIPs states that:
"Members may also exclude from patentability…plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof..."

The TRIPs Agreement makes mandatory for microorganisms, non-biological and microbiological processes to be patented, but allows members to exclude from patentability plants and animals and essentially biological processes. Concerning plant varieties, members may either protect them by patent or by an effective *sui generis* system or by combination of both.

The issue of patents on life forms is a current topic of debate worldwide. Several factors have led to the emergence of this debate namely:

i. The advances within the last decade in the field of biological sciences, including the ability to isolate and manipulate genes, which has resulted in the rapid development of genetic engineering and the growth of biotechnology industry.
ii. Bioprospecting activities have been accompanied by the problem of biopiracy; where traditional knowledge is employed to assist in the search for plants or other materials with commercial potential. The incidence of biopiracy has been facilitated, to an extent, by the patents applied for by foreign individuals or companies over the biological resources and their genetic components.
iii. The growing demand for biological or genetic resources, due to their demand in biotechnology, pharmaceutical, cosmetics, agriculture and other industries. This demand for biological resources has resulted in increased bioprospecting activities in developing countries.

The aspects of Article 27.3(b) of the TRIPs Agreement have practical consequences in Africa, because almost all developing countries including Africa excluded living organism from patentability in their domestic legislation before the TRIPs Agreement came into force in 1995. In addition, African countries with the exception of South Africa and Kenya do not have plant breeders' rights (PBR) legislation for plant varieties. For this reasons, questions are being raised as to the appropriateness of patents on life forms, and the implications of such patents for Africa and developing countries at large.

The Africa Group proposal on Article 27.3(b)

In July 1999, as part of the preparatory process for the WTO'S Seattle Ministerial Conference, Kenya on behalf of the Africa Group submitted a paper to the General Council on the TRIPs Agreement, which proposed clarification of, and changes to, Article 27.3(b) of the TRIPs Agreement.
In its proposal, the Africa Group questioned the artificial distinction made by Article 27.3(b) between:

- Plants and animals, on one hand, and microorganisms on the other; and
- Essentially biological processes for the production of plants and animals, on one hand, and microbiological and non-biological processes, on the other.

In light of these artificial distinctions, the proposal called for a revision of Article 27.3(b) so as to prohibit the patenting of all life forms and natural processes. There is also lack of clarity on the criteria/rationale used to decide what can and cannot be excluded from patentability in Article 27.3(b). By stipulating compulsory patenting of microorganism and microbiological processes, the provisions of Articles 27.3(b) contravene the basic tenets on which patent laws are based: that substances and processes that exist in nature are a discovery and not an invention.

4.2 Convention on Biological Diversity (CBD).

The Convention on Biological Diversity (CBD) is a legally binding international agreement, which was adopted in 1992. The Convention has to be implemented through the application of protocols and through the enactment of national legislation which is in harmony with the objective of the CBD and in line with decisions of the Conference of Parties. The Convention acknowledges that states have sovereign rights over their natural resources (Art. 15.1); that states also have the authority to determine access to these resources through national legislation (Art.15.1); and such access is subject to the prior informed consent of the country housing the resources (Art. 15.5).

Although CBD requires countries to take measures to protect genetic resources (Art. 8), it does not explicitly call on host countries to institute systems of proprietary protection for genetic resources. It does refer to the need to seek the approval of the holders of the knowledge, and, in Article 8(j), it encourages the equitable sharing of benefits arising from the utilization of such knowledge. Significantly, it makes no reference to the need for such systems to be internationally recognized. These aspects weaken the impact of the CBD in the sustainable utilization of biological resources.

Articles 8(j) of the CBD requires parties to address the issue of protecting traditional knowledge, innovations and practices of indigenous and local communities at national level and states that:

"subject to its national legislation, respect preserve and maintain knowledge, innovations and practises of indigenous and local communities embodying traditional lifestyles relevant for the conversion and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practise and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practises"

To date African countries have been slow to implement both Article 15.1; 15.5 and Article 8 of the CBD, largely due to continued absence of implementing mechanisms and regimes. Thus access to genetic resources and protection of traditional knowledge remain as Africa's main issues of the CBD requiring further attention and consensus on the role of IP and way forward.

4.3 World Intellectual Property Organization (WIPO).

The people of Africa are endowed with an abundant heritage of a diversity of cultures, languages and biological diversity. This great heritage is expressed through traditional knowledge systems, innovations and practices.

Traditional knowledge, innovations and practices have contributed significantly to the present body of knowledge in science, agriculture, medicine and environmental conservation. There has been little recognition and protection of this body of knowledge. The lack of legal recognition and protection has lead to a situation where custodians of knowledge and innovations derived from traditional knowledge systems are not rewarded for contributions rendered.

Since 1999, discussions on this situation have gained momentum internationally with greater gains and concern for protection of traditional knowledge and folklore in developing countries. At the Doha Ministerial Conference of 2001, WTO members agreed to exercise the relationship between the CBD and the production of traditional knowledge and folklore previous to the in 2000, the WIPO general assembly agreed to establish an Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. On-going deliberation are expected to determine the future directions of these discussions for conclusive outcomes.

4.4 International Treaty on Plant Genetic Resources for Food Agriculture (ITPGRFA)

ITPGRFA was adopted in Rome in November 2001 and came into force in June 2004. This is a multilateral system for access for food and agriculture to 35 crop genera and 29 forage species and also associated benefit sharing. It conditions for facilitated access to *in situ* plant genetics resources for food and agriculture according to national law and also allows for protection of property and other rights of communities. Most benefits will be shared on a multilateral basis rather than with the specific providers of genetic resources. Benefits such as the exchange of information, access to and transfer of technology, capacity building and even a commercial benefit-sharing package should be available to communities through the system. The concept of Farmers' Rights arose in debates in the FAO where it was recognised that there was an imbalance between the IP rights afforded to breeders of modern plant varieties and the rights of farmers who were responsible for supplying the plant genetic resources from which such varieties mainly derived. A second concern was the consistency between making available plant

genetic resources as the common heritage of mankind, and the taking out of private IP rights on varieties derived from them.

Article 9 of ITPGRFA encourages countries to take steps to protect and promote Farmers Rights including protection of their TK and the right to participate in benefit sharing and in national decision-making. Communities may also benefit through improvement in conservation and sustainable use activities.

Under ITPGRFA member countries recognize the enormous contribution that the local communities and farmers have made and will continue to make for the conservation and development of plant genetic resources, which constitute the basis of food and agriculture production throughout the world. This contribution of farmers to the conservation and development of plant genetic resources is the basis of Farmers' Rights.

The implementation of specific Farmers' Rights is not an international obligation like that imposed under provisions in TRIPs Agreement.

Subject to its national legislation each country should take appropriate measures to protect and promote Farmers' Rights, which include:

a. Protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
b. The right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;
c. The right to participate in making decisions, at national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

Note that nothing in the Farmer' Rights provisions under ITPGRFA shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

Another issue which may arise from the ITPGRFA is the fate of germplasm left out of the treaty and held in various international research organisations such as the CGIAR centres. Although this germplasm is held in trust for countries from which collection was done, its ownership may become an issue in the future should the CGIAR decide to have IP arrangements with third parties over biotech products of such germplasm.

4.5 International Union for the Protection of New Varieties of Plants (UPOV).

The purpose of the International Union for the Protection of New Varieties of Plants (UPOV) is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.

The OPOV Convection was signed in 1961 and revised in 1972, 1978 and 1991. The 1991 came into force on April 1998. Both South Africa and Kenya are members of UPOV 1978.

To be eligible for protection, plant varieties have to be:
i. Distinct from existing, commonly known varieties,
ii. Sufficiently uniform,
iii. Stable and new in the sense that they must not have been commercialised prior to certain dates established by reference to the date of the application for protection.

Both the 1978 and the 1991 Acts set out a minimum scope of protection and offer members the possibility of taking national circumstances into account in their legislation. Under the 1978 Act, the minimum scope of the plant breeders right requires that the holder's prior authorisation is necessary for the production for purposes of commercial marketing, the offering for sale and the marketing of propagation material of the protected variety. The 1991 Act contains more detailed provisions defining the Acts concerning propagating material, in relation to which the holder's authorisation is required. Exceptionally but only where holder has had no reasonable opportunity to exercise his right in relation to the propagating material, his authorization may be required in relation to any of the specified acts done with material of the variety. Like all intellectual property rights, plant breeder's rights are granted for a limited period of time, at the end of which varieties protected by them pass into the public domain. The rights are also subject to controls, in the public interest, against any possible abuse. It is also important to note that the authorisation of the holder of the plant breeder's rights is not required for the use of his variety for research purposes, including its use in the breeding of further new varieties.

Reasons for protection of new plants varieties are that:

- Agricultural productivity needs to be increased since land and other resources are scarce.
- Improved quality and high value crop varieties are in demand.
- Better resistance to pests and diseases.
- More efficient use of inputs.
- Economic development.

Protection is afforded to new varieties both as an incentive to the development of agriculture, horticulture and forestry and to safeguard the interest of plant breeders. Improved varieties are a necessary, and cost effective, element in the quantitative and qualitative improvement of the production of food, renewable energy and raw material.

Breeding new varieties of plants requires a substantial investment in terms of skill, labour, material resources, money and time. The opportunity to obtain certain exclusive rights in respect of his new variety provides the successful plant breeder with a better chance of recovering his costs and accumulating the funds necessary for further investment.

In the absence of plant breeder's right, those aims are more difficult to achieve since there is nothing to prevent others from multiplying the breeder's seed or other propagating material and selling the variety on a commercial scale, without recognising in any way the work of the breeder.

4.6 IPR and Access to Essential Medicines in Africa: The DOHA Declaration

African countries should make use of policy options such as compulsory licensing and parallel importation to increase the supply of low-price medicines and vaccines in the continent. The Doha Declaration on the TRIPS Agreement and Public Health mandates that the agreement be interpreted in a manner that supports public health interests and promotes access to medicines for all. As of January 1, 2005, developing countries (excluding least developed) will be required to implement and enforce pharmaceutical product patent protection and operationalize patents based on mailbox applications that were submitted during the TRIPS transition period. At that time, the world supply of low-price off patent medicines will decrease. Not only will supplies of

low-price medicines within developing countries decrease, but also supplies available for export by these countries will gradually diminish.

The Doha Declaration provides to Least Developed Countries (LDCs) an extension until January 1, 2016, to implement or enforce pharmaceutical product patent protection. The 35 out of 49 LDCs are in Africa. That extension will have a limited effect on supplies since LDCs will remain dependent on low price imports from developing countries that may no longer be available. LDCs might best take advantage of the transition period by increasing their intra-LDC capacities to make and trade medicines and vaccines, but there are practical obstacles to accomplishing this.

The restriction imposed by Article 31(f) of the TRIPS Agreement on exports under compulsory license is likely to have a significant effect on the world supply of low price medicines and vaccines, when the transition period for developing countries ended in January 2005. If a predominant part of compulsory licensed production must supply the local market, the quantity of available exports will be limited. To remedy this problem, the Decision of 30 August 2003 of the General Council in the WTO waived the provisions of Article 31(f).

Article 30 of the TRIPS Agreement regarding exceptions to patent rights must be interpreted so as to permit making and export of pharmaceutical products and other public health related inventions to meet public health needs. The adoption of a formal interpretation by the WTO Ministerial Conference or General Council would provide legal security for countries following this approach. Article 8:1 of the TRIPS Agreement authorizes the adoption of necessary public health measures provided they are "consistent" with the terms of the TRIPS Agreement. There is no justification for the TRIPS safeguard to be more restrictive than the safeguards applicable to goods and services. Article 8:1 should be amended to permit the adoption of necessary public health measures inconsistent with the TRIPS Agreement.

Developing countries may consider revisiting the position many of them advocated during the GATT Uruguay Round, and propose amendment of Article 27:3(a) of the TRIPS Agreement to allow exception from patenting of public health related inventions, including medicines and vaccines. Developing countries should implement the TRIPS Agreement recognizing that its provisions do not demand excessive levels of protection promoted by developed countries. Meeting the public health developing countries and international organizations such as the IMF and World Bank. The Global Fund does not to date evidence that it will be adequately funded so as to address urgent developing country needs for public health supplies. Developing countries must be prepared for self-reliance, and this self-reliance requires increased capacity to produce low price medicines and vaccines, whether or not such products are under patent by Pharma enterprises. This intensifies the importance of interpreting and amending the TRIPS Agreement to reinforce developing country capacity to act in their own best interests.

Increasing attention must be devoted to research and development on medicines and vaccines of particular relevance to Africa. Neither the market nor the TRIPS Agreement provides a solution for the lack of attention to this R & D. The WTO Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") provisions relating to medicines resulted from the pursuit of an industrial policy directed toward maintaining and increasing the dominance of developed countries-based pharmaceutical companies in the world market for innovative drugs.

A review of the currently available literature by independent researchers on the TRIPS Agreement and access to medicines, including vaccines, in developing countries reveals a striking level of agreement on the essentials.

Present TRIPS Agreement standards will principally benefit commercial pharmaceutical enterprises located in the developed countries, and more specifically in the United States, Japan, Switzerland, Germany and the United Kingdom. Increased African countries' R & D on medicines and vaccines brought about by adoption of strong patent protection is highly unlikely for the foreseeable future to yield the development of new pharmaceutical products, the income from which would offset increased patent rents that will flow from Africa to the developed countries based on the introduction of such protection. African countries should take advantage of the policy options afforded by the TRIPS Agreement including the granting of compulsory licenses and authorization of parallel importation. Price controls may be effective in specific contexts. Restrictions on exports of tiered-priced drugs may be useful in specific contexts also. Substantial subsidization of African country purchases of medicines is necessary if highly active antiretroviral (ARV) treatment (HAART) is to be provided to address the HIV/AIDS pandemic in Sub-Sahara Africa. Funding for R & D on medicines and vaccines of particular relevance to developing countries is inadequate. Private enterprise will not undertake such research as a consequence of lack of perceived market incentives. Mechanisms to facilitate R & D on medicines and vaccines of particular relevance to developing countries should urgently be developed and put into operation. African countries should take advantage of policy options available under the terms of the TRIPS Agreement to address public health needs. These are the policy options of granting compulsory licensing and authorizing parallel trade. To improve the effectiveness of the compulsory licensing option, it is recommends that Article 31(f) of the TRIPS Agreement that limits exports of licensed products be waived and amendment of the TRIPs Agreement and national laws be effected accordingly. Also formal interpretation of Article 30 should be adopted to make clear that WTO Members may authorize an exception to the rights of patent holders to make and export medicines and vaccines to countries that need them. The TRIPS Agreement should be amended to make its basic safeguard provision, Article 8:1, compatible with the safeguard provisions of the GATT 1994 and GATS, and allow acts inconsistent with the TRIPS Agreement necessary to protect public health. There is no valid reason why intellectual property should be accorded a higher level of protection in the WTO hierarchy of norms than goods and services, particularly since IPRs rules may be the most likely to have an adverse effect on public health. To meet the immediate public health needs of the African continent requires substantial subsidization, and there is little present evidence that such subsidization will be forthcoming. There is need to improve funding for purchases of medicines and R & D on diseases of relevance to Africa. Nonetheless, present evidence strongly suggests that African countries like other developing countries may need to rely on their own efforts and resources to deal with their public health needs, and increasing capacity to make and distribute generic medicines and vaccines may be their only and best way to accomplish this.

Pharmaceuticals and other research institutions based in the OECD hold the vast preponderance of patents on pharmaceutical products. U.S.-based inventors hold about 45% of these patents, and 18.5% are held by Japan-based inventors.

The TRIPS Agreement is structured such that pharmaceutical product patent protection will be mandatory for all developing countries as of January 1, 2005. The least developed countries were granted an extension until January 1, 2016 (from the previous deadline of January 1, 2006), under Doha Declaration on TRIPs and Public Health to implement and enforce patent protection with respect to pharmaceutical products. Patents are used to restrict competition and sustain prices higher than would be available in a competitive market The introduction of

pharmaceutical patent protection in countries where such protection formerly was not available will (a) redirect production and sales from generic producers to on-patent producers (b) increase prices of pharmaceuticals to consumers, and (c) result in transfers of patent rents to African countries-based producers. This is the explicit purpose of introducing patent protection. The introduction of generic versions of patented products is delayed, and trade in generic pharmaceuticals is reduced. The aggregate effects on Africa might be calculated by examining price differentials between patented and off-patented versions of the same drugs, examining present rates of consumption and the ways in which demand patterns shift upon transition to reliance on patented drugs, examining the effects of reduced drug demand (resulting from higher prices) on various aspects of local health care systems, and a variety of other factors.

While estimates of the overall effects of the TRIPS Agreement on developing countries have been made, there is yet to be a comprehensive systematic investigation of the overall effects in economic terms on developing country access to medicines and health care.

Access to essential medicines has been substantially inhibited by patent protection. The most striking evidence is from sub-Saharan Africa where prices of patented antiretroviral medicines (ARVs) were maintained at OECD levels until large scale international pressure forced Pharma to move toward approximating prices offered by generic producers in India and Brazil. OECD-based pharmaceutical manufacturers have actively opposed introduction of generic ARVs in South Africa, Kenya, Uganda and elsewhere. The world political situation has most recently made it more difficult for Pharma to aggressively attack sub-Saharan African plans to market generic versions of HIV-related medicines, but current political circumstances are not an appropriate basis upon which to base multilateral trade and IPRs policy. Moreover, the political pressure pertaining to actions in sub-Saharan Africa does not necessarily pertain in other parts of the world. Reliance on voluntary restraint by Pharma is not an adequate basis upon which to analyze and frame TRIPS Agreement rules.

A concern expressed by Pharma is that exports of drugs by developing countries to OECD markets would seriously affect Pharma's profitability, research mission, and so forth. This concern might be more realistic than concern over loss of profits within developing country markets. However, OECD patent laws generally prevent the importation of drugs produced without the consent of patent holders. If developing country generic producers that are not operated by Pharma seek to export to OECD markets, the firms are able to block imports of those drugs under existing patent legislation.

The social disruption caused by the TRIPS Agreement in developing countries has widely publicized the effects of patents on price, and the means by which consumers support Pharma R & D.
Increasing emphasis on publicly supported research in the OECD might be effective in generating new medicines and vaccines, thereby reducing the importance of protecting Pharma profits to support R & D. Many of the new chemical entities marketed by Pharma are initially discovered in university or hospital research laboratories operating with substantial government funding.

Pharmaceutical industries in the developed countries frequently suggest that patents are not impeding access to medicines in developing and least developed countries, and that the principal impediments to access are in the area of health care infrastructure and medical personnel. Public health and IPRs experts have not questioned the importance of improved infrastructure, personnel recruitment and training, and related factors in addressing disease burdens. However, the fact that there are important additional considerations in effectively addressing disease does

not diminish the importance of addressing the fundamental element of pharmaceutical costs. Most patented products are dependent for their usefulness on additional elements of infrastructure.

The price of medicines directly affects the ability of prospective consumers to obtain them, and this is especially true in the case of life-saving medicines for which demand is highly price elastic among poorer populations (in the sense that lowering prices substantially enhances effective demand).

Pharmaceutical industries in the North have also suggested that because potentially patentable medicines have not always been patented in certain African countries, this demonstrates that patenting is not a significant obstacle to access. Yet inventing enterprises have always patented selectively, strategically targeting those countries with the greatest sales potential, and those countries where they are most likely to confront competitive production capacity and other commercial threats. The patenting pattern in Africa represents strategic planning that was deemed appropriate by Pharma in its specific time-frame, emphasizing South Africa as the principal potential source of competitive production, and countries such as Kenya, Nigeria and Zimbabwe as markets with comparatively high income. Major new commercial threats from generic producers in Brazil and India form the backdrop of Pharma's aggressive efforts toward accelerated implementation of the TRIPS Agreement.

To analyze the role of Pharma patents in developing countries it would be useful to be able to identify the extent to which Pharma profits derive from patent rents from these countries, whether from direct or indirect sales of patented pharmaceutical products, from patent licensing royalties and otherwise.

Available data raises questions regarding Pharma's contention that lower standards of patent protection in developing countries will impede the "research mission" of its members. It seems unlikely that a shortfall of less than one billion dollars in R & D finding would undermine the basic mission of an industry with an aggregate market size of $337.2 billion in 1999, and OECD company R & D expenditures of ECU 22 billion in 1995. Compulsory licensing has long been recognized as the most important tool for addressing the adverse effects of the patent grant on public welfare. Exploiting compulsory licensing may involve the actual grant and implementation of a license. It may also involve the threat of a license that results in a patent holder revising its own pricing or supply strategy.

Developing countries that provide patent protection for pharmaceuticals may obtain low-price drugs by authorizing their local manufacture or importation under compulsory license. A compulsory license may be issued on any grounds, including addressing public health needs. There is a requirement that adequate compensation under the circumstances be paid to the patent holder, but this is a flexible standard that would allow a royalty to be based on the local wholesale selling price, which should result in a manageable amount. The effective use of compulsory licensing as a tool of public policy presupposes that certain conditions are met:

- There must be a party within the country granting the license that is able to exploit it, either by manufacturing the subject invention or importing it. This requires, *inter alia*, technical expertise and financial capital;
- If local manufacturing is to be undertaken, there must be sufficient purchasing power among the population to justify investments undertaken by the party exploiting the license (or

export opportunities must be available). If the local population is small and/or poor, there may not be a consumer base adequate to provide an adequate return on investment;

- The government may act as the party exploiting the compulsory license (e.g., for government use), and/or it may act as purchasing agent on behalf of the population acquiring the exploited invention. In either case, the government will require technical expertise and financial resources.
- Legal and political infrastructure must be in place to permit the granting and supervision of the license.

Countries are in substantially different circumstances regarding the extent to which they may need to use compulsory licensing as a policy instrument. Countries in the OECD with high levels of purchasing power maintain strong production bases that are distributed among member countries, and rely on production from developing countries. Countries with high levels of purchasing power and strong industrial bases are unlikely to require the use of compulsory licensing except in exceptional circumstances, such as for remedial purposes when producers are found to be engaged in anticompetitive behaviors, or to address supply emergencies. The recent Anthrax episode in the United States (discussed infra) illustrates that developed countries may confront supply emergencies that require the threat and/or grant of compulsory licenses.

In the case of African countries with lower levels of purchasing power and weaker industrial bases are more likely to require the use of compulsory licensing as a tool to address public policy objectives.

The price of goods is a more significant determinant of market demand in low-income countries because consumers have fewer resources to allocate among goods.
Although countries are at substantially different stages of technology capacity development, in general there is a wide disparity between the research and development capacities of developing and developed countries. The vast preponderance of patented technology is owned and controlled by enterprises based in developed countries. Developing countries on the whole are in a position of reliance on technological development in the developed countries, and are in the position of systemic net payers for technology. For a variety of reasons, the technology needs of developing countries often may not be met by acquisition of technology licenses on voluntary terms. Compulsory licensing provides a means for developing countries to obtain technology necessary for development and social welfare.

A weak industrial base implies dependence on imports for goods. Suppliers based outside the territory of a country are less sensitive than local suppliers to internal economic and political pressures to provide goods at prices affordable within the country.

There is substantial evidence that the availability of generic (off-patent) drugs, especially from multiple sources, substantially reduces prices.

Competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug's price when there is just one generic competitor, and to 29% with 10 competitors

It is essential to many African countries that sources of generic or low-cost drugs be made available. However, it is difficult for many of these countries to manufacture drugs, and it is particularly difficult for them to manufacture a variety of drugs such as may reasonably be

necessary to meet the demands of the local market. As such, the problem is two-fold: (1) establishing manufacturing capacity and (2) establishing a network of low-cost suppliers.

5. CONCLUSION

KEY ISSUES ON IPR AND BIOTECHNOLOGY

5.1 Access to Medicines

Africa is ravaged by numerous diseases, AIDS being a key killer today. Currently 26 million people have died of it in Africa and twenty five million are living with the disease. Access to retrovirals is constrained by high costs, inadequate supplies and poor distribution mechanisms. On the other hand, the use of generics generates sharp objection by companies holding IP on originals. The Doha Declaration which paves way for access to drugs cheaply and access to technology through compulsory licensing has yet to be put to test successfully in Africa. Only South Africa and Kenya have made moves in this direction, but there are hurdles still to overcome. Facilitations by Governments to local entrepreneurs to acquire technology and the know-how (IP) for local manufacture remains a major challenge. Outdated and conflicting policies governing health and lack of the necessary physical and technological capacity hinder quick progress shown by the experience of the company Cosmos in Kenya whose application to acquire the technology from foreign manufacturers has taken over a year to process, and still the procedures remain incomplete.

It is important that research on key killer diseases in Africa such as AIDS, Malaria, Cholera, TB etc, be carried in Africa as most of these are “orphan” diseases whose research in developed countries is not a priority. However the technology for their production remains in the hands of foreign companies.

Dialogue should focus on engaging international pharmaceutical companies to lower prices of retrovirals, consider support for manufacturing of the drugs in poor countries and facilitate the manufacture of drugs for orphan diseases in Africa. There is need for African governments to review their IP laws to provide for compulsory licensing, government use and parallel importation to ease the requirements of access to drugs and healthcare facilities in Africa.

5.2 Access to and Development of Technology for Food Security

Frequent famine occurrence is a key obstacle to development in Africa. In spite of the presence of international research institutions on the continent such as the CGIAR centres who have made significant contribution to crop productivity by developing superior crop varieties, challenges still exist. Drought, insect pests and diseases cause enormous losses to harvests. Biotechnological approaches have promise of increasing food productivity in Africa. Access to such technologies and concerted research undertaking may bring about significant solutions.

However, these technologies come at great cost and there is need for negotiations to avail protected technology to Africa at affordable cost.

5.3. Human resources in IP for Africa

Although most countries in Africa are in the process of building up their capacities in IP in terms of implementation of relevant laws (see appendix III), development of human resources is minimal. Most offices are scantily staffed, and without strategies for skills development such as drafting of patents in biotechnology. Therefore there is need for attention to be paid to human resource development both at government level and in the private sector in areas of IP management.

Appendix I

Controversial patent cases involving Traditional Knowledge and Genetic Resources.

TURMERIC

Turmeric *(curcuma longa)* is a plant of the ginger family yielding saffron coloured rhizomes used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and as a colour dye. As a medicine it is traditionally used to heal wounds and rashes.

- In 1995, two Indian nationals at the University of Mississippi medical Centre were granted US patent no. 5,401,504 on "use of tumeric in wound healing"
- The Indian Council of Scientific and Industrial Research (CSIR) requested the US Patent and Trademark Office (USPTO) to re-examine the patent.
- CSIR argued that tumeric has been used for thousands of years for healing wounds and rashes and therefore its medical use was not novel.
- Their claim was supported by documentary evidence of traditional knowledge, including and ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical association.
- Despite arguments by the patentees, the USPTO upheld the CSIR objections and revoked the patent.

Observations: the turmeric case was a landmark case as it was the first time that a patent based on the traditional knowledge of a developing country had been successfully challenged. The legal costs incurred by India in this case have been calculated by the Indian government to be about US $10,000.

NEEM

Neem (azadirachta indica) is a tree from India and other parts of South East Asia. It is now planted across the tropics because of its properties as a natural medicine, pesticide and fertilizer. Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops; the oil extracted from its seeds is used to treat colds and flu; and mixed in soap, it is believed to offer low cost relief from malaria, skin diseases and even meningitis.

- In 1994 the EPO granted European Patent no. 0436257 to the US Corporation W.R Grace and USDA for a "method for controlling fungi on plants by the aid of hydrophobic extracted neem oil".
- In 1995 a group of international NGOs and representatives of Indian farmers filed a legal opposition against the patent.
- They submitted evidence that the fungicidal effect of extracts of neem seeds had been known and used for centuries in Indian agriculture to protect crops, and thus was the invention claimed in EP257 was not novel.
- In 1999 the EPO determined that according to the evidence "all features of the present claim have been disclosed to the public prior to the patent application…and [the patent] was considered not to involve an inventive step".
- The patent was revoked by the EPO in 2000.

Appendix II

HOODIA CACTUS

The San, who live around the Kalahari Desert in southern Africa, have traditionally eaten the Hoodia cactus to stave off hunger and thirst on long hunting trips. In 1937, a Dutch anthropologist studying the san noted this use of hoodia. Scientists at the South African Council for Scientific and Industrial Research (CSIR) only recently found his report and began studying the plant.

In 1995 CSIR patented Hoodias appetite suppressing element (P57). In 1997 they licensed P57 to the UK biotech company, Phytopharm, in 19998, the pharmaceutical company Pfizer acquired the rights to develop and market P57 as a potential slimming drug and cure for obesity (a market worth more than £6billion), from Phytopharm for up to $32 million in royalty and milestone payments.

On hearing of possible exploitation of their traditional knowledge, the san People threatened legal action against the CSIR on grounds of "biopiracy". They claimed that their traditional knowledge had been stolen, and CSIR had failed to comply with the rules of the convention on biodiversity, which requires the prior informed consent of all stakeholders, including the original discoverers and users.

Phytophamr had conducted extensive enquiries but were unable to find any of the "knowledge holders". The remaining San were apparently living in a tented camp 1500miles from their trial lands. The CSIR claimed they had planned to inform the San of the research and share the benefits, but first wanted to make sure the drug proved successful.

In March 2002, an understanding was reached between the CSIR and the San whereby the San, recognised as the custodians of traditional knowledge associated with the Hoodia plant, will receive a share of any future royalties. Although the San are likely to receive only a very small percentage of eventual sales, the potential size of the market means that the sum involved could still be substantial. The drug is unlikely to reach the market before 2006, and may yet fail as it progresses through clinical trials.

Observations: this case would appear to demonstrate that with goodwill on all sides, mutually acceptable arrangements for access and benefit sharing can be agreed. The importance of intellectual property in securing future benefits appears to have been recognised by all parties including the San.

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