

## Review

# Pharmaceutical patents and access to essential medicines in sub-Saharan Africa

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**The World Trade Organisation (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has reawakened old arguments over the impact of the intellectual property (IP) system on public access to essential medicines. As used here, essential medicines are those needed in symptom management, palliative care, and in the treatment of infections, such as human immunodeficiency virus (HIV), malaria, tuberculosis, and sleeping sickness in places like sub-Saharan Africa. Some argue that patents will further inhibit access to these medicines in sub-Saharan Africa. Others, however, argue the opposite. The latter maintain that patent protection under TRIPS can promote the growth of the pharmaceutical industry in places like sub-Saharan Africa. Moreover, they assert that pharmaceutical patents are not responsible for the limited access to essential medicines in sub-Saharan Africa. Instead, they trace the problem of access to non-patent factors, such as poverty, the lack of supportive infrastructure, and poor governance. This paper set out to assess these contrasting arguments, with a view to determining the actual impact that pharmaceutical patents may be having on access to essential medicines in sub-Saharan Africa. Keyword search of electronic databases was conducted, in addition to a review of relevant literature from print sources. A manual analysis then followed. It was found that, rather than a single set of factors, both patent and non-patent factors combine to inhibit access to essential medicines in sub-Saharan Africa. It is imperative for sub-Saharan African countries to review current tariff and taxation policies, take steps to improve the supply of vital infrastructure, and strengthen their overall healthcare systems. They should also ensure that their IP systems are supportive of public healthcare needs. Equally important, is that TRIPS and the IP system should be more supportive of sub-Saharan Africa's struggle to bear its disease burden, rather than focusing narrowly on profit maximisation for pharmaceutical companies. Sub-Saharan Africa also needs increased international financing, private-public collaboration in research, and the sharing of benefits in order to cater effectively for the health needs of its citizens.**

**Key words:** Trade-related aspects of intellectual property rights (trips), essential medicines, sub-Saharan Africa, pharmaceutical, patents, access, malaria, human immunodeficiency virus/ acquired immunodeficiency syndrome (HIV/AIDS).

## INTRODUCTION

The impact of patents on the availability of essential medicines to poor people in places like sub-Saharan Africa has been the subject of protracted disagreements. Trade-related aspects of intellectual property rights (TRIPS), which became effective on January 1st 1995, have intensified such disagreements. TRIPS requires all world trade organization (WTO) members to strengthen

their intellectual property (IP) protection systems, and for those that do not already provide for IP protection in their domestic legislation to do so. Those opposed to TRIPS fear that the intensification of IP protection and in particular, patents, will exacerbate the problem of access to essential medicines in places like sub-Saharan Africa. Such fears are, however, dismissed by others who trace

the problem of access to non-patent factors. This latter group stresses that patents have, in fact, the potential to help developing countries, including those in sub-Saharan Africa, build their own pharmaceutical industry. This paper argues that both patent and non-patent factors are responsible for the problem of access to essential medicines in sub-Saharan Africa. It explains how this is so, and suggests useful measures for addressing the problem.

## INTELLECTUAL PROPERTY AND THE TRIPS

### Intellectual property (IP)

IP refers to creations of the mind, that is, intellectual creations, such as literary and artistic works, inventions and more. In order to encourage the continuous and beneficial enrichment of society with such creations, governments grant specific rights to their creators. Those rights are called intellectual property rights (IPRs), and entitle the holders to prevent others from misappropriating their creation for a specified period of time. Two main categories of IP exist: industry property and artistic and literary property. Until fairly recently, these were respectively governed by the Paris Convention (1883) and the Berne Convention (1896). Both Conventions, which have been revised several times, are administered by the Geneva-based World Intellectual Property Organisation (WIPO).

Of immediate relevance to this paper is industrial property, and specifically, that specie known as patent. A patent is an IPR granted to protect an invention. An invention is any product, process, or improvement thereof, which is new, not obvious to an ordinarily skilled person in the relevant field, and is useful to society (TRIPS Article 27). Through a patent, an inventor is able to control, for a limited period of time, who is able to use the invention and in what manner.

### TRIPS

The conclusion of the Uruguay Round of Multilateral Trade Negotiations, led to the birth of the WTO, with the signing of the Marrakesh Agreement on April 15, 1994. Part of the Agreement, Annex IC, is TRIPS. All WTO Members are automatically signatories to, and are bound

by TRIPS, which is administered by the TRIPS Council based in Geneva. Members are expected to comply with the TRIPS provisions, subject to certain exceptions, and some measure of appreciation in the mode of implementation. At present, TRIPS serves as a global reference point for WTO Members in the protection and enforcement of IPRs at national levels.

In the period before TRIPS, there were divergences among countries in the protection of IPRs. While effective protection was provided in developed countries, such as the U.S. (Lockwood, 2009), in many other countries, protection was either absent, or enforcement was lukewarm (Karapinar and Temmerman, 2008). As it was considered that this imbalance would work against the interests of the predominantly IP exporting developed countries, especially the U.S. (Kirchanski, 1994), developed countries, spearheaded by the U.S., fought frantically and succeeded in inserting TRIPS into the Marrakesh Agreement (Mellino, 2010). Article 7 of TRIPS provides for the effective protection and enforcement of IPRs globally, with a viewing to facilitating technological innovation and the diffusion of technology.

To some observers (Lucyk, 2006; Goodwin, 2008; Mellino, 2010), the real objective of TRIPS, thus, was to promote the global protection and enforcement of IPRs. That may, in fact, be true. But, as will be explained, a purposeful look at Articles 7, read conjointly with other relevant provisions, such as Article 8, 30 and 73, and based on the analyses of TRIPS provided by sources, such as the Doha Ministerial Declaration of November 2001, as well as the August 2003 Decision of the TRIPS Council, the objective of TRIPS extends well beyond the protection of IPRs. In fact, as it has been correctly described, TRIPS is only a means to an end (International Intellectual Property Research Institute, 2000). Presently, most sub-Saharan African countries are WTO Members and are, therefore, bound by TRIPS, although, as indicated below, compliance in terms of the protection of pharmaceutical patents has been deferred for sub-Saharan African countries recognised as least developing countries (LDCs).

Article 27 (1) of TRIPS requires all members to extend patent protection to any invention in all fields of technology, and for a minimum period of twenty years (Article 33). These provisions cover pharmaceutical patents, which give the holders internationally recognisable exclusive rights to produce, use, sell and import patented medicines (Article 28). These are significant new developments. The Paris Convention did not require the extension of patents to any area of technology, neither did it mandate the grant of exclusive patents, nor specify a minimum duration for such rights (International Intellectual Property Institute, 2000).

Thus, several countries, such as India, hitherto excluded pharmaceuticals from protection (Barton, 2004). In sub-Saharan Africa, Angola, Ghana and Malawi did not grant patents for pharmaceutical products before the advent of TRIPS (International Intellectual Property

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**Abbreviations:** WTO, World Trade Organization; **TRIPS**, trade-related aspects of intellectual property rights; **IP**, intellectual property; **ARVs**, antiretroviral medicines; **USTR**, United States Trade Representative; **HIV**, human immunodeficiency virus; **AIDS**, acquired immunodeficiency syndrome; **CAMR**, Canada's access to medicines regime; **CBD**, Convention on Biological Diversity.

Institute, 2000). Even those countries that granted patents did so for a comparatively shorter duration. Examples are Thailand where patents lasted for just three years. South Africa allowed only sixteen years (Williams, 2001).

Furthermore, Article 31(f) qualifies the circumstances under which Members may use compulsory licensing; a process that allows Members to “break” a patent by authorizing a third party to manufacture a patented drug, without the consent of the patent holder. All WTO members are subject to these rules. Developed countries were allowed until January 1, 1996 to bring their domestic IP laws into conformity with TRIPS, while developing countries were given until January 1, 2000 to do so (Article 65). The LDCs were given until January 1, 2006 to comply (Article 66(1)). Developing countries that did not hitherto grant patents in required areas such as pharmaceuticals as of January 1, 1995 were given an additional transition period of 5 years, that is, until January 1, 2005 to provide for protection (Article 65(4)). However, they were immediately obliged to start receiving patent applications through the establishment of a “mail box” system as provided for under Article 70(80(c)). Due to their peculiar circumstances, the Doha Declaration (Paragraph 7) extended the deadline for LDCs to provide for pharmaceutical patents in their domestic laws to January 1, 2016, with the possibility of further extensions.

Compliance with the TRIPS provisions is compulsory for all WTO Members, and is a condition for membership of the organization. This obligation is not to be viewed lightly because non-compliance is sanctionable. An erring Member could be summoned by any other aggrieved Member before a WTO dispute panel under the Dispute Settlement Understanding (DSU); a mechanism established to resolve IP and other trade disputes between WTO Members. If a complaint is upheld, the WTO could authorize an aggrieved Member to adopt retaliatory trade measures against an erring Member, which could have serious negative consequences on the latter’s domestic economy. An erring member could also suffer negative international publicity, and be perceived as an unreliable treaty partner, unsuitable for foreign investment.

## REVIEW OF THE DEBATE ON PHARMACEUTICAL PATENTS

As noted, the impact of increased IP protection on public access to essential medicines in sub-Saharan Africa has been fiercely debated. Do pharmaceutical patents inhibit access to essential medicines in that region of the world? Or is the lack of access traceable to non-patent factors? Both critics and supporters of the patent system, apparently agree that a range of non-patent factors contributes to the problem of access. One of such factor

that has been identified is the lack of effective political leadership that correctly identifies domestic healthcare needs (Donald, 1999; Attaran and Gillespie-White, 2001). Another factor is the inability of some governments in developing countries to shape negotiations at international trade fora, such as the WTO (Donald, 1999). In addition, many developing countries, including those in sub-Saharan Africa, lack effective economic systems, the technical skills necessary to operate complex medical equipment, and the spare parts needed to sustain such equipment (Donald, 1999).

In addition, the problem of access is blamed on high prices (Dutfield, 2008). This is coupled by the low purchasing power of sub-Saharan Africans, which makes local markets unattractive to potential producers and suppliers of essential medicines (Attaran and Gillespie-White, 2001). Poor infrastructure (Dutfield, 2008) and inefficient competition policies that make it difficult for rival pharmaceutical products to enter the market, as well as high import tariffs and sales taxes are also cited to as factors limiting access to essential medicines in sub-Saharan Africa (Attaran and Gillespie-White, 2001). Other factors include debt burden (International Intellectual Property Institute, 2000), the absence of personnel who are trained in the use and dissemination of essential medicines in local communities (Kessel and Chattopadhy, 1999; Dutfield, 2008), and the distant location of the few available medical facilities (Mellino, 2010).

Despite the broad consensus on the role of non-patent factors in inhibiting access to essential medicines in places like sub-Saharan Africa, views get polarised when it comes to ascertaining what role pharmaceutical patents play in that regard. For example, Donald (1999) argues that, apart from non-patent factors, the broadening and intensification of IP protection under TRIPS, and particularly patents, would place further limitation on access to essential medicines in poor countries like those in sub-Saharan Africa. Specifically, it would prevent competition, especially from generics, stifle innovation, and intensify the misappropriation of the genetic resources of indigenous communities. This would result in an overall increase in the prices of pharmaceutical products. These views are shared by Williams (2001) who argues, in addition, that the vagueness of some TRIPS provisions, for instance, Article 31 (to be discussed), and the uncertainty stemming from this, would expose poor countries to expensive litigation and dispute settlement procedures, which could delay treatment and further divert their meagre resources away from pressing healthcare needs.

But presenting the flip side to the debate are those who argue, equally strongly, that pharmaceutical patents do not really deny people in poor countries access to essential medicines. For example, the former Chairman of GlaxoSmithKline, Sir Richard Sykes (2002), insists that pharmaceutical patents do not prevent developing countries from accessing the medicines they need. Instead, patent protection helps those developing countries that

have the necessary technological capacity to establish their own pharmaceutical industry. Proponents of this view also maintain that patents are not usually sought in small and technologically-disadvantaged developing countries, such as those in sub-Saharan Africa. Even when patents are sought, they do not affect costs or access.

A study on patenting trends in antiretroviral (ARV) medicines in 53 African countries, which was conducted between October, 2000 and March, 2001, seemingly validate the claim that patents are not the cause of the problem of access. That study (Attaran and Gillespie-White, 2001), examined how many patents existed in 53 African countries, including those in sub-Saharan Africa, for 15 ARVs belonging to eight pharmaceutical patent holders. It was found that most of the ARVs were patented in only a few African countries. The only exception was South Africa, where there were patents for 13 out of the 15 ARVs.

Another study on the same issue by the International Intellectual Property Institute (2000) similarly concluded that the problem of access is not caused by pharmaceutical patents. The study concluded that the major factor inhibiting access was inadequate government and private sector finances, essential to the proper functioning of the general healthcare system. This analytical stalemate on the impact of pharmaceutical patents on access to essential medicines in sub-Saharan Africa provides the impetus for the present paper. The objective is to carefully assess these contrasting arguments, in order to foster a clearer understanding of the complex interaction between both phenomena, and identify specific steps that need to be taken at both national and international levels based on such insight.

## ANALYSING THE ARGUMENTS

### The role of non-patent factors

It is appropriate to acknowledge that a myriad of factors unrelated to the IP system, play a crucial role in determining access to essential medicines in places like sub-Saharan Africa (Anna, 1999; Attaran and Lee, 2001). Also, it is useful, for the purposes of completeness, to develop, in slightly greater detail, some of the more important initial impressions given by the above authors on those factors. However, one important non-patent factor militating against access to essential medicines in sub-Saharan Africa not mentioned by the authors must first be noted. This relates to the often misleading social beliefs held in some parts of that region. For instance, South Africa, which accounts for the highest level of HIV/AIDS cases on the continent. Long after the onset of the pandemic in that country, its former President, Thabo Mbeki, repeatedly denied the link between HIV and AIDS, until mounting international pressure forced him to rethink

his position. Manito Tshabalala, who was Health Minister at the time, also described ARVs as dangerous and advocated beetroot, lemons, garlic and African potatoes as a cure for AIDS (Shah, 2009). Tshabalala apparently supported one Mathias Rath, a vitamin dealer, who vigorously campaigned against ARVs, condemning them as poisonous. Rath claimed that the use of multivitamins decreased the risk of HIV by 50%, purportedly relying on a study by Harvard School of Public Health researchers, which he had interpreted incorrectly (Shah, 2009).

The Harvard study suggested that the number of patients on vitamins who were seriously ill or dead (25%) was lower than those on placebo (31%). But, while this result suggests that the use of vitamins may slow down the development of HIV into AIDS, it in no way undermines the visibly positive effect of ARVs. In fact, the Harvard researchers were so alarmed by Rath's misinterpretation of their findings that they issued a rejoinder denouncing him and acknowledging the importance of medication (Shah, 2009). This account spectacularly illustrates how social or cultural beliefs and taboos could deny or delay access to essential medicines to those who need them in sub-Saharan Africa.

Partly evident from the above, is the lack of political will, which contributes to the denial of access to essential medicines (Donald, 1999). The failure of political leadership is typical of much of Africa. The result of this is the absence of decisive actions to identify and champion public healthcare needs. There are, however, a few instructive exceptions. In Senegal, for example, the existence of strong political will was instrumental to the early identification of the HIV/AIDS problem; the mobilisation of financial resources, the use of mass media to countervail cultural and religious taboos, the promotion of the use of condom, and the provision of universal access to ARV treatment. The enviable outcome was that at the end of the 1990s, Senegal recorded one of the lowest rates of HIV infection in sub-Saharan Africa (UNAIDS, 1999).

But there are other factors, which may impede access to essential medicines that are beyond the control of governments in sub-Saharan Africa. Countries in that region of the world are entrapped in an international political-economic structure that controls the flow of vital goods and services, including the costs at which they may be accessed. They have so far not been able to influence that structure in any significant manner. The circumstances surrounding their ascension into the WTO, exemplifies the vulnerable situation in which sub-Saharan African countries find themselves.

Developing countries, especially those in sub-Saharan Africa, accepted the WTO agreements, including TRIPS, not because they were genuinely convinced about their benefits. Instead, it was because they faced the unwellcome alternative of being denied access to the lucrative Western market for agriculture and textiles that was promised in return for their acceptance of the agreements, these promise remains essentially unfulfilled to

date (Gerhart, 2000). For sub-Saharan African countries, this weak position means that the availability and costs of essential pharmaceutical products are unfavourable to universal access.

Owing to a combination of poor leadership and a lopsided international political-economic structure, people in sub-Saharan Africa have persistently contended with poverty, which limits their ability to afford even the barest essential healthcare needs (Simms et al., 2001; Bird and Cahoy, 2008). For example, 28 of 48 African countries had an average per capita income of less than \$1 per day in 1999 compared to 19 of 36 countries in 1981 (UNICEF, 2001). In addition, most sub-Saharan African countries spend less than an average of US\$ 10 per person per year on healthcare, which is 20 to 40% below the World Bank's advocated minimum level of healthcare services (Simms et al., 2001; Sanders, 2009).

But the IMF and the World Bank structural adjustment programmes that were imposed on African governments in the 1980s increased the level of poverty on the continent and further limited the ability of people to obtain essential medicines. This exposed them helplessly to deadly diseases, such as HIV/AIDS, tuberculosis and malaria (Medact and World Development Movement, 1999). In the 1960s and 1970s, many African countries made major improvements in their healthcare systems, which had neglected the interest of a sound majority of the people during the colonial era (Bremner and Shelton, 2001). Primary healthcare was extended to a lot more people. However, all this unraveled as a result of the economic crises of the 1980s, many African countries were forced to seek assistance from the IMF and the World Bank. Both institutions subjected them to harsh loan "conditionalities" and destructive structural adjustment programmes (Bremner and Shelton, 2001).

By 1997, sub-Saharan African countries were already remitting to Western creditors more than four times the amount invested in their domestic healthcare systems. In 1998, Senegal alone reportedly spent more than five times the amount spent on health in loan repayments (Colgan, 2002). As of 2000, Africa's total debt was US \$230 billion, with annual repayments of US 15 billion, amounting to approximately 5% of its income (International Intellectual Property Institute, 2000). This financial squeeze disrupted African healthcare systems, and made people increasingly vulnerable to diseases. The situation worsened with the privatisation of healthcare advocated by the World Bank, which led to the commercialisation of health services, thus denying ever more people access to essential healthcare (Colgan, 2002).

The recent global financial crisis did not help matters either, as it forced governments to cut down on their already meagre health budgets, despite the spate of infection from major diseases such as HIV/AIDS, tuberculosis, malaria and sleeping sickness. The global financial crisis also undermined the activities of international donor agencies. In 2009, the global fund for AIDS,

TB and Malaria reported a US\$ 4 billion shortfall in what it needed to sustain the funding of essential services for these illnesses in 2010. That was in addition to a US\$ 10.7 billion funding deficit for the execution of the Global Plan to Stop TB at regional levels (Colgan, 2002).

Another factor impeding access to essential medicines in sub-Saharan Africa is poor international media coverage of diseases that more commonly afflict people in that region. In the 1990s, HIV/AIDS in sub-Saharan Africa gained international limelight only when it became perceived as a threat to U.S. national security (Gellman, 2000). But as fears dissipated in the U.S. and other parts of the Western world, media attention correspondingly waned. The absence of international media coverage could prevent or delay the mobilisation of the resources needed to ensure a timely and steady stream of medicines to help sick people in sub-Saharan Africa (Gellman, 2000).

Finally, the "brain drain" of qualified medical personnel from sub-Saharan Africa to overseas countries (Novak, 2003; Coombes, 2005), the lack of effective infrastructure and healthcare delivery systems (Attaran and Gillespie-White, 2001), and high import tariffs (Médecins Sans Frontières and Health Action International, 2000), which, in some cases, could be as high as 30% (International Intellectual Property Institute, 2000) all contribute to the problem of access to essential medicines in sub-Saharan Africa.

Unarguably, therefore, non-patent factors play a role in denying access to essential medicines in sub-Saharan Africa. In other words, even amid the absence of pharmaceutical patents, many people in sub-Saharan Africa may still not gain access to essential medicines due to a combination of non-patent factors, as discussed above. But, as will be shown below, this does not mean that pharmaceutical patents have no impact at all on access to essential medicines in sub-Saharan Africa.

### **The role of pharmaceutical patents**

Before examining the role pharmaceutical patents play in determining access to essential medicines in sub-Saharan Africa, the philosophical justification for the patent system is worth considering. The often given rationale of the patent system is rooted in the Lockean idea that a person who labours upon resources that are either unowned or "held in common" has a natural property right to the fruits of his or her labour, and that the State has a duty to respect and enforce that right (Hughes, 1998; Laslett, 1970). In *Anarchy, State and Utopia*, Robert (Nozick, 1974) identifies with this Lockean perspective. But Locke also points out that the acquisition of property right is legitimate only if after such acquisition, there are still enough common good left for others. Nozick explains that correctly read, this proviso means that, the acquisition of property right is legitimate only if

others are not thereby hurt or left in a condition worse than would have existed if the State did not grant that right (Nozick, 1974).

Nozick (1974) reported the grant of a patent does not breach the Lockean proviso because, although public access to the invention is necessarily restricted, it would not have existed in the first place without the inventor's effort. In other words, the patent benefits, rather than harms the public. Thus, the grant of a patent is doubly important both as a reward for the inventor's labour, and as an incentive for more inventions that are beneficial to the public. This exposition helps to explain the objectives that underpin pharmaceutical patents.

In the pharmaceutical industry, R and D costs are high, just as is the risk of failure (Angell, 2004; Dutfield, 2008). Without patents, inventors may find it challenging to recoup their costs and generate profit (Angell, 2004). And they are unlikely to be motivated to research into more new medicines (Bird and Cahoy, 2008). This result would be detrimental to society as a whole. Thus, the monopoly rights embedded in patents enable pharmaceutical companies to recover research costs and post profit. Thus, it is believed that patenting would encourage them to embark on further research, in order to produce new medicines for the benefit of society (Commission on Intellectual Property Rights Report, 2002; Lockwood, 2009).

Nevertheless, it remains an important question whether, given their small markets and weak purchasing power, pharmaceutical patents do incentivize research into medicines for the treatment of diseases that are prevalent in sub-Saharan Africa. The evidence suggests otherwise. It has been estimated that on average, pharmaceutical companies require a minimum guaranteed profit of about \$1 billion to induce them to assume the risk of researching into any particular disease (Commission on Intellectual Property Rights Report, 2002). As such, pharmaceutical patents provide only a limited incentive for pharmaceutical companies to research into diseases associated with people in developing parts of the world, especially sub-Saharan Africa, given their low purchasing power (Commission on Intellectual Property Rights Report, 2002; Dutfield, 2008). As an illustration, the amount of global research spending devoted to diseases affecting the developing world is under 5% (Commission on Intellectual Property Rights Report, 2002).

And out of the 1393 medicines approved from 1975 to 1999, only 13 related to diseases that also affect sub-Saharan Africa (Commission on Intellectual Property Rights Report, 2002). Also, there is hardly any research on malaria, TB and sleeping sickness (Commission on Intellectual Property Rights Report, 2002). On the other hand, as of 2002 in the U.S. alone, there were 64 approved medicines for the treatment of HIV/AIDS, and 103 in progress, because this disease equally affects the developed world (Commission on Intellectual Property Rights Report, 2002).

A study conducted in 2005, ten years after TRIPS, found that the level of research on diseases affecting people in poor parts of the world remained largely low in relation to the overall level of pharmaceutical research (Lanjouw, 2005). For example, the amount of research money committed to those diseases fell from 16% in 1998 to 10%, with more emphasis being placed on global products for the European and American markets. The study also found that, in certain cases, pharmaceutical companies were reluctant to introduce new medicines in low and middle income countries because it was not lucrative to do so due to their weak purchasing power. Although, there has been an increase in innovative activities on tropical diseases in recent years, the major diseases plaguing sub-Saharan African countries are still generally neglected (Council on Health Research for Development and New Partnership for Africa's Development, 2009).

Moreover, if patents are meant to induce new research, then the fact that only few patents are claimed in sub-Saharan Africa, as Attaran and Gillespie-White (2001) suggested that there is no reason to expect new research into diseases that commonly affect people in this part of the world. Since, their study took place in 2000/2001, it is not clear to what extent that their study correctly depicts the situation well after the implementation of TRIPS. A new study, as discussed below, is evidently required to demonstrate current patenting trends in ARVs in sub-Saharan Africa. In any case, as both authors acknowledge, their findings do not conclusively resolve the core question of whether pharmaceutical patents do inhibit access to essential medicines in sub-Saharan Africa. In fact, they stress that it would be wrong to interpret their findings, suggesting that pharmaceutical patents never impede access to essential medicines in sub-Saharan Africa.

The Attaran and Gillespie-White (2001) study was reviewed fairly recently. Deiss (2007) examined developments in pharmaceutical patenting since Attaran and Gillespie-White published their findings. Deiss found a significantly higher number of patents in sub-Saharan African countries that are either members of ARIPO or OAPI, compared to those that do not belong to any of these organisations. ARIPO (African Regional Intellectual Property Organisation) is an African regional intellectual property protection organisation, which has mainly English-speaking members. OAPI (Organisation Africaine de la Propriété Intellectuelle) is the French equivalent, with mainly French-speaking members. Most of the members of these organisations also belong to the WTO. Deiss' study found that there was a positive relationship between HIV infection levels and the number of existing patents, which is explained by membership in an intellectual property organization, ARIPO or OAPI. Also, the average number of patents in ARIPO countries (6.4), as well as in OAPI countries (3.5), was higher than the average number (1.1 to 1.7) in sub-Saharan African countries that did not belong to any of those organisations. These new-

er findings place a caveat against those of the Attaran and Gillespie-White study.

But, even if collectively, patenting rates were still to be low in sub-Saharan Africa, why this is so, warrants some curiosity. While such a scenario might suggest altruism on the part of pharmaceutical companies, it could, alternatively and more tenably, be construed as the result of shrewd economics (Commission on Intellectual Property Rights Report, 2002). Since sub-Saharan Africa has a weak technological capacity, the risk of patent infringement is potentially low. Moreover, given that markets are small, companies might consider patenting imprudent, in view of the high cost of patent acquisition and enforcement (Attaran and Gillespie-White, 2001).

Based on this logic, it is unsurprising that the only sub-Saharan African country where patenting was very high, based on Attaran and Gillespie-White (2001), was South Africa, which has the highest rate of Africa's HIV cases. There, 13 of the available 15 ARVs were under patent. The inescapable explanation for the high patenting rate is that South Africa has a bigger and more profitable market. Moreover, it has a higher technological capacity and, therefore, presents a higher level of infringement risk (Commission on Intellectual Property Rights Report, 2002). The protracted legal challenge mounted against South Africa's attempt to procure cheap HIV/AIDS medicines in the late 1990s, lends further credence to this alternative interpretation. In 1997, former President Nelson Mandela signed the Medicines and Related Substances Control Amendment Act No. 90. This was meant to boost the availability of cheap HIV/AIDS medicines through compulsory licensing and parallel importation of medicines that were then under patent in the country.

Undoubtedly, HIV/AIDS is of national emergency, and, as will become clearer later on, the adopted measures were TRIPS-compatible. Despite this, the South African Pharmaceutical Manufacturers' Association, including international pharmaceutical companies from Europe and America, sued the South African Government. They alleged that the 1997 Act violated TRIPS. South Africa also came under pressure from the U.S. Government to repeal the Act, and was placed on a Watch List under the Section 301 Special Report of the United States Trade Representative (USTR), pursuant to the Trade Act of 1974 (Bond, 1999; Doctors Without Borders, 2001; Lucyk, 2006).

Nevertheless, the South African Government refused to yield to these pressures, and with the support of civil society groups, the pharmaceutical companies and the U.S. Government eventually capitulated (Hong, 2000; Mellino, 2010). But this was only after about 400,000 South Africans had reportedly succumbed to HIV/AIDS (Kasper, 2001). And despite the U.S. retreat and the withdrawal of the law suit by the pharmaceutical companies, South Africa was required, as part of the deal that resolved the stalemate, to guarantee that it would recognise IPRs and comply with TRIPS. Ultimately, the

1997 legislation was never implemented (Lucyk, 2006; Mellino, 2010). This event vividly demonstrates how pharmaceutical patents deny people in sub-Saharan Africa access to essential medicines.

Profit maximisation is not the end of pharmaceutical patents. Rather, patents serve only as a means to an end; that end being to enrich society with medicines that are essential to its survival. Failing this, the profits reaped by pharmaceutical companies are unjustifiable. And in line with the Lockean proviso, the patents granted are illegitimate, and, as seen in this case, may be undermined, even under TRIPS.

### **The Doha declaration**

Provisions on parallel importation (Article 6) and compulsory licensing (Article 31) are enshrined in TRIPS. Regrettably, some members failed to interpret and implement TRIPS in a manner supportive of public health. They tended to prioritize the protection of IPRs, to the neglect of health concerns, especially of developing countries, including sub-Saharan Africa (Reichman, 2009; Mellino, 2010). The South African case is one example of how developed countries and pharmaceutical companies exert undue pressure on weaker countries that seek to exploit the TRIPS flexibilities in order to meet their healthcare requirements.

That unsatisfactory state of affairs was strongly criticized by civil society groups, notably Médecins Sans Frontières (MSF) and Oxfam, which clamoured for the supremacy of the human right of access to essential medicines over IPRs. This and other pressures ultimately led to the Doha (WTO) Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001 (Sun, 2004). Paragraph 5(b) of the Declaration reiterates Members' right to grant compulsory licences, as well as the right to determine the grounds for doing so. Paragraph 5(c) emphasizes on members' right to determine what constitutes a national emergency, or other circumstances of extreme urgency, such as, but not limited to HIV/AIDS, malaria and TB. In a nutshell, the Doha declaration sought to assure that TRIPS was responsive to the healthcare needs of developing countries and to highlight how they could deploy its flexibilities toward that end (Sun, 2004). But despite that Declaration, uncertainties remained, especially with regard to developing countries that lack the manufacturing capacity needed to exploit the right to grant compulsory licences.

Even if a developing country granted such a licence, there was no domestic manufacturing capacity to put it into use. And 31(f) of TRIPS limits the supply of medicines produced under a compulsory licence predominantly to the domestic market of the WTO member granting the licence. In other words, the medicines must be produced within the territory of the member granting the compulsory licence. This qualification posed further practical difficulties for most governments in sub-Saharan

Africa, and in other similarly placed developing countries, where the infrastructure needed to support the manufacturing process is non-existent (Kohr, 2002; Abbott, 2005; Reichman, 2009; Mellino, 2010).

Although, members with large markets and appropriate technological capacity, such as Brazil, India, and China could issue compulsory licences to manufacture patented medicines in response to domestic healthcare requirements, they could not supply medicines produced under such a license to other developing member countries, which lack productive capacity. This is because supply must be predominantly to their domestic markets (Correa, 2002). Again, even if a sub-Saharan African country lacking manufacturing facilities chose to issue a compulsory licence say to Brazil or India, it would still be trapped by the Article 31(f) dilemma because either country could only supply the medicines produced under that licence predominantly to its domestic market (Mellino, 2010). Before 2005, when they became obliged to implement TRIPS, developing countries, such as India, which did not grant pharmaceutical patents, could produce cheap generic versions of patented medicines for their domestic markets and for other developing countries, including those in sub-Saharan Africa. However, that alternative ceased to be available after 2005 (Scherer and Watal, 2002; Shashikant, 2005).

### **Post Doha - The August 2003 decision**

The difficulties explained above made the problem associated with the Article 31(f) provision more critical. Consequently, the matter was referred back to the TRIPS Council for further consideration. That led to the clarification provided in the August 30, 2003 decision. That decision provides that under certain conditions, the requirement to supply predominantly to the domestic market contained in Article 31(f) may be waived. Under paragraph 2 of the decision, a member desirous of importing pharmaceutical products must notify the TRIPS council, stating the names and intended quantities of the products. It must also confirm, if the products are patented in its territory, and that it has issued, or intends to issue a compulsory licence under TRIPS Article 31. Prospective importing Members, not being LDCs must, in addition, confirm that they lack sufficient manufacturing capacity. The exporting Member can only manufacture quantities necessary to meet the needs of the importing Member as notified to the TRIPS council. And it must ship all the quantities so manufactured to that importing member.

Also, the products must be clearly labeled or marked, and if possible, packaged in such a manner as to identify them as having been produced under the system provided for in this decision. The exporting member must pay adequate compensation to the patent holder. The TRIPS council will then grant a waiver of the Article 31(f)

requirement to the exporting member (Weber and Mills, 2010; Mellino, 2010). The 2003 decision was subsequently adopted by the TRIPS general council as an amendment to TRIPS in December, 2005. It would be integrated into TRIPS after ratification by two-thirds of WTO members (Mellino, 2010).

The EU and several other members such as Canada, Switzerland, Norway, India and China have implemented the 2003 decision through domestic legislation (Weber and Mills, 2010). But, despite this, as of September 2008, only Canada had used the August 2003 system to supply essential generic ARV medicines to Rwanda (Raja, 2010; Weber and Mills, 2010). And less than twelve members had used it to manufacture essential medicines for their domestic use (Weber and Mills, 2010). This situation has been attributed to the complexities associated with the practical operation of the system under the August 2003 decision. This is exemplified by the Canada's Access to Medicines Regime (CAMR). The CAMR specifies the conditions that prospective importing LDCs must meet. Some of the problems associated with the 2003 system, as well as the CAMR, include confusing legal technicalities, the failure of LDCs to understand how to go about the process of obtaining an import licence, the costs and time involved in trying to get a voluntary licence, or to renew a compulsory one (Apotex, 2009; Cohen-Kohler et al., 2006; Goodwin, 2008).

The more significant factor, however, is the general reluctance of both importing and exporting members to utilize the system due to fears of reprisals from strategic trading partners and pharmaceutical companies (Weber and Mills, 2010). The office of the USTR and international pharmaceutical companies has continued to pressurize and dissuade members from invoking compulsory licences. For example, Abbott laboratories held back the launching of several new medicines in Thailand when the latter invoked a compulsory licence to produce an HIV/AIDS medicine that was under Abbott's patent (Wong-Anan, 2008).

The U.S. Government also included Thailand on its Watch List under the Special Section 301 Report of the USTR because it issued compulsory licenses for several medicines used to treat cancer and HIV/AIDS (Evans, 2008; Weber and Mills, 2010). Being named on the "Watch List" exposes a country to U.S. trade sanctions. This discourages members from exploiting the TRIPS flexibilities (Evans, 2008; Weber and Mills, 2010). This is so even though the U.S. uses the compulsory licence flexibility to meet its own healthcare needs. In 2001, it issued a compulsory license for the production of ciprofloxacin, which was under Bayer's patent, as a protective measure against Anthrax attack (Love, 2005; Mellino, 2010).

The U.S. also pressurizes developing countries through Free trade agreements (FTAs) to adopt "TRIPS-plus" standards. That means standards that are higher than the TRIPS minimum IP protection requirements

(Smith et al., 2009). This ignores the fact that TRIPS Article 1 provides that members are under no such obligation. These pressures, and the practical problems associated with TRIPS hinder access to cheap and affordable medicines. The view, therefore, that TRIPS and pharmaceutical patents do not hinder access to essential medicines in sub-Saharan Africa, especially given the in-built flexibilities, remains far-fetched. As can be seen, the exploitation of those flexibilities has proven to be problematic, both as a practical matter, and in strategic terms.

Returning to Richard Sykes' earlier argument that pharmaceutical patents will enable developing countries with the relevant technological capacity to establish their own pharmaceutical industry that is not entirely convincing. Although, that argument may hold true for specific developing countries such as Brazil, India, China and South Africa, most developing countries, especially those in sub-Saharan Africa, lack the needed technological expertise, and financial resources to set up their own pharmaceutical industry. Thus, patent protection is unlikely to be of any significant benefit to them in this regard (Commission on Intellectual Property Rights Report, 2002).

Another way in which TRIPS impedes access to essential medicines in sub-Saharan Africa lies in the expansion of patent lifespan for pharmaceuticals to twenty years. This prolongation favours pharmaceutical companies, which can continue to charge monopoly prices (Geradin et al., 2008). At the same time, it delays the production of cheap off-patent equivalents on which poor people in sub-Saharan Africa depend (Commission on Intellectual Property Rights Report, 2002).

Access to essential medicines depends partly on the ability of people in sub-Saharan Africa to pay for them (Commission on Intellectual Property Rights Report, 2002; Bird and Cahoy, 2008). In some developing countries that have strong pharmaceutical industries, prices rose with the introduction of patents (Fink, 2000; Watal, 2002). Unlike developed countries where governments or insurance companies bear a large proportion of the cost of treatment, people in sub-Saharan Africa are individually responsible for their own treatment, given limited public healthcare services caused by scarce resources (Mellino, 2010). Sub-Saharan Africa accounts for only 1% of global health expenditure, and despite being home to approximately 67% of worldwide HIV/AIDS patients (AVERT, 2008), only one-third of those in need of ARVs are able to access them (Palitza, 2009). Moreover, health insurance schemes are hardly effective in sub-Saharan Africa because most people are engaged in the informal sector (Shah, 2009). Only about 10.3% of the people there are covered by health insurance, and individual spending accounts for 80% of total healthcare expenditures in some countries (International Intellectual Property Institute, 2000).

A related problem is that pharmaceutical companies

charge prices that do not take account of differences in purchasing power. The result is that often, poor consumers, such as those in sub-Saharan Africa, pay prices that are higher than those paid by consumers in developed countries, such as the U.S (Scherer and Watal, 2002). Although the threat of compulsory licensing could promote competition, and force prices to fall, this option is bedevilled by numerous obstacles, including, as explained, international pressures, and sub-Saharan Africa's generally weak finances and manufacturing capacity (Commission on Intellectual Property Rights Report, 2002; Dutfield, 2008).

Even if there were a local manufacturer with the relevant technical expertise and finances to produce a patented medicine under compulsory licensing, the small markets in sub-Saharan Africa do not offer the critical mass essential to profit maximisation at reduced prices (Commission on Intellectual Property Rights Report, 2002). Added to these challenges are the difficulties involved in the replication of original medicines, and the problems of lengthy lead times and delays in the production and supply of medicines to those in urgent need of them (Commission on Intellectual Property Rights Report, 2002).

Finally, pharmaceutical patents restrict access to essential medicines by encouraging biopiracy in biologically-rich developing countries, including those in sub-Saharan Africa. They enable pharmaceutical companies to pirate medicinal plants and other genetic materials from resource-rich developing countries, which are subsequently used to produce patented medicines. While patented medicines are expensive and unaffordable to the indigenous communities that own the biological resources used in producing them, biopiracy further deprives them of the traditional medicines that serve as alternative means of meeting their healthcare requirements.

The Convention on Biological Diversity (CBD) was adopted in 1992, as well as the Nagoya Protocol in 2010, to tackle the problem of biopiracy. These instruments aim to ensure that access to the genetic resources and traditional knowledge of indigenous communities, mostly in developing countries, is based on the prior informed consent of those communities. They also seek to promote the equitable sharing of biomedical research benefits, including access to treatment, with those communities. Yet, some key WTO members, mainly developed countries, have opposed both instruments on the grounds that they undermine IPRs, and are, therefore, TRIPS-incompatible. Others that have not expressed direct objections to the instruments pay only lip service to them.

In April 2011, WHO members adopted an agreement on the sharing of influenza viruses as a flu pandemic response measure. But the preceding negotiations were, once again, overshadowed by disagreements over IPRs. Developing countries, such as Indonesia, supplied flu

samples, part of their genetic resources, to the WTO, which, in turn, made them available to developed countries and their pharmaceutical companies. But while developing countries continued to suffer high casualties from the H5N1 virus, the pharmaceutical companies were busy patenting the viruses and the vaccines made from them, which were sold at costs unaffordable to developing countries (IP Watch, 2011). That led to protestations from developing countries. In the final agreement that was reached recently, pharmaceutical companies offered to pay 50% of the costs of administering the global influenza monitoring scheme and to supply 10% of vaccines and ARVs to developing countries. It is not yet clear how effectively these promises would be fulfilled. Concerns have also been expressed that these commitments are far too insignificant in meeting the needs of developing countries that account for 80% of the global population (Third World Network, 2011).

As has been commented, the real objective of TRIPS may be to protect IPRs, and numerous practical and other difficulties may, indeed, be associated with that agreement. Still, Sub-Saharan African countries should remember that TRIPS allows them the flexibility to formulate or modify their domestic IP legislation, and to take measures necessary to protect public health. Article 7, which sets out the TRIPS objectives, adds that the protection and enforcement of IPRs should promote the mutual benefit of producers and users of IP, and in a manner that enhances social and economic welfare. This provision aims to balance rights and responsibilities, and clearly acknowledges that IP protection is only a means to an end, not an end in itself (International Intellectual Property Research Institute, 2000).

Article 8(1) also provides that in making their domestic laws, members may take measures necessary to protect public health and nutrition and promote the public interest in sectors of vital importance to their socio-economic and technological development, so long as those measures are TRIPS-compliant. Under Article 8(2), members have the right to apply their domestic legislation to prevent IPRs from being exercised in ways that conflict with their healthcare requirements (Correa, 2002; Weber and Mills, 2010). These provisions further envisage striking a balance between IP protection and the wider societal interest (International Intellectual Property Research Institute, 2000). Moreover, under Article 73, members are free to adopt any measure they consider necessary for the protection of their essential security interests, or in response to other emergency. In these instances, members can even take actions that undermine TRIPS (International Intellectual Property Research Institute, 2000).

Also, paragraph 5(c) of the Doha declaration grants Members the right to determine what constitutes a national emergency, or other circumstances of extreme urgency. These rights are relevant to the use of compul-

sory licences, or the adoption of other measures under Article 8(1) (Correa, 2002). Sub-Saharan African countries should retain the right to issue compulsory licences and to admit parallel imports in their domestic legislation. Parallel importation would enable them to buy patented medicines, without the patent holder's approval or interference, from a market which offers a price that is lower than the one charged by the patent holder. This is based on the "exhaustion" principle, which means that having once put the goods on the market; the patent holder can no longer interfere with their movement (Junaid, 2006; Mellino, 2010).

In addition, Article 6 of TRIPS, which was reaffirmed in paragraph 5(c) of the Doha declaration, allows members to independently determine the point at which the exhaustion of the patent holder's right occurs (Commission on Intellectual Property Rights Report, 2002; Correa, 2002). Under Article 6, matters relating to the exhaustion of IPRs are not subject to the WTO dispute settlement mechanism. No complaint can, for example, be brought against a member that adopts an international exhaustion principle in its domestic patent law, and permits the parallel importation of medicines (International Intellectual Property Institute, 2000).

Pursuant to Article 30, sub-Saharan African countries can derogate from exclusive patent rights granted under Article 28 insofar as this does not unreasonably interfere with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent holder. In *EC v Canada* (2000), the WTO dispute settlement panel agreed that a member could rely on the Article 30 provision (otherwise called the "Bolar" exception) to authorize the production of patented medicines for the purposes of pre-marketing testing. However, the exception did not extend to production for commercial use or stockpiling.

In that case, the dispute settlement panel found that the aspect of Canada's law, which allowed production for pre-marketing testing, was consistent with Article 30, but that aspect, which allowed for stockpiling amounted to a violation. Worthy of note is the Panel's observation that while the limits and objectives in Articles 7 and 8(1) need be borne in mind, the exceptions to patent rights permitted in Article 30 under certain circumstances, are pointers to the malleability of the exclusivity of patent rights provided under Article 28. The Article 30 exception to the rights of patent holders allows producers of generics to carry out experimental tests while a patent is still valid, in order to be able to apply for and obtain necessary regulatory approvals. They can then produce and sell the generic medicines immediately the patent expires, without undue delay (International Intellectual Property Institute, 2000).

Retaining the rights of compulsory licensing and parallel importation will also be useful in pursuing systematic differential pricing by pressurizing pharmaceutical companies to cooperate with such a scheme. But sub-

Saharan African governments need to ensure that medicines obtained under differential pricing schemes do not slip back onto the higher priced markets of developed countries (Commission on Intellectual Property Rights Report, 2002). It should be noted, however, that in order to utilise the TRIPS flexibilities, sub-Saharan African countries must incorporate the relevant provisions, for example, on compulsory licensing, parallel importation, in their domestic laws. This is because the flexibilities do not automatically become part of Members' domestic laws. Therefore, in the absence of such incorporation, a Member may not be able to protect itself against legal challenges (Correa, 2002).

Governments in sub-Saharan Africa should equally give careful consideration to the compensation payable to the patent holder under Article 31 (g) when invoking a compulsory licence. The compensation rate should be compatible with the primary goal of providing universal access to cheap medicines (Correa, 2002; Love, 2005). Sub-Saharan African countries that qualify as LDCs should recognise that following the Doha Declaration, they can enjoy an extension of the transitional period granted under Article 66.1 of TRIPS. And although Paragraph 7 of the Doha Declaration relates to the extension of the transitional period specifically for pharmaceutical patents, the declaration also gives them the right to claim extensions for other non-pharmaceutical matters under Article 66.1 (Commission on Intellectual Property Rights Report, 2002; Correa, 2002). In addition, they can claim more extensions even for pharmaceutical patents after the expiry of the initial extension in 2016 (Commission on Intellectual Property Rights Report, 2002; Correa, 2002).

It is particularly astonishing that some LDCs had gone ahead to implement TRIPS in their domestic laws, even before the expiration of the transitional period they were granted (International Intellectual Property Institute, 2000). Sub-Saharan African LDCs that have already granted patents for pharmaceutical products should amend their domestic laws and withdraw such patents, since they are not required to do so until at least, 2016 (Commission on Intellectual Property Rights Report, 2002; Correa, 2002).

By tailoring their IP systems to meet their domestic needs, sub-Saharan African countries will not be doing anything new under the sun. In the 19th century, developed countries similarly used their IP systems to advance their national interests. For example, the U.S., then a net consumer of IP, granted patent rights only to its citizens and residents, and when patents were granted to foreigners, they were charged about ten times the domestic fee (Commission on Intellectual Property Rights Report, 2002). Some European countries, such as Switzerland, were also reluctant to grant patents so that their citizens could continue to use the inventions of foreign competitors (Commission on Intellectual Property Rights Report, 2002).

More recently, East Asian countries, such as Taiwan

and South Korea, also applied only weak IP protection standards that suited their domestic conditions and levels of development (Commission on Intellectual Property Rights Report, 2002).

Sub-Saharan African countries should also endeavor to reconcile their TRIPS commitments with the rights granted under other international instruments, for example, Article 25 of the Universal Declaration of Human Rights (1948), which recognizes the right to medical care. Stricter standards for granting patents should be imposed and stringent measures taken to curb biopiracy incidents. In this regard, they should incorporate the provisions of the CBD and the Nagoya Protocol into their domestic laws, and try to utilize them as effectively as possible. They should also seek to strengthen the effectiveness of the implementation of both instruments internationally, using the platform of the Conference of the Parties acting as a Meeting of the Parties (COP/MOP). But in addition to these measures, sub-Saharan African countries must try to improve their healthcare systems, provide necessary infrastructure and review current tariff and taxation policies.

Of course, the cooperation of developed countries is required. They should amend their domestic laws in order to facilitate the waiver of the Article 31(f) provision, and be able to supply essential medicines to sub-Saharan Africa (Correa, 2002). Based on the lessons learnt from the Canadian CAMR, the formulation of domestic laws should not be so cumbersome as to discourage the meaningful use of the system provided for in the August 2003 decision. It is equally important that, in light of paragraph 4 of the Doha declaration, TRIPS should not only be interpreted, but also implemented consistently with the right of other members, particularly those in sub-Saharan Africa, to safeguard public health (Correa, 2002).

Therefore, developed countries should desist from actions likely to undermine the exercise of this right, for example, by threatening retaliatory trade measures, or refusing to take steps under the August 2003 decision to supply essential medicines to sub-Saharan African countries that lack manufacturing capacity (Correa, 2002). Since TRIPS grants members certain flexibilities, which have been recognised by the Doha declaration and the August 2003 decision, attempts to discourage their use, as was the case in South Africa, are inimical to the intent and purposes of TRIPS. This is all the more so, given the glaring public health crisis facing sub-Saharan African countries (Correa, 2002).

In light of their limited financial resources, sub-Saharan Africa needs increased international funding, in order to acquire essential medicines, provide adequate healthcare infrastructure and improve their overall healthcare services. Such assistance is also necessary to enable them meet the costs of instituting and maintaining optimal IP protection systems. All this calls for strong commitments, on the part of developed countries and the pharmaceutical industry. It is equally imperative to strengthen

global actors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the International Drug Purchase Facility (UNITAID), the Global Forum for Health Research, Oxfam, MSF, and WHO. Verbal declaration of support must be translated into concrete action. But whatever assistance that is provided should be with a sense of public support, free of any form of obligation, or ideological cleavages. Increased media campaign, public-private collaboration in funding, as well as in research specifically focused on diseases prevalent in sub-Saharan Africa should be encouraged. This is with the ultimate objective of providing universal access to essential medicines in sub-Saharan Africa. As UNAIDS (2010) correctly observes, TRIPS does not, and should not prevent members from taking measures necessary to protect public health.

## CONCLUSION

It is clear from this discussion that several non-patent factors affect access to essential medicines in sub-Saharan Africa. However, despite that, pharmaceutical patents also have negative impacts on access to essential medicines. And, attempts to use the TRIPS flexibilities to ameliorate the situation have been fraught with problems.

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