

THE UNDER-UTILIZATION OF TRIPS FLEXIBILITIES BY DEVELOPING COUNTRIES: THE CASE OF AFRICA

*Moses Nkomo

ABSTRACT

This paper shall review the national laws of several African countries¹ to assess the incorporation and utilization of TRIPS flexibilities. Kenya is specifically referred to as an example of a country with relatively advanced legislation incorporating TRIPS flexibilities. The practical applications of the enacted flexibilities in Zimbabwe and Zambia shall also be reviewed in order to demonstrate that African countries are undermining their own interests by failing to take full advantage of the TRIPS flexibilities. The effect of Free Trade Agreements (FTAs) on TRIPS flexibilities shall also be discussed with specific reference to the Free Trade Agreement between the United States and Morocco. The use of competition law and policy as a flexibility shall also be assessed with specific reference to the example of South Africa. Comparative analysis shall be undertaken, where appropriate, between the practice in Africa and in other developing regions in Latin America and Asia.

Introduction

There is no doubt that it is a matter of time before the curtain comes down on the Doha Round of Trade Negotiations. It is also beyond doubt that developed countries will not make further concessions regarding the flexibilities enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This research is motivated by the fact that despite considerable flexibility enshrined in the patent provisions of the TRIPS Agreement, many African countries appear hesitant to implement and utilize these flexibilities for the benefit of their people.

Further, the global intellectual property system appears to be firmly embedded in one-way traffic leading to higher levels of intellectual property protection. Confirmation of this trend is evidenced by developments such as the ongoing negotiations on the draft Substantive Patent Law Treaty (SPLT) SCP/10/2² and the current wave of Free Trade Agreements and Economic Partnership Agreements. The SPLT negotiations could reduce flexibilities for all member countries, while the bilateral and regional FTAs have significantly cut back on the ability of national governments to provide public goods that involve intellectual property inputs.

* **Mr Moses Nkomo** (Zimbabwe) is a Lecturer of Intellectual Property Law at the Department of Private Law, Faculty of Law, University of Zimbabwe in Harare. Mr Nkomo holds a Master's Degree in Intellectual Property (MIP) from the Africa University (jointly sponsored by WIPO and ARIPO). He also holds a Bachelor of Laws (Honours) Degree from the University of Zimbabwe. Mr Nkomo is also a lawyer and Senior Partner at Donsa-Nkomo and Mutangi Legal Practice in Harare, Zimbabwe. He is responsible for the firm's Intellectual Property division. Mr Nkomo is also the Founder of the Zimbabwe Intellectual Property Trust and the Southern Africa Intellectual Property Trust. Both are voluntary organizations which advocate the promotion of Intellectual Property in Zimbabwe and the Southern Africa Region. Mr Nkomo is a member of the Zimbabwe Institute of Patent and Trademarks Agents (ZIPTA) and the Law Society of Zimbabwe.

¹ Data on the national legislation was compiled from national patent laws, where these were available. Additional information was found in the reports of the WTO TRIPS Council review of implementing legislation as well as the UNDP Best Practice Report, 2009.

² Substantive Patent Law Treaty (SPLT)
http://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_2.pdf [Accessed May 4, 2011].

The TRIPS Agreement does provide substantial flexibilities in its patent provisions. These range from pre to post-grant phases of the IP system. Further, the Doha Declaration clarified and cemented the scope and interpretation of TRIPS flexibilities by adopting a rule of interpretation to provide a safeguard for their effective use. However, the Doha Declaration does not provide a mechanism for practical implementation.

Speaking at the advent of the Declaration, Mr Boniface Chidyausiku, Zimbabwe's Ambassador to the World Trade Organization stated, 'The question is now, how do we make it effective? How do we make it deliver the medicines to the people? How do we avoid this Declaration ending up as a dead letter?'³ Initially, the question of how to make the Doha Declaration workable in practical terms was left unaddressed by the Declaration itself. However, to some extent, the matter was later addressed through the WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the 'Waiver Decision')⁴ that was entrenched in the December 2005 Protocol of Amendment.⁵

Whereas the TRIPS Agreement spells out the flexibilities available for developing countries to overcome IP rights-related barriers, it is critical to note that these flexibilities are not self-executing. They do not automatically translate into national legal regimes. Accordingly, it is necessary for specific provisions to be enacted in domestic laws to enable countries to make full use of the flexibilities.

Incorporation of TRIPS flexibilities in national legislation

The flexibilities contained in the TRIPS Agreement, and confirmed by the Doha Declaration allow (a) different types of exceptions to patent rights; (b) compulsory licences to permit third parties to make generic versions of patented medicines; (c) parallel importation through an international exhaustion regime; (d) remedial action against anti-competitive practices; (e) limitation on the types of subject matter on which patents may be granted; (f) accelerating the introduction of generic medicines into the market by allowing third-party testing, manufacturing and exportation for purposes of regulatory approval; (g) refusal of patent term extensions on the basis of regulatory delays in registration of medicines; and (h) permitting regulatory agencies to rely on test data provided by the originator to register generics. However, as noted above, these flexibilities do not automatically translate into national regimes. They must be formally incorporated into the domestic legislation.

*Kenya case study*⁶

The principal legislation governing patents in Kenya is the *Industrial Property Act*, which was passed by the Kenyan Parliament in 2001. It was granted presidential assent in July that year and was published a month later in August, 2001. A key focus of the debate during the drafting of the Act

³ Ambassador B. G. Chidyausiku, Zimbabwe, on the Doha Declaration. Quoted from 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance - How to get it Right', Conference report, 28 March 2002, page 4.

⁴ The WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WTO document WT/L/540 and Corr.1).

⁵ Amendment of the TRIPS Agreement. Decision of 6 December 2005. General Council WT/L/641, 8 December 2005, http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

⁶ Information on this case study was drawn from papers by Musungu (2002) on the IP Act 2001 and access to medicines in Kenya, Lettington and Munyi 'Willingness and ability to use TRIPS Flexibilities: Kenya case study' (2004).

was the effect of patents on the prices of essential medicines, and the need to incorporate public health safeguards aimed at promoting the availability of essential medicines in Kenya. As a result, the Act incorporates the majority of recognized TRIPS-compatible flexibilities, including expansive interpretations of the principles of international exhaustion of intellectual property rights, parallel importation, government use, and compulsory licensing.

The Act also contains provisions on the Bolar exception and discretionary restrictions on patents whose subject matter may be used to address serious health hazards.

Of particular interest in this study are the provisions relating to parallel importation, compulsory licensing, and government use.

Exhaustion of rights

The 2001 Act adopts an expansive international exhaustion principle. This is a departure from the approach taken under the previous *Industrial Property Act, 1989*. Section 58(2) of the new Act now provides that: 'The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.'

As it currently stands, the text contemplates the valid importation of any products legitimately placed on the market abroad, including products put on the market under compulsory licences.

Voluntary licences

The *Industrial Property Act, 2001* makes explicit reference to voluntary licensing.⁷ The Act provides that all voluntary licences must be registered with the Kenyan Intellectual Property Institute (KIPI), which retains the right to refuse to register a licensing agreement, if it has not satisfied all the necessary conditions. The Managing Director of KIPI also retains discretionary powers to do so where he or she deems that a voluntary licence, or any provision thereof, imposes a restriction that may be harmful to Kenya's economic interests. To date, two voluntary licences for the production of anti-retrovirals (ARVs) have been concluded. Both involved Cosmos Pharmaceuticals in agreements it entered with GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI).

This mechanism can be made more effective by including a timeframe in the *Industrial Property Act*, by which negotiations for a voluntary licence must be concluded.

Compulsory licensing

The Kenya *Industrial Property Act, 2001* provides narrower scope for compulsory licensing. Unlike the South African Act, which provides four grounds for compulsory licensing, the Kenyan legislation contains only two grounds. These are (a) that the patented invention is not being supplied on reasonable terms in Kenya, and (b) for dependent patents.

The Act goes on to impose several conditions which have to be met before a compulsory licence can be issued. The legislation also sets several limitations. One of these is the provision that a compulsory licence cannot be issued, where the rights holder can prove that there are justifiable reasons why the patented product is not being supplied in Kenya on reasonable terms.⁸ Another

⁷ Section 69.

⁸ Section 72 (2).

condition is that unless there is a situation of extreme urgency, the applicant for a compulsory licence must demonstrate that a request for a voluntary licence was either not answered within a reasonable time, or that reasonable commercial terms were refused.⁹ The Act further requires the applicant for a compulsory licence to provide assurances that the deficiencies in the market supply of the patented product will be remedied. Otherwise, the licence may be revoked.¹⁰

To date, there has been no compulsory licence issued in Kenya. An application by Cosmos Pharmaceuticals was turned down on the basis that it lacked clarity on whether it sought a government use licence or a compulsory licence *sensu stricto*. A factor which has been highlighted as hindering the compulsory licensing regime in Kenya is the complexity and legal uncertainty that a judicial interpretation of the provisions might cause. Moreover, the provisions in the *Industrial Property Act* of 2001 go far beyond the minimum standards set by the TRIPS Agreement. For instance, there is no requirement for a period of extreme urgency to exist before a compulsory licence can be issued under Article 31 of TRIPS. Neither is there a requirement that the applicant must give assurances that the deficiencies in supply will be remedied.

Government use

Section 80 of the *Industrial Property Act, 2001* provides two grounds for government use of a patented technology. These are (a) where it is considered to be in the public interest; and (b) when exercising their discretion, the Managing Director of KIPi decides that the manner in which the patented invention is being exploited is anti-competitive. In such a case, a recommendation can be made to the Minister of Trade and Industry to issue a government use order.

To date, there has been only one attempt to use the government use provision. In 2003, Cosmos Pharmaceuticals was awarded a tender by the Ministry of Health to supply generic ARVs. The company made an application for a government use order, but before a decision could be made on the application, the company concluded a voluntary licensing agreement with the patent holder.

From the Kenya *Intellectual Property Act, 2001*, it is notable that the government use flexibility is hampered by the inclusion of restrictive legislative conditions, which are not mandated by the TRIPS Agreement. For instance, the Act states that in cases of government use, consultation, negotiation¹¹ and the patent holder's permission are required.¹² These are not formal requirements of Article 30 or Article 31 of TRIPS.

However, a commendable feature of Kenya's government use provision is the broad ambit of its 'public interest' grounds. The 'public interest' includes national security, nutrition, health, environmental conservation, and the development of other sectors of the economy, which are considered vital for economic development.

⁹ Section 74(1)(a).

¹⁰ Section 74(1)(b).

¹¹ Section 80(2).

¹² Section 80(1)(b).

Paragraph 6(i) of the Waiver Decision

By virtue of its membership in the East African Community (EAC) together with Tanzania, Uganda, Rwanda and Burundi, Kenya is entitled to export medicines produced or imported under compulsory licensing in its least developed country (LDC) neighbours.

Shortly after the Waiver Decision was announced, Kenyan manufacturing firm Cosmos Pharmaceuticals, which had won a government tender to supply generic ARVs, announced its intention to begin producing drugs for the East African market. When the application for a compulsory licence was made, a conflict developed between the Ministry of Health and the Ministry of Trade and Industry. The former ordered that the company produce generic drugs, while the latter refused to issue a compulsory licence. Eventually, after protracted negotiations with the patent holder, a voluntary licence was concluded.

The potential for Kenya to use the Paragraph 6(i) flexibility was hindered by the differences in the regulations relating to the manufacture, import, export, and distribution of pharmaceutical products in each of the EAC countries. Therefore, there is a need to harmonize the regulatory frameworks in the region. To date, this has not been accomplished. Moreover, the essential drugs produced by the Kenyan manufacturer will have to be included in the WHO's Essential Drugs List, which entails the high costs of bio-equivalency testing. A similar setback was faced by a South African generic drug manufacturer, Aspen Pharmacare, when it attempted to export ARVs to Ethiopia, Nigeria, Tanzania, and Uganda in June 2005.¹³ Therefore, the need for harmonization of regulatory frameworks cannot be over-emphasized.

An overview of the patent legislation in the African countries discussed in this paper, shows that where flexibilities are provided, they are narrow and restrictive. For example, with the exception of the Kenya IP Act of 2001, there are no references to general public interest grounds for granting compulsory licences. It is submitted that where public interest grounds are broadly framed in legislation, it may ensure greater access to medicines by encompassing public health needs.

The majority of countries reviewed provided few grounds for justifying compulsory licence grants. Countries like Burundi, Madagascar, Mauritius, and Rwanda do not include abuse of rights/anti-competitive practices, or other public interest grounds despite the flexibility in Article 31 of the TRIPS Agreement.

Practical application of TRIPS flexibilities in developing countries

The TRIPS Agreement recognizes government use of patents through its reference to the concepts of 'public, non-commercial use' and 'patents used by or for the government'.¹⁴ The fact that the Agreement also does not specifically define these terms leaves developing countries with policy space to interpret the term. Many national patent regimes allow government use of patents without the need to grant compulsory licences. This is one of the most widely implemented TRIPS flexibilities in Africa. It has been implemented in Zimbabwe, Zambia and Mozambique. This study will refer to the use of this flexibility in Zimbabwe and Zambia.

¹³ T. Avafia, J. Berger and T. Hartzenberg, 'The Ability of Select Sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries', page 20.

¹⁴ Article 31(b) of the TRIPS Agreement.

*Zimbabwe's declaration of a period of emergency*¹⁵

In 2002, Zimbabwe's Minister of Justice issued a notice declaring a period of emergency on HIV/AIDS. This was done for the purpose of enabling 'The State or a person authorized in writing by the Minister to make or use any patented drug, including any anti-retroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions.'¹⁶

The Declaration authorized the local production and use of any patented drug and restricted imports only to generic drugs. The Declaration announced an initial emergency period of six months. Through the Declaration of Period of Emergency on HIV/AIDS Notice, 2003, Statutory Instrument 32 of 2003¹⁷, this was later extended by another six years from January of that year to December of 2008.

Pursuant to the Declaration, three licences were issued to three companies in 2003. One was for the local production of ARVs, and two were for the importation of ARVs from India.

Varichem Pharmaceuticals (Private) Limited was granted the authority to 'make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the purposes of achieving the objectives of statutory Instrument 32 of 2003'. Under the terms of the authorization, Varichem was directed to produce anti-retroviral or HIV/AIDS-related drugs and to supply three-quarters of its production to state-owned health institutions.

Datlabs, a local pharmaceutical manufacturer, was authorized to import ARVs from Ranbaxy in India. Omahn, an agent for the giant Indian pharmaceutical manufacturer Cipla, was also authorized to import Cipla products.¹⁸

The impact of the Declaration in ensuring the availability and affordability of medicines was almost immediate. The cost of anti-retroviral *stavudine* dropped from US\$400 (according to the official exchange rate) per patient per month in 2001, to between US\$15 and US\$30.¹⁹

Despite the encouraging results, the system was plagued by Varichem's limited capacity, the lack of foreign currency to import active pharmaceutical ingredients, and Zimbabwe's hyper-inflationary environment which rendered the local currency virtually worthless.

Moreover, despite being presented as a government use order, the licensing regime introduced by Statutory Instrument 32 of 2003 was a *de facto* compulsory licence. This resulted in unnecessarily cumbersome procedures which were not required for a government use order such as the declaration of a period of emergency. Article 31 of the TRIPS Agreement does not require a declaration of emergency prior to government use. The positive impact of the government use flexibility could have been enhanced if it had been employed as part of a deliberate, organized, and systematic scheme of utilizing TRIPS flexibilities.

¹⁵ Information on this case study was largely drawn from local media reports, information available on the Internet (<http://cptech.org/ip/health/c/zimbabwe/zim05242002>) as well as from a report published by the Common Market for Eastern and Southern Africa (COMESA) and interviews with officials from the Ministry of Justice, Legal and Parliamentary Affairs and the Medicines Control Authority of Zimbabwe (MCAZ).

¹⁶ Declaration of Period of Emergency (HIV/AIDS) Notice 2002, General Notice 240 of 2002.

¹⁷ Declaration of Period of Emergency on HIV/AIDS Notice 2003, Statutory Instrument 32 of 2003.

¹⁸ Information from the Medicines Control Authority of Zimbabwe.

¹⁹ Maonera and Chifamba, report published by the Common Market for Eastern and Southern Africa, (2003).

Implementation of the compulsory licensing flexibility in a least developed country: the case of Zambia

Zambia is classified as a Least Developed Country (LDC), with a GDP per capita of US\$870 in 2001. The nation was ranked 143rd out of 162 countries surveyed in the UNDP's Human Development Index (HDI) in 2001.²⁰

LDCs were initially expected to become TRIPS compliant in 2006, with an additional ten-year extension until 2016 granted for pharmaceuticals. However, the TRIPS Council decision of 29 November 2005 extended the time for full compliance to 1 July 2013, while the deadline for pharmaceuticals remained 2016. There are a number of flexibilities that LDCs, such as Zambia, could utilize by enacting domestic legislation. They have the flexibility to continue to provide either no patent protection at all for pharmaceuticals, or to provide patent protection for a period less than the minimum 20-year term. Like Zimbabwe, Zambia first declared a state of emergency before proceeding with its compulsory licensing order.²¹

The justification of the compulsory licence was that the patent holders of the three ARVs in question were not able to come to an agreement on the manufacture of a Fixed Dose Combination (FDC), which was imperative to the Government's AIDS treatment plan. A tender was awarded to a local manufacturer to produce the Fixed Dose Combination for use only in Zambia, with a royalty cap of 2.5 per cent being paid to the patent holders.

The Zambian case study is significant in a number of ways. It is a classical illustration of how developing countries undermine their full enjoyment of the available flexibilities under TRIPS. To start with, Article 31 of the TRIPS Agreement neither requires a state of emergency, nor does it limit the unilateral issue of government or 'public, non-commercial use' orders to specific diseases. However, instead of opting for a government use order, the Zambian Government opted for a compulsory licence, which for non-emergency situations requires consultations and negotiations for reasonable commercial terms with the rights holder.

Secondly, subsequent research revealed that the two rights holders concerned had not applied for, and did not hold corresponding patents in Zambia.

Thirdly, the royalties were significantly higher than what Zambia could bargain for on the basis of its position on the Human Development Index (HDI). According to the WHO/UNDP Royalty Paper, based on the HDI royalty rates, Zambia's compulsory licence could have been limited to a 0.32 per cent margin.²²

Like many LDCs in Africa, Zambia has not taken advantage of its LDC status to delay full patent protection for pharmaceuticals. The only territory that has amended its legislation to take advantage of the transition period flexibility in Africa is Zanzibar. Section 3(1)(x) of the Zanzibar Industrial Property Act of 2008 excludes from patentability 'Pharmaceutical products and processes until 1 January 2016 or the expiry of such later period of extension agreed upon by the WTO TRIPS Council.'

²⁰ United Nations Development Programme, 2001. Human Development Report. Lusaka, Zambia.

²¹ The Patents (Manufacture of Patented Anti-Retroviral Drugs)(Authorization) Regulations, Statutory Instrument 83 of 2004.

²² Available online at http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1OMS.pdf

Zambia and other LDCs should consider amending their patent legislation to take advantage of the transition period flexibility, and to broaden its compulsory licensing regime by incorporating more public interest grounds for issuing compulsory licences.

*The use of competition law and policy as a flexibility: the case of South Africa*²³

The majority of patent laws reviewed in this study provide for compulsory licensing to remedy anti-competitive practices. However, their most significant setback is that they do not have the necessary legislation and infrastructure to enhance the effectiveness of their IP competition frameworks.

The use of competition law and policy provides developing countries with several advantages, including (a) the TRIPS Agreement gives Members considerable flexibility in implementing competition frameworks most appropriate for their purposes; (b) countries have the flexibility to define what constitutes anti-competitive behaviour; (c) competition law and policy is well suited for implementation by an independent competition authority vested with extensive investigative powers; and (d) competition law and policy have been successfully used by South African activists and stakeholders to reduce the prices of essential medicines.

South Africa has one of the most advanced regulatory frameworks integrating TRIPS flexibilities. These are included in three Acts, namely, the *Patents Act* (Act No. 57 of 1978)²⁴, the *Medicines and Related Substances Control Act* (Act 101 of 1965, as amended)²⁵, and the *Competition Act* (Act No. 200 of 1993).²⁶ To date, the Competition Commission has heard two cases challenging anti-competitive practices in the pharmaceutical sector, including restrictive practices and abuse of dominant position.

In the first case of *Hazel Tau and Others v. GlaxoSmithKline and Boehringer Ingelheim*²⁷, the complainants alleged that the prices charged by the patent holders for their essential medicines were directly responsible for the premature, predictable and avoidable loss of lives. The Competition Commission found both companies guilty of excessive pricing and for failing to licence generic manufacturers in circumstances which the Commission felt deserved such licences. For instance, the companies were selling the patented drugs at much lower prices in other countries, especially in Europe. The matter was referred to the Competition Tribunal for a ruling. However, in a bid to avoid a damaging precedent, the two companies entered into a number of agreements, which allowed generic versions of their patented products to become available in South Africa for the first time.²⁸

²³ Information on this case study is derived from a paper by T. Avafia, J. Berger and T. Hartzberg on the 'Ability of Select Sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines', (2006).

²⁴ Patents Act No. 57 of 1978 (as last amended by Act No. 49 of 1996). http://www.wipo.int/wipolex/en/text.jsp?file_id=130480 [Accessed on 5 May 2011].

²⁵ Medicines and Related Substances Control Act (Act 101 of 1965, as amended). http://www.nda.agric.za/daoDev/fisheries/03_areasofwork/Aquaculture/AquaPolGuidLeg/Legislation/MedicineRelatedSubstancesControlAct101of1965.pdf [Accessed on 5 May 2011].

²⁶ Competition Act (Act No. 200 of 1993) http://www.saflii.org/za/legis/num_act/ca1998149.pdf. [Accessed on 5 May 2011].

²⁷ See 'The Price of Life: *Hazel Tau and others v. GlaxoSmithKline and Boehringer Ingelheim*', page 5, available online at www.alp.org.za/modules.php?op=modload&name=news&article&sid=222

²⁸ See T. Avafia et al., supra in footnote 13.

The second case, *Treatment Action Campaign v. Bristol-Myers Squibb (BMS)*²⁹, came about when civil society groups threatened to lodge an excessive pricing complaint against BMS for charging inflated prices for a product that was off patent, but for which the patent holder still held a *de facto* monopoly. Moreover, the patent holder was charging far lower prices for the product in some developed countries. The matter was settled out of court with BMS agreeing to slash prices by approximately 80 per cent.³⁰

These two cases demonstrate the potency of competition law and policy as a resource available to developing countries. It has also been observed that 'despite these two legal successes, there are ways in which the *Competition Act* could be amended to increase its effectiveness as a tool for reducing prices of essential medicines'.³¹ This includes adding a provision in the Act to confer power on the Commission to issue compulsory licences, to recommend a suggested royalty rate in the event of such an order, and to expressly allow for the export of products produced under compulsory licences.

The impact of Free Trade Agreements on the utilization of TRIPS flexibilities

The foregoing discussion clearly demonstrates that the TRIPS Agreement affords developing countries substantial flexibility in the implementation of their intellectual property obligations under the Agreement. However, it is common knowledge that the United States has sought to undermine the utilization of these flexibilities through bilateral and regional Free Trade Agreements (FTAs). In various notification letters to Congress regarding negotiations of FTAs, the US Trade Representative (USTR) stated that the main objective of negotiating FTAs was 'to enhance the levels of protection of intellectual property in third countries beyond TRIPS and to have the 3rd countries apply levels of protection that are in line with United States law and practices'.³²

It is the declared policy of the United States to increase intellectual property protection. Through FTAs and trade and investment framework agreements (TIFAs), it is seeking 'higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement'.³³

It is important to note that under Section 301 of the *United States Trade Act*, there are provisions (known as Special 301 provisions) that include a range of categories under which countries perceived to have policies adverse to US interests may be listed. Section 301 also provides investigatory powers and remedies that are meant to 'persuade' other nations to yield to US demands and views on intellectual property protection.³⁴ Under the Special 301 provisions, mere compliance with the TRIPS Agreement does not amount to adequate and effective intellectual property protection.

²⁹ Ibid.

³⁰ Ibid.

³¹ Ibid.

³² See various letters of notification available online at <http://www.ustr.gov>

³³ 2004 Special 301 Report, page 2. Available online at <http://www.ustr.gov>

³⁴ Under Special 301, countries that have what the United States considers the most egregious acts, polices or practices or whose acts, policies or practices have the greatest adverse impact (actual or potential) on relevant US products and are not engaged in good faith negotiations to address these problems, may be identified as 'priority foreign countries'. If so identified, such a country could face bilateral US trade sanctions, if changes are not made (in the laws, policies or practices) that address the US concerns. In the 2004 Special 301 Report, Ukraine, China and Paraguay were listed as priority foreign countries. (Musungu and Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?', South Centre, (April 2006), page 76.

The United States uses the Special 301 mechanism to push developing countries into enacting TRIPS-plus legislation or to discontinue their exercise of TRIPS flexibilities.

Seeking higher levels of protection beyond TRIPS and requiring developing countries to apply standards similar to the United States suggests that the net effect of the FTAs is to curtail the use of legitimate flexibilities under the TRIPS Agreement, including compulsory licensing.

The US approach also suggests that even where flexibilities are preserved, their interpretation may be construed very narrowly. This generally aggressive approach to intellectual property rights is evident even beyond the FTAs. For example, in the 2004 Special 301 Report, the US Trade Representative asserted that under Article 39.3, 'the TRIPS Agreement recognizes that the original applicant should be entitled to a period of exclusivity ... During this period of exclusive use, the data cannot be relied upon by regulatory officials to approve similar products'.

However, the text of Article 39.3 of the TRIPS Agreement does not mandate data exclusivity nor does it prohibit reliance on test data by public officials. It simply provides that Members 'shall protect such data against unfair commercial use'.

In Africa, the only country that has concluded a FTA with the United States is Morocco. In terms of Article 15.10 of the United States-Morocco Agreement, Morocco is required to grant data exclusivity way beyond what is provided for under Article 39 of TRIPS. While Article 39.3 of the TRIPS Agreement envisages protection of test data submitted to governments to meet regulatory approval, Article 15.10 goes far beyond this requirement, and introduces many layers of protection. The FTA provides for a mandatory five-year period of test data exclusivity. Article 39.3 only requires the application of unfair competition rules as opposed to exclusivity. This is calculated to prevent generic drug manufacturers from relying on test data submitted by originator companies.

The United States-Morocco FTA does not provide for an exception to data exclusivity, even where it is necessary for the protection of public health. The FTA also seeks to define patentability criteria such as 'utility' (as a criteria for patentability), so as to conform to the US standard. The FTA also requires Morocco to provide patents for plants and animals, as well as to grant patents for new uses of known pharmaceutical products.³⁵ This makes the ever-greening of patents relatively easy. It also delays the entry of generic medicines into the market with potentially catastrophic consequence. The FTA also prohibits, or at the very least restricts, parallel importation.

The foregoing discussion clearly shows that FTAs may undermine the use of TRIPS flexibilities by developing countries. They may be used to frustrate the object and purpose of intellectual property regimes, such as those provided through the TRIPS flexibilities. Such FTAs do not contribute to the promotion of technological innovation or the transfer of technology. Neither do these FTAs contribute to the realization of mutual benefits by producers and users of technological knowledge, in a manner that is conducive to social and economic welfare. Instead, they maintain the advantages that developed countries enjoy over developing countries.

FTAs constitute the worst risk to the utilization and enjoyment of TRIPS flexibilities by developing countries. Those developing countries that have already entered into such agreements should find ways of mitigating the resulting damages. Those that are negotiating FTAs must be vigilant so that they do not lose the flexibilities provided by the TRIPS Agreement.

³⁵ See Article 15.9(2).

Recommendations for maximizing use of the flexibilities

National level

- There is a need for developing countries to develop legal, technical and institutional capacities, and to develop the necessary expertise for using the TRIPS flexibilities at the local level. As noted earlier, one of the major problems is developing countries' lack of awareness and legal expertise necessary to incorporate and implement the flexibilities. For example, the use of competition law and policy as demonstrated by South Africa would require substantial infrastructure and expertise, which currently does not exist in many developing countries. The same applies to the regulation and post-marketing surveillance of medicines.
- African countries must engage in a deliberate and systematic revision of their legislation, so they can take full advantage of the public health safeguards and regulatory flexibilities permitted by the TRIPS Agreement.
- Instead of focussing on remedial flexibilities that merely mitigate the repercussions of intellectual property abuse, greater attention must be paid to those flexibilities with preventative effects. This would require diligent and competent policymaking, as well as for lawmakers to provide the necessary legal and policy frameworks.
- Legal reforms must be shaped by developmental objectives, industrial policy and strategic economic interest. While compliance with the TRIPS Agreement is an obligation, the major consideration in legal reform should be national strategic interests. African countries must not trade off the flexibilities provided under the TRIPS Agreement for ambiguous benefits, such as market access, which have no direct relationship with the policy objectives of developing countries. Patent law reform must facilitate the development of local pharmaceutical manufacturing capacities; allow for the widest possible scope of parallel importation; establish a simple and expeditious procedure for compulsory licensing; provide for extensive flexibility for the use of Bolar Exceptions; and disallow data exclusivity.
- There is a need for the harmonization of laws and regulatory frameworks to facilitate South-South cooperation. For example, South Africa has not taken full advantage of the flexibilities available to it through the TRIPS Agreement for exporting larger volumes of essential generic medicines to other African countries. This has been due to factors such as the lack of licences, inadequate domestic legal frameworks in most target African countries, and the incompatibility of the regulations of specific domestic systems.
- There must be a deliberate policy to safeguard TRIPS flexibilities when negotiating bilateral and regional FTAs. This may be done through regional frameworks such as that created by the Andean Community.

Recommendations for regional integration and cooperation

In addition to measures that may be taken at a national level, there is an opportunity for developing countries to adopt a regional approach to tackling the constraints they face in fully utilizing TRIPS flexibilities. A regional approach is a logical and beneficial step that can provide creative solutions founded on common purpose, cooperation, collaboration, and collective action.

Such an approach can help address a number of constraints that individual countries face in utilizing flexibilities, by adopting complementary policy and legal measures.

Developing local technical expertise in the use of TRIPS flexibilities

A regional approach would see countries benefiting from the pooling of financial, human and other resources that currently exist in each country. For example, South Africa could provide valuable experience in dealing with lawsuits filed by pharmaceutical companies against the government, the recent decisions by the Competition Commission against GlaxoSmithKline and Boehringer Ingelheim, and the pressures from the United States. These experiences would benefit many other countries in the SADC region.

Further, a Regional Economic Community (REC), such as SADC or COMESA, could establish a division to help member countries address intellectual property matters within its Secretariat. Such a body would assist them in training and research. It would also provide a forum for discussion and the exchange of information on best practices with respect to the use of TRIPS flexibilities.

Addressing the problem of insufficient manufacturing capacity

In order to address the problem of insufficient manufacturing capacity by operationalizing the Waiver Decision, developing countries could establish a regional compulsory licensing system, as was implemented by the African Intellectual Property Organisation (OAPI). Where there are no regional patents, a system of mutual recognition of compulsory licences could be established, whereby members of an REC can issue their own licences based on the issuance in other member countries.

Developing technical and infrastructural capacities for the regulation of medicines

Regional coordination on regulatory issues will offer significant benefits for developing countries, and will help them overcome current constraints in this regard. The existing institutional frameworks in RECs can be used to address challenges in drug registration, post-marketing surveillance, development of essential medicines lists, medicines policies, and rules on pharmaceutical advertising and labelling.

Establishing efficient pharmaceutical management and procurement systems

Significant cost savings, efficiency and other benefits can accrue to developing countries through regional pooled procurement frameworks. Member countries would jointly conduct a tender process through an entity acting on their behalf, and a central purchasing agency managing purchases on behalf of all member countries.

Resisting bilateral and other TRIPS-plus pressures

Regional cooperation has the potential of enhancing political capacities and the economic clout of developing countries. The establishment of regional Non-Governmental Organization (NGO) and Community-Based Organization (CBO) networks should be facilitated through RECs. These could play a significant role in resisting bilateral and other pressures to implement TRIPS-plus measures, as was the case in the South African medicines cases.

Regional competition enforcement mechanisms

The enforcement of market competition is critical in ensuring a thriving pharmaceutical industry that facilitates lower prices and ensures the availability of essential medicines. Individual countries lacking expertise, as well as economic and political clout, should work within REC frameworks in order to enforce competition rules.

Ultimately, the conclusion is that though the TRIPS system may not be the optimal framework for developing countries, it still provides them with substantial flexibilities. If these flexibilities are effectively incorporated and implemented, they could go a long way in ensuring the protection and promotion of the public interest in developing countries, especially in the area of public health. All that is required is skilful lawyering, political will, determination, and coordinated planning at both the local and regional levels. The use of TRIPS flexibilities is analogous to 'tight-rope' walking; with the will and skill, they can be made to work effectively for the benefit of developing countries.

BIBLIOGRAPHY

- F. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO', *Journal of International Economic Law*, (JIEL), (2002)
- F. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Trade Agreements', Occasional Paper 14, QUNO, (2004)
- F. Abbott, 'The Cycle of Action and Reaction: Latest Developments in IP and Health', (2004b), mimeo
- F. Abbott, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', *American Journal of International Law*, (2005)
- F. Abbott, and J. Reichman, 'The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', *Journal of International Economic Law* (JIEL), (2007)
- T. Avafia, J. Berger, and T. Hartzenberg, 'The Ability of Select Sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A study of Producing and Importing Countries', ICTSD, UNCTAD and tralac, (2006)
- J. Berger, 'Advancing Public Health by other Means: Using Competition Policy to Mitigate the Impact of Patent Protection' ICTSD, UNCTAD, (2004)
- C. Correa, 'Intellectual Property and the Use of Compulsory Licences: Options for Developing Countries', T.R.A.D.E Working Paper 5, South Centre, (Geneva, 1999)
- C. Correa, 'Integrating Public Health Concerns into Patent Legislation in Developing Countries', South Centre, (Geneva, 2000)
- C. Garrison, 'Patent Exceptions in Developing Countries', UNCTAD, (2005)
- R. Lettington, and P. Munyi, 'Willingness and Ability to Use TRIPS Flexibilities: Kenya Case Study', DFIF Health Systems Resource Centre, (London, 2004)
- F. Maonera and C. Chifamba, 'Developing a Regional Framework on Access to Medicines for Protecting Public Health Needs in the COMESA Region', COMESA, (Lusaka, 2003)
- M. M. Mneta, 'Amendment to the TRIPS Agreement: Consensus or Dissension?', tralac Trade Brief No. 5, (Stellenbosch: US Printers, 2006)
- S. Musungu, S. Villaneuva and R. Blasetti, 'Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks', South Centre, (Geneva, 2004)
- S. Musungu and C. Oh 'The Use of Flexibilities by Developing Countries: Can they Promote Access to Medicines', Study 4C, CIPIH, (2005)
- P. Roffe, 'Bilateral Agreements and a TRIPS-Plus World: The Chile – USA Free Trade Agreement', Issues Papers 4, QIAP, Ottawa
- J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, (Kluwer Law International, 2001)