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Is it Time for African Countries to Harmonise their Intellectual Property

Management and Development – Reference to TRIPS agreement?

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Africa's continued dependency on foreign medicines and intellectual property (IP) is increasingly becoming a serious concern. This is compounded by an upsurge in drug resisting diseases like N1H1 and Tuberculosis that have been witnessed in the past years. A threat posed by the safety-concerned is that some of these diseases are potential agents of weapons of mass destruction. Of notable significance is that even though the World Trade Organisation's (WTO) TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement has provided opportunities for African countries to review and adjust their intellectual property systems so as to migrate towards producing their own medicines. African countries have failed to capitalise on these opportunities. This is due to various reasons. First being a possibility that most African countries are still dependent on donor funds for their health systems, thus reviewing IP policies might upset funding arrangements. Second, being that some African countries lack capabilities to develop their own technologies, due to financial constraints and limited research activities. In the face of these challenges it is here argued that African states need to consider a possibility of harmonising their approach towards strengthening intellectual property development as well as their stance in international agreements such as TRIPS, so that the position of one country complements that of the region or the continent. This paper, with reference to TRIPS, further discusses how African countries fail to openly express their positions in IP development and management at international stage.

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Introduction

The threats posed by the outbreaks of diseases such as the N1H1, cholera, along with others that continue to plague Africa such as meningitis, drug-resistant tuberculosis (XDR) and Congo fever points to a need for African states to reconsider their position on TRIPS and other international agreements that regulate intellectual property management. This needs to be done within the context of Africa's desire to invest in research and produce own medicines.[1] The constant risk posed by the expansion of HIV/AIDS in the continent and the possibility that the continent might experience outbreaks of various drug-resistant disease, points to a need for African states to approach TRIPS and other similar agreements in a better coordinated approach. This, together with safety concerns around the possibility of drug-resistant diseases being used as weapons of mass destruction leaves Africa with no choice but to seriously review these agreements. Of critical note is that as the knowledge on genetic engineering expands, new strains of dangerous incurable diseases are emerging. In addition, the unknown effects of climate change in the emergence of new diseases are also of great concern. Many disease researchers have already warned that rising global temperatures are likely to lead to more diseases. For example, by allowing tropical diseases to expand their range into what are now temperate regions. This together with general threats posed by the possible eruption of drug-resistant diseases means that Africa should start to consider safe and practical approaches through which it will secure essential drugs during times of crisis and emergency.

The fact that most African countries are unable to provide free essential drugs to their citizens means that African countries are struggling to access essential drugs at current intellectual property (IP) arrangements and prices. This, therefore, provides a compelling reason for African states to re-assess their approach to systems and arrangements of acquiring essential medicines. Furthermore, considering the prevalence of HIV/AIDS in Africa and the continuous existence of controllable diseases such as malaria, polio and others, which have been successfully eradicated in the developed world, suggests that it is time for African states to exploit alternatives routes of acquiring essential drugs and those that can be needed during moments of emergency.

Under TRIPS agreement, African states have three options that they can use to access essential drugs, namely:

a) move towards producing own drugs (i.e. compulsory licensing),
b) negotiate cheaper prices by allowing importation of cheap generic drugs (i.e. parallel importation) or
c) intensify research capabilities (Bolar provision) using background information (data) from existing patents.

All these were intended to make medicines accessible and affordable.

Compulsory licensing allows a WTO (World Trade Organization) member state to produce a patented product or process without the consent of the patented owner for public non-commercial purposes (i.e. government use). This has to take place under the following considerations:

a) that an effort is made first to obtain a voluntary license on a reasonable commercial terms and conditions and
b) that adequate remuneration is paid to the right holder in each case, taking into account the economic value of the license.

Under *Parallel importation*, the government can permit the parallel importation in which a product manufactured under a patent held in one country but sold at lower prices in another country, can be imported from that second country without permission from the patent holder. TRIPS state that governments permitting parallel imports cannot be challenged under the WTO dispute settlement system provided they do not discriminate on the grounds of nationality of the patent holder.

Bolar provision allows generic manufacturers to conduct research and develop generic equivalent of brand-name drugs still under patent and to submit a registration application to a drug regulatory authority. This allows the generic manufacturer to begin production and sale of the drug after the 20 year patent has expired. In general, compulsory licensing lowers prices to consumers by creating competition in the market for the patented good. It can lower the price of medicine by 75 per cent or more. Under *Bolar provision* the manufacture of generic pharmaceuticals can be allowed to use the technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of the generic product, while the patent is in force. The *Bolar provision* allows the generic producers to market and manufacture their goods as soon as the patent expires.

Despite these options, what is clear is that most African countries are unable to utilize or implement them. This is largely due to different

constraints. The first constraint being the strong dependency of African countries on donor funds for their health systems.[2] Secondly, the inability to invest in research and thirdly, a general lack of resources to set up production facilities.

It is against this background that it is here proposed that African states need to consider a possibility of harmonising their approach to IP development and associated international agreements such as TRIPS by collectively exploiting all available options that are provided by such agreements so that the position or action of one country complements that of the region or the continent.

TRIPS agreement: How it has affected Africa?

TRIPS have changed the international environment with respect to intellectual property[3] sharing. While it can be perceived as a breakthrough in the field of management of intellectual property, what is clear is that it generally accommodates the demands of industrialised countries, due to its character of strict international standards of protection by mandating the extension of patentability to virtually all fields of technology that is recognised as valuable in developed country patent systems.[4]

For instance, TRIPS requires that WTO member states give copyright and patent protection to a wide range of products, including pharmaceutical goods and genetic resources. A patent provides the owner of an invention with legal means to prevent others from selling it for a period of 20 years or more. What this means is that during this period, no one may use, make or sell a product without the owner's authorisation. What is being lamented is that before TRIPS, many developing countries, including Africa did not recognise patents for such a wide range of application and this provided a room for copies of new drugs to be made through reverse engineering or patenting in another pathway.

In countries like India, that did not have patent regimes covering a wide range of applications including pharmaceuticals, manufacturers made generic versions of in-patent drugs and this increased access to a variety of drugs. Generics are usually cheaper than in-patent drugs since generic manufacturers do not have to be concerned about recouping research and development expenses. How the use of generic drugs could be beneficial to Africa is that, whereas it costs ± US$10 000 per year to administer an internationally accepted combination of therapy for HIV/AIDS, generic version of the same combination can cost as little as $250 per year.

What TRIPS has unfortunately introduced is the obligation to all WTO member states to implement product patent protection for various drugs patented after 1995 and the extension of patents to various forms of life including genetic resources and biodiversity. For this, least developed countries, including most African states, were given up to 2006 to align their patent laws with TRIPS agreement.

The impact is that it made it impossible to produce generic copies for at least 20 years and had raised prices for medicines. As a result prices of some drugs have increased substantially and this has restricted access to the effective treatment of HIV/AIDS, in particular for 90 per cent of suffers who are in developing countries, including Africa.

An analysis of access to treatment shows that for 6 million people in the developing world in need of anti-retroviral drug therapy just 230 000 (i.e. less than 4 per cent) are receiving anti-retroviral drugs. This picture is far worse for African countries.

Challenges associated with TRIPS: African perspective

Demands posed by TRIPS have exerted negative influences on implementing domestic public health policies in Africa and other developing countries. As a result African governments have asked WTO's TRIPS Council to consider their concerns about the way intellectual property rights and patents are restricting poor countries from obtaining medicines needed to fight illnesses that plague the continent. Unfortunately, the 'take what you have and comply approach', that is built within TRIPS meant that developing countries, and Africa included, should avoid taking political decision that may be seen to be contrary to the interest of the developed world. In this regard, interesting examples are provided by South Africa and Brazil.

In 1997, South Africa introduced the Medicines and Related Substances Control Amendment Act Number 90. This was intended to provide a legal framework for a national drugs policy. The Act allowed the government to override patent rights in the pharmaceutical sector on public health grounds. This would have allowed the Health Minister to permit the use of parallel importing

and compulsory licensing. This legislation led to legal action against the South African government by no less than 40 pharmaceutical companies, which argued that the new law conflicted with the South African constitution and contravened WTO patent rules.

Parallel to this, Brazil introduced a patent law it considered TRIPS compliant. The law included pharmaceutical products within its scope. It required that all patent owners manufacture their patented products in Brazil or be subjected to compulsory licensing. The US questioned whether the law was TRIPS compliant and responded by placing Brazil on its Section 301 Watch list and started proceedings under WTO dispute system (although this action was later withdrawn).

Both these cases illustrate the complexity of the issues arising from the interpretation of TRIPS and both cases were triggered by attempts to introduce new laws which were supposedly TRIPS compliant. In both of them laws were challenged on the grounds that they contravened WTO patent rules and ever since these cases and similar others most African states became reluctant to review their policies to accommodate TRIPS agreement for the fear of being challenged by pharmaceutical companies or being black listed by the USA.

TRIPS and Indigenous Knowledge Systems: How this suppresses IKS

The extension of TRIPS to genetic and biological resources has raised some concerns around the protection of indigenous knowledge and communities. Africa is well endowed with the abundance and the diversity of genetic and biological resources. These, with exceptions, are in far better condition than anywhere in the world. African indigenous communities have been relying on genetic and biological resources for a variety of uses that include food, medicine, building materials and many more.

Approximately 20 000 tons of plant materials are harvested annually and sold as traditional medicines in Africa. Trading with these plants provides income for a wide range of communities and an estimated $90 million is generated annually.[5,6,7,8,9] This illustrate how valuable genetic and biological resources are to African indigenous communities.

Thus the extension of TRIPS agreement to genetic and biological resources means that discoveries that can be made either through scientific methods or consultation with indigenous societies will be protected for periods no less than 20 years. This inevitably implies that original users of such resources will be excluded from using it for a period of twenty years. Obviously, through this arrangement, there is a high possibility that valuable traditional knowledge that would be based on protected resources will be lost forever.

In fact the extension of TRIPS to genetic and biological resources underscores the concept of equitable sharing that was envisioned during the Convention on Biological Diversity (CBD). The CBD assumes that when state allows access to a sample of genetic resources, it is, in return, entitled to insist on benefits sharing. Research activities on the genetic resources (it provides access to) have to be done in its territory to build capacity. Information generated by research on the genetic resources should be repatriated. Any biotechnology applied on the genetic resource must be made accessible to the states. A fair and equitable share of benefits accruing from the use, including from commercial gains, of the genetic resources must also be given to the state.

Unfortunately, in Africa there is not even one country that has developed appropriate legislation to cover these forms of agreements. Hence, on the other hand, industrialised countries being aware of this, are continuously undertaking major expeditions to Africa thus exploiting the gap.

Concluding Remarks

There is a general consensus that prior to TRIPS there was a wide scope of interpreting and implementing intellectual property at national government levels. All this has been narrowed down through TRIPS agreement.[10]

Tracing trends of standpoints of various countries (at regional levels) during TRIPS negotiations, those of the European Union and other developed nations were quite clear while those of African states were quite obscure. The EU's stand was that of accession to multi-lateral treaties and protection of geographical indications while that of the United States of America's was the protection of copyrights in the digital environment, patents and protection of undisclosed information.

What this brings to our attention is that Africa does not only lag behind in terms of taking a stand on IP but it is also behind with the integration of IP and associated international agreements to its economies. What is clear is that positions of the

west differ very much from those of the African continent when it comes to IP protection as such Africa needs to take a solid stand on how it wishes to see IP conventions and agreements being implemented in Africa.[11]

While this could be helpful, the bleak picture of innovation in the continent as reflected by granted international patents is a great obstacle as the continent may not afford to continue relying on IP that has been produced elsewhere. As an example, in 2006 United States Patent and Trade Marks Office (USPTO) granted 173 771 patents, of these just 125 (0,07 per cent) went to inventors from Africa. Out of 125, 109 were granted to South Africans and 16 to inventors from the other 60 states. The picture in other major offices is similar. At the European Patent office there were just 63 patents granted to African applicants in 2006. Of these 59 were granted to South Africans, three from Mauritius and one from Morocco. This therefore suggest that national and regional patent offices in Africa should embark on intensive capacity building and awareness raising campaigns and African nations should enhance their role as custodians of the governance of Africa's International Property Rights.[12]

What can be concluded is that while most African states are still grappling with TRIPS, the World Intellectual Property Organisation (WIPO) has proposed a new scheme of international patents – the 'world patents'. According to this scheme, the world patents will only be conducted by the European Patent Organisation (EPO), USPTO and the Japanese Patent Office (JPO). With this arrangement it is obvious that other registration offices of WIPO member states will be forced just to recognise this 'world' patent and this will in all aspects disadvantage African countries.

For the purposes of promoting regional and continental integration African countries should try to approach TRIPS in a new different way.[13] This should promote the harmonisation of IP regimes in the region.[14] It should further enhance the purchasing powers of the regions and later facilitate local production of essential drugs.[10]

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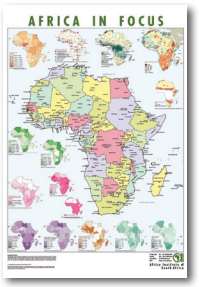

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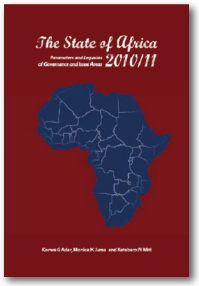

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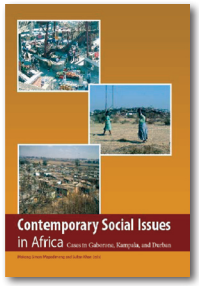

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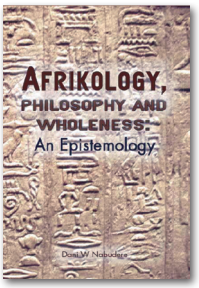

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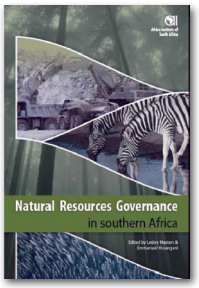

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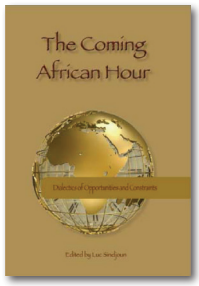

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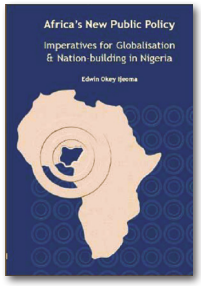

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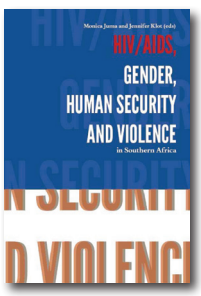

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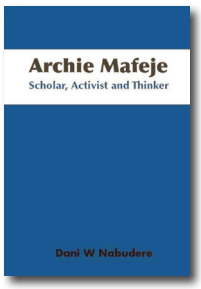

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