IMPLEMENTATION OF TRIPS PUBLIC HEALTH FLEXIBILITIES IN THE AFRICAN INTELLECTUAL PROPERTY ORGANISATION (OAPI) REGION: PROBLEMS AND PROSPECTS

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Declaration

I declare that this thesis, which I hereby submit for the degree Doctor of Laws (LLD) at the University of Pretoria, is my own work and has not been previously submitted by me for a degree at this or any other tertiary institution.

Enga Kameni

Signature _____

Dedication

To my mother, Enga Elisabeth. Mama, you are my all and I cannot thank you enough for the fatherly, motherly and spiritual roles you have played in my life. You are simply the BEST.

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Abstract

Countries that are members of the African Intellectual Property Organisation (OAPI) are facing many problems with regard to facilitating access to medicines in their respective territories. These problems have been caused by both internal and external factors. Central to these problems have been the perceived inability and unwillingness of OAPI to put in place a regional intellectual property (IP) framework conducive to the promotion and protection of access to medicines. This has been an unwelcome development, not least because neither OAPI members that are least-developed countries (LDC)s, nor those that are developing countries, have taken full advantage of the flexibilities negotiated within the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This unfavourable development is neither justifiable nor sustainable, especially at a time when many African countries (non-OAPI members) are in the forefront of protecting access to medicines through law reforms.

This thesis traces the origins of OAPI from its inception in 1962 to the present. It looks, in particular, at the successive OAPI patent regimes and discusses their impact on access to medicines. The overall conclusion drawn is that successive amendments to the initial agreement have strengthened patent rights. This in turn has stymied access to medicine initiatives in the OAPI region because it has, for instance, limited the use of compulsory licences. However, it is submitted that the current situation can be changed through a combination of policy initiatives, including using a human rights approach to access to medicines; getting non-governmental organisations (NGOs) involved and, above all, reforming the entire patent regime under the Bangui Agreement.

ACRONYMS

ACP	**African, Caribbean and Pacific**
ACTN	**Advisory Committee on Trade Negotiations**
APRM	**African Peer Review Mechanism**
ARIPO	**African Regional Intellectual Property Organisation**
AU	**African Union**
BI	**Boehringer Ingelhiem**
BITs	**Bilateral investment treaties**
BMS	**Bristol-Myers Squibb**
CAT	**Convention Against Torture**
CEMAC	**Central African Economic and Monetary Community**
EC	**European Community**
ECOWAS	**Economic Community of West African States**
EPA	**Economic partnership agreements**
EPO	**European Patent Office**
FDA	**Food and Drug Administration**
FTA	**Free trade agreement**
GATT	**General Agreement on Tariffs and Trade**
GSP	**Generalised System of Preference**
GSK	**GlaxoSmithKline**
GTAG	**Global Treatment Access Group**
HAI	**Health Action International**
ICESCR	**International Covenant on Economic, Social and Cultural Rights**
ICTSD	**International Centre for Trade and Sustainable Development**
ICTY	**International Criminal Tribunal for the Former Yugoslavia**
IMF	**International Monetary Fund**
IPC	**Intellectual Property Committee**
LDC	**Least-developed country**
MNC	**Multinational company**
MSF	***Medecins Sans Frontières***

NGO	**Non-governmental organisation**
OAPI	**African Intellectual Property Organisation**
OAU	**Organisation of African Unity**
PMA	**Pharmaceutical Manufacturers' Association**
TACD	**Trans-Atlantic Consumer Dialogue**
TAC	**Treatment Action Campaign**
TBT	**Technical barriers to trade**
TPPA	**Trans-Pacific Partnership Agreement**
TRALAC	**Trade Law Centre for Africa**
TRIPS	**Trade-Related Aspects of Intellectual Property Rights**
TWN	**Third World Network**
UNCTAD	**United Nations Conference on Trade and Development**
UPR	**Universal Periodic Review**
USTR	**United States Trade Representative**
WHO	**World Health Organization**
WIPO	**World Intellectual Property Organization**
WTO	**World Trade Organization**

List of key terms

Access to medicines; TRIPS flexibilities; public health; African Intellectual Property Organisation; World Trade Organization; Bangui Agreement; developing countries; least-developed countries; compulsory licences; TRIPS Council

TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION

This chapter sets out the problem statement giving rise to the study, identifies the main and sub-research questions, defines some important recurring terms. In addition, it identifies the significance of the research, provides the outcome of a literature review and explains the research methodology used in the study. Lastly, it sets out an overview of chapters and concludes with a brief delineation of the scope of the study.

1.1 Background to the WTO TRIPS Agreement and access to medicines in sub-Saharan African countries and problem statement

> *We consider AIDS as a state of emergency on the continent. To this end, all tariff and economic barriers to access to funding of AIDS-related activities should be lifted.*[1]

The burden of diseases in developing countries is staggering and this burden is exacerbated by inadequate access to skilled medical care and to medicines routinely used to cure and treat illnesses in richer countries.[2] Sub-Saharan African countries remain the worst affected by the HIV pandemic, with 68 per cent of the global HIV burden and with an annual prevalence rate of 2,7 per cent occurring in a region of the world that is home to only 10 per cent of the world's population.[3] There are also very high prevalence rates of tuberculosis and malaria in the region. According to estimates released in December 2013, there were about 207 million cases of malaria in 2012 and an estimated 627 000 deaths with most of the cases and the deaths occurring in Africa.[4] This disease burden and the resulting high death rates warrant an increase in

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1 OAU/Heads of State and Government/African Summit on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases, held at Abuja, Nigeria, 26-27 April 2001.

2 B Baker 'Processes and issues of improving access to medicines: Willingness and ability to utilise TRIPS flexibilities in non-producing countries' (2004) DFID Health Systems Resource Center, Issues paper – Access to medicines, London 5.

3 HIV estimates annex table http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf. (accessed 6 July 2014).

4 Malaria, Fact Sheet 94. http://www.who.int/mediacentre/factsheets/fs094/en/ (accessed 6 July 2014).

access to medicines in this region. However, this has unfortunately not been forthcoming.

The tension between private interests and individual rights, on the one hand, and public interest and community (collective) rights, on the other, is not novel.[5] The current debate pitting access to medicine and the stringent protection of intellectual property rights against each other can be traced back to the entry into force of the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[6] Until well into the twentieth century, a large number of developing and even developed countries had not provided for patent protection in respect of pharmaceuticals, although many of them had been forced to do so during the colonial era. However, there were countries that provided protection only to pharmaceutical process patents while refusing the same protection in respect of pharmaceutical products. This led to a lengthy debate in the Uruguay Round General Agreement on Tariffs and Trade (GATT) negotiations, culminating in the adoption of the Agreement on TRIPS, which provided, inter alia, for minimum intellectual property norms and enforcement measures that member states had to implement at the national level.

As mentioned above, the problem of access to medicines has for a long time been causally attributed to overly-stringent intellectual property laws, especially with the coming into force of the TRIPS Agreement. Because patent rights in particular create rights to exclude competitors, patent holders can charge supra-competitive prices for medicines that are frequently unaffordable both to poor people and low- and middle-income countries. The TRIPS Agreement was one of the most astonishing outcomes of the Uruguay Round of multilateral trade talks, which saw the establishment of the World Trade Organization (WTO).[7] This is because prior to its entry into force, there was no

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5 T Kongolo 'Public interest versus the pharmaceutical industry's monopoly in South Africa (2001) 4 *Journal of World Intellectual Property* (JWIP) 5 609.

6 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, on 15 April 1994, http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 6 July 2014).

7 A Capling 'Intellectual property' in B Hocking & S McGuire (eds) *Trade politics*: *International, domestic and regional perspectives* (1999) 79.

international agreement on intellectual property compelling signing parties to put in place IP enforcement mechanisms.[8] Besides, TRIPS introduced the concept of minimum protection, which requires that signing parties must give effect to the minimum standards of compliance set out by the provisions of TRIPS.[9] However, countries are at liberty to introduce IP protective measures more stringent than the ones contained in the TRIPS Agreement.[10] Before and during the Uruguay Round, developed countries pressed and lobbied hard for the incorporation of an agreement on intellectual property within the multilateral trading system. In the area of drugs and medicines, pharmaceutical companies were concerned that they would lose potential profits from sales to developing countries' elites if the knowledge behind the invention was utilised without a profit to them. Thus, the north responded by introducing TRIPS as a means of ensuring that the countries of the south provide an intellectual property system similar to their own.[11]

Within a few years of its existence, concerns were raised that TRIPS, as interpreted and enforced by certain rich countries, more especially the United States (US), was inequitable to the south, especially as the US made it difficult for countries experiencing chronic health crises to utilise TRIPS-compliant measures for accessing medicines, including parallel importation and compulsory licences for the production of generic versions of certain medicines. A special need also arose from concerns related to article 31(f) of the TRIPS Agreement, which requires that production under compulsory licensing must be primarily for the supply of the domestic market, meaning that countries with inadequate domestic pharmaceutical capacity might find it impossible to source generic medicines by means of a compulsory licence. Early concerns about access to essential life-saving medicines reached their climax in 1998 when 39 pharmaceutical companies filed a law suit against the South African government for allegedly breaching TRIPS provisions as well as certain

8 See art 41 of the TRIPS Agreement.
9 See art 1 of the TRIPS Agreement.
10 As above.
11 Capling (n 7 above).

sections of the South African Constitution, when South Africa enacted the controversial Medicines and Controlled Substances Amendment Act of 1997.[12]

The ensuing protests and criticisms caused WTO members to revisit the TRIPS Agreement and to clarify a number of TRIPS flexibilities. Thus, in Qatar in November 2001, member states adopted the Doha Declaration on the TRIPS Agreement and Public Health,[13] which specifically allowed parallel importation, country-determined use of compulsory licences, a further transition period until 2016 for least-developed countries with respect to patent and data protection on pharmaceuticals, and a prioritisation of public health and access to medicines for all. Paragraph 6 of this Declaration also noted the particular problems faced by countries with insufficient manufacturing capacities and economies of scale to make effective use of one of the key flexibilities afforded by the TRIPS Agreement, namely, the right to undertake compulsory licensing, for some or all drugs.[14] It is a humanitarian imperative that in case of public health need, including, but not limited to, the HIV emergency, companies in exporting countries should be given the authority to produce and export predominant quantities of medicine to save lives in importing countries. However, the unresolved question was exactly how countries lacking manufacturing capacity to produce anti-retroviral drugs to fight HIV could benefit from the compulsory licence regime provided for under article 31 of TRIPS.

On 30 August 2003, the WTO announced that it had resolved the issue by creating a waiver to solve the export/import problem left open by paragraph 6.[15] The decision settled one of the key remaining pieces of unfinished business on intellectual property and health that remained after the 2001 WTO ministerial

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12 Medicines and Related Substances Control Amendment Act 90 of 1997, South African Government Gazette 18,505 of 12 December 1997 (amending the Medicines and Related Substances Control Act 101 of 1965, as amended by Acts 65/1974, 17/1979, 20/1981 & 94/1991).

13 WT/MIN(01)/DEC/2 20 November 2001 Declaration on the TRIPS Agreement and public health.

14 Kongolo (n 5 above).

15 WT/L/540 and Corr.1 1 September 2003 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Decision of the General Council of 30 August 2003.

conference in Doha. It set out conditions under which article 31(f) of the TRIPS Agreement could be waived to allow developing country members to issue compulsory licences to import and export inexpensive generic drugs to fight diseases, including, but not limited to, HIV, tuberculosis and malaria.

However, the WTO's 2003 Decision came under a barrage of criticism. In a joint non-governmental organisation (NGO) statement, it was described as 'a gift bound in red tape'.[16] Critics say the conditions and the requirements attached to it made it very difficult for developing countries to use the Decision.[17] They also stated that as a means of trade policy, it contradicted the basic principles of the WTO and free trade because certain developed countries were allowed to opt out.[18] Use of the Decision required legal and regulatory implementation in importing and exporting countries, as well as actual decisions to issue compulsory licences, ordinarily in both importing and exporting countries. Given its complexity, the mechanism has only been used once in nearly 11 years.

Sub-Saharan African countries, in general, and member countries of the African Intellectual Property Organisation (OAPI),[19] in particular, have not made full use of the flexibilities clarified by the Doha Declaration and detailed in the 30 August Decision.[20] For instance, only a few countries have adopted, let

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16 See joint NGO statement released on 10 September 2003, http://www.essentialaction.org/access/index.php?/archives/27-NGO-Statement-on-TRIPS-and-Public-Health-Deal-at-WTO-19k (accessed 12 September 2008). See also J Subhan 'Scrutinised: The TRIPS Agreement and public health (2006) 2 *McGill Journal of Medicines* 152; D Matthews 'WTO decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: A solution to the access to essential medicines problem?' (2004) 7 *Journal of International Economic Law* 75.

17 As above.

18 R Weissman 'Paragraph 6 implementation recommendations' http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2323529 (accessed 12 September 2012).

19 'OAPI member countries' is a name given to those countries that are signatory to the Bangui Agreement of 1977 (as revised in 1999), creating the African Intellectual Property Organisation (OAPI). These 17 countries are Cameroon, Chad, Central African Republic, Comoros, Congo, Côte d'Ivoire, Benin, Burkina Faso, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo; http://www.wipo.int/wipolex/en/other_treaties/parties.jsp?treaty_id=227&group_id=21(accessed 28 October 2015).

20 Eg, least-developed OAPI member countries are required to grant 20 years for patent protection on pharmaceuticals, whereas they are not obliged to do so under a waiver to the LDC transition period adopted pursuant to para 7 of the Doha Declaration.

alone used, the compulsory licence mechanism.[21] Also, some least-developed countries are granting patents for pharmaceutical products, despite the WTO's 2016 extended transition period relating to pharmaceutical products.[22] In fact, the problems could be exacerbated by including TRIPS-plus provisions in bilateral and regional agreements with the US and European Union (EU). The adoption of TRIPS-plus intellectual property protection is neither justifiable nor sustainable in view of the chronic health crises affecting most of these countries and the often limited budget they can allocate for health care.

The OAPI region was selected for this research because, unlike the countries of Eastern and Southern Africa,[23] the reasons why the countries of the OAPI regime have not taken full advantage of the TRIPS public health flexibilities and what needs to be done to rectify this policy lapse have not been sufficiently researched and analysed. In the same vein, there is a dearth of academic writing that specifically proffers to the countries of this region the best ways to make full use of TRIPS-compliant flexibilities. Besides, unlike their African Regional Intellectual Property Organisation (ARIPO) counterparts who have had the advantage of hosting national and regional conferences[24] dealing with access to medicines and the use of TRIPS flexibilities, thereby creating national awareness and capacity building on the subject, to date, very few

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21 Examples of African countries that have used compulsory licences include Mozambique (2004), Rwanda (2007), Zambia (2004) and Zimbabwe (2002).

22 WTO Extension of the Transition Period under Article 66.1 for Least Developed Country Members. Decision of the Council for TRIPS of 11 June 2013.

23 Some authoritative work on the subject with regard to Eastern and Southern Africa include A Tenu et al 'The ability of select sub-Saharan African countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: A case study of producing and importing countries' (2006) ICTSD/TRALAC working paper, Stellenbocsh; M Sisule & C Oh ('The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' 2005) paper commissioned by the Commission on Intellectual Rights, Innovation and Public Health (CIPIH); P Munyi & R Lewis-Lettington 'Willingness and ability to use TRIPS flexibilities: Kenya case study' (2004) DFID Issues Paper – Access to Medicines; and C Banda & R Lewis-Lettington 'Willingness and ability to use TRIPS flexibilities: Malawi case study' (2004) DFID Issues Paper – Access to Medicines.

24 Eg Health Action International (HAI) meeting for Eastern and Southern Africa CSOs to discuss their role in advocating for access to medicines, Nairobi, Kenya, 6-8 October 2008; HAI meeting on the proliferation of anti-counterfeiting legislation in the East African Community: Addressing Public Health, Copyright and Developmental Concerns, Arusha, Tanzania, 25-26 March, 2010. Also see S Sangeeta 'The African Regional Intellectual Property Organisation (ARIPO) Protocol on Patents: Implications for access to medicines, http://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_ENl.pdf (accessed 10 May 2015).

conferences, training and workshops on the subject have been held in the OAPI region. Accordingly, this study is necessary to contribute to the debate on reforming the OAPI regime. In addition, the author is familiar with the countries of the said region and the OAPI regime. Of note is the fact that the author also speaks French, which is the principal language of most of the OAPI member countries, and he is familiar with the work of OAPI, having done a three-month internship there in 2005. Countries that are signatory to the Bangui Agreement[25] are obliged to apply locally the provisions of the Bangui Agreement.

This study proposes to investigate the peculiar problems faced in implementing TRIPS public health flexibilities to facilitate access to medicines in OAPI member countries. This study has as objective investigating the OAPI intellectual property regime affecting access to medicine and policy factors standing in the way of needed reforms. Finally, the study proposes recommendations on how OAPI member states can adequately implement and reap benefits from the developments that have taken place since the coming into force of the TRIPS Agreement in 1995.

1.2 Research questions

The main research question of the study, posed against the background set out above, is as follows: Why have OAPI member countries not been able to fully implement TRIPS public health flexibilities with regard to access to medicines, and how can this situation be rectified?

In addressing the main research question, the following sub-questions need to be answered:

(i) What problems related to access to medicines did the adoption of the TRIPS Agreement bring about?

(ii) What is the nature, scope and content of public health flexibilities, specifically as they relate to access to medicines, developed before and after the coming into force of TRIPS?

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25 See joint NGO Statement (n 16 above).

(iii) To what extent have institutional problems constrained OAPI countries from utilizing TRIPS public health flexibilities and what are the institutional problems within OAPI, such as (a) the failure by the OAPI Secretariat to initiate amendments; (b) local problems within OAPI member countries leading to a failure by the respective countries to push for such amendments; and (c) external/international factors, such as pressure from developed countries and multilateral bodies, that have constrained OAPI countries from using TRIPS public health flexibilities?

(iv) What legislative and other changes need to be effected to enhance the full use of public health flexibilities by OAPI countries?

1.3 Definition of concepts

The term 'OAPI region' refers to the 17 countries that are parties to the revised Bangui Agreement of 1999[26] regulating the African Intellectual Property Organisation (OAPI). These 17 countries are: Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Benin, Burkina Faso, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo.

The phrase 'TRIPS public health flexibilities' refers to flexibilities that exist within the TRIPS Agreement itself and the few that came into being after the adoption of TRIPS. Flexibilities in the context of TRIPS could be defined as policy spaces provided by the TRIPS Agreement, which WTO members could use without being held liable for breaches of the TRIPS Agreement. Public health flexibilities in the TRIPS Agreement can be categorised into two types: time-based and substantive flexibilities. Time-based flexibilities are in the form of transition periods,[27] which allow developing and least-developed countries

[26] The Revised Bangui Accord of 24 February 1999 http://www.wipo.int/wipolex/en/other_treaties/parties.jsp?treaty_id=227&group_id=21 (accessed 8 November 2015).

[27] Sisule & Oh (n 23 above) 5. The transition periods are (i) the 1995-2000 period at the end of which developing countries were obliged to implement the TRIPS Agreement; (ii) the 2000-2005 period, which provided an additional period of five years to put in place product patent protection pharmaceuticals or agro-chemicals for those countries without such protection at the entry into force of the Agreement; and (iii)the 1995-2006 period, after which least developed countries would be required to implement their TRIPS obligations. This period

additional time for the implementation of their TRIPS obligations.[28] The substantive flexibilities are texts that can be said to delineate the WTO legal framework for the protection of intellectual property rights in the context of the countries' right to protect the public, including promoting access to medicines.[29]

1.4 Significance of research

This study investigates and exposes TRIPS-plus problems in existing OAPI patent law and proposes instead the adoption and implementation of TRIPS public health flexibilities in a revised Bangui Agreement and/or within OAPI member countries. The study will add to the current discussions on how sub-Saharan African countries in general, and OAPI member countries in particular, could utilise TRIPS public health flexibilities to make medicines more accessible in their respective countries. In addition, the study will promote greater awareness of the right to health and of access to medicines among policy makers, lawyers, health practitioners, trade negotiators and patent officials. Lastly, the thesis will consider international best practices with regard to IP and access to medicines friendly laws and consider the extent to which they can provide guidance in the reform and revision of the current OAPI patent regime.

1.5 Literature review

Discussions on the problems hindering access to medicines, especially in sub-Saharan African countries, have gravitated around the WTO TRIPS patent regime. There is consensus that the WTO TRIPS regime and its subsequent declarations and decisions have not done much to alleviate the predicament of citizens of sub-Saharan African countries with regard to access to medicines.[30]

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has been extended to 2016 with respect to patents on pharmaceutical products and exclusive marketing rights.

28 As above.

29 As above. These texts are the TRIPS Agreement, the Doha Declaration and the WTO Decision on Paragraph 6.

30 T Pogge 'Medicines for the world: Boosting innovation without obstructing free access' (2008) 5 *SUR International Journal on Human Rights* 117.

Chaves, Vieira and Reis hold that the obligation to grant patents in many developing countries was imposed by the WTO TRIPS Agreement.[31] In their opinion, TRIPS completely overhauled existing legal regimes that permitted medicines to be produced locally at affordable prices by generic companies. In so doing, TRIPS radically changed the *status quo* and seriously undermined the universal access policies in force in certain developing countries such as Brazil.

These criticisms and the leadership of the African Group led to the adoption of the Doha Declaration, which confirmed, clarified and created certain flexibilities with respect to the TRIPS Agreement. This Declaration was followed by the August 2003 Decision. However, countries of the OAPI region have not made use of these flexibilities.

Some authors have held that the widespread lack of clarity about the options available, combined with the lack of local, legal and technical expertise to incorporate and implement TRIPS flexibilities in national law and policy, are the obvious and major problems facing countries to facilitate access to medicines.[32] Re-echoing this position in a conference held by *Medicins Sans Frontières* and other NGOs, Falou Samb of the Senegalese Mission to the WTO noted that OAPI countries face legal challenges in the revised Bangui Agreement and needed sample Doha-compliant legislation.[33]

In addition, the effects of the intellectual property-related policies of developed countries and recent free trade agreements (FTAs) have made it difficult for countries to fully utilise TRIPS public health flexibilities. Although this has not been the situation of OAPI member countries, it is feared that the EU might want to include an intellectual property chapter in the ongoing economic

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31 G Chaves et al 'Access to medicines and intellectual property in Brazil: Reflections and strategies of civil society' (2008) 5 (8) *SUR International Journal on Human Rights* 166.

32 Musungu & Oh (n 23 above) 68.

33 Statement by Falou Samb of the Senegalese Mission to the WTO on the occasion of the one-day conference on 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to get it right' by *Medecins Sans Frontières*, Consumer Project on Technology and Health Action International, 28 March 2002, International Conference Centre, Geneva, Switzerland.

partnership agreements (EPAs) with African, Caribbean and Pacific (ACP) countries (including OAPI countries). As noted by t'Hoen in her book, in their report to the European Parliament, Abbott and Reichman hold the view that the EU's insistence in the EPA's of ACP's adherence to the Patent Co-operation Treaty and the Patent Law Treaty and on its IP enforcement directives may have a negative effect on access to medicines.[34]

Another issue is that, to fully implement TRIPS public health flexibilities, countries are required to take public policy measures that actually enact TRIPS flexibilities.[35] As has been experienced in Thailand in the early 2000s, sometimes it is difficult, if not impossible, to take the measures referred to above as legislators do not understand much about the TRIPS Agreement or what is in fact underlying these flexibilities – the issue of public health.[36] This notwithstanding, it should be pointed out that Thailand eventually became one of the leading countries that have actually issued government-use compulsory licences.[37]

Gavin[38] and Deere[39] are of the opinion that OAPI countries have not been able to implement TRIPS public health flexibilities because the revised Bangui Agreement, which regulates intellectual property in the OAPI member states, was drafted with the assistance of WIPO and the French Intellectual Property Law Office.[40] This process resulted in what Gavin termed the 'TRIPS plus plus plus' provision in the Bangui Agreement. This position has been criticised for not reflecting the true decisional factors. It has been advanced that

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34 E t'Hoen *The global politics of pharmaceutical monopoly power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and public health* (2008) 72.

35 n 20 above.

36 Views expressed by Pornchai Danvivathana, member of the Thai delegation to the WTO on the occasion of the one-day conference (n 33 above).

37 See I Yamabha et al 'Government use licences in Thailand: An assessment of the health and economic impacts' (2011) *Globalisation and Health* http://www.globalizationandhealth.com/content/7/1/28 (accessed 6 July 2014).

38 Presentation by Catherine Gavin on the occasion of the one-day conference (n 33 above).

39 C Deere 'TRIPS implementation in Francophone Africa' in *Implementation game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries* (2009) 282.

40 Presentation by Catherine Gavin (n 38 above).

OAPI countries, and not WIPO, made the final decision on what should appear as provisions in the Bangui Agreement.[41]

This study aims to go further than the limited existing literature on the subject as concerns intellectual property and access to medicines in the OAPI region. Some of the issues raised in the existing literature are not peculiar to OAPI members. For instance, no country in the OAPI region is currently contemplating signing a free trade agreement with a developed or developing country that contains TRIPS plus provisions. In fact, the only FTA, the recently-concluded interim economic partnership agreements between the EU and Cameroon and the EU and Côte d'Ivoire, does not contain a chapter on intellectual property. Thus, it cannot be said that FTAs are hampering the implementation of TRIPS flexibilities in the OAPI region, although ill-advised agreements in the future might interfere with the full use of TRIPS public health flexibilities.

Furthermore, most of the examples cited by the works reviewed are drawn from countries from East and Southern Africa, which are mostly members of the African Regional Intellectual Property Organisation (ARIPO). This might not necessarily reflect the position of OAPI countries, as ARIPO has a British law intellectual property regime quite distinct from OAPI's Francophone-influenced regime.

In addition, as a result of different views as to the reasons why OAPI countries failed to fully incorporate TRIPS flexibilities in the Bangui Agreement (as highlighted in part of the literature review above), this research aims to investigate the reasons behind the non-incorporation.

It should be pointed out that discussions on access to medicines and IP rights have taken many dimensions. As pointed out in the thesis, there have been for instance, many discussions on IP, access to medicines and

41 M Ndjana, representative officer at the Intellectual Property Office in Cameroon, responding to the presentation by Gavin (n 38 above). See also comments from Roberto Castelo (then WIPO Deputy Director-General) during the said conference.

competition law and more importantly, IP, access to medicines and human rights. It should be noted that there is abundance of literature (books, articles, reports etc) linking IP, human rights and access to medicines.[42] The books, articles and reports are some of the important sources making that link between IP, human rights and access to medicines. These sources are important as background. They are being referred to in many instances in the thesis because of its link in the broader thematic area of IP and access to medicines to which this thesis is anchored. They are not fully discussed because this thesis has a more specific focus which is access to medicines in the OAPI region.

1.6 Research methodology

The approach in this study is descriptive, analytical, comparative and prescriptive. The descriptive approach is employed to provide an overview of the existing situation with regard to the use of TRIPS public health flexibilities. The analytical approach is employed to evaluate the compatibility of the OAPI regime with post-TRIPS developments, for instance, to assess the extent to which the Bangui Agreement has incorporated TRIPS public health flexibilities. A comparative approach is used to determine the ways in which other countries have incorporated these flexibilities. Such a comparison provides experience and best practices on the incorporation of TRIPS public health flexibilities from other countries, which OAPI member countries may replicate. Lastly, the prescriptive approach is used when, in conclusion, recommendations are formulated aimed at encouraging OAPI member states to effect legislative changes so as to take full advantage of the TRIPS public health flexibilities.

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[42] See for instance: 'HIV estimates annex table http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf. (accessed 8 November 2015); A Capling 'Intellectual property' in B Hocking & S McGuire (eds) Trade politics: International, domestic and regional perspectives (1999) 79; I Yamabha et al 'Government use licences in Thailand: An assessment of the health and economic impacts' (2011) Globalisation and Health http://www.globalizationandhealth.com/content/7/1/28 (accessed 8 November 2015) and Intellectual Property and Human Rights CHR Res 2001/21, UN ESCOR, Sub-Commission on Human Rights UN Doc. e/2001/23-e/cn.4/sub.2/res/2001/21 (2001); World Health Organisation (WHO) 'Data exclusivity and other TRIPS plus measures' Briefing note on access to medicines (2006) and H Brennan et al ' A human rights approach to intellectual property and access to medicines' (2013) 1 *Global Health Justice Partnership Policy Paper* http://apps.who.int/medicinedocs/documents/s20952en/s20952en.pdf (accessed on 7 November 20115)

Furthermore, intensive library research and desk-top literature-based review and to some extent an open-ended in-depth interviews are employed, entailing the gathering of and analysing available literature from the library, the internet and from key informants. Survey research is also employed, using the observational method of data collection suitable for investigating phenomena that can be observed directly by a researcher.[43] In view of the fact that all the issues may not be available from direct observation, discussions were organised with members of the OAPI legal department, members from health NGOs from the OAPI region, a WIPO expert[44] on IP access to medicine issues in Africa and scholars in the field, to fill this void.

In addition, in-depth and general interviews interviews[45] with stake holders, including the general counsel of OAPI, representatives from civil society organisations (CSOs) and NGOs, law lecturers and intellectual property practitioners, focusing on the adoption of the Bangui Agreement and their collective failure to adopt TRIPS flexibilities, are conducted. Some of the interviewees were selected through purposive sampling. This method enables the researcher to select samples based on experience or knowledge of the group.[46] The life situation or experiences of those in the group selected reflect the themes of the study.[47] Thus, some of the stake holders were selected on the basis of their experiences gained from either working at the OAPI headquarters or at their respective offices and dealing directly with intellectual property and access to medicine issues. In addition some of the selection was done on their availability, referrals and desk-top research of their work.
The interviews were used as a basis for general discussions and where pertinent issues were discussed with the interviewees, references to the interviewees and the discussions were included.

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43 C Nachmias & D Nachmias *Research methods in the social sciences: Study guide* (2007) 179.
44 Please find the list of interviewees as Annex 1 to this thesis.
45 As above.
46 R Jacobs 'Educational research: Sampling a population' (2009), http://www83.homepage.villanova.edu/richard.jacobs/EDU%208603/lessons/sampling.ppt#256 (accessed 1 June 2009).
47 S Sarantakos *Social research* (2004) 17.

Court decisions from certain countries, including South Africa, Kenya and Thailand, have been selected to examine how national courts have interpreted TRIPS flexibilities in the context of their national health exigencies. The cases examined are not exhaustive. Cases will keep coming up. However, their in-depth analysis of issues or independence amidst the pressure from different stake holders, especially foreign powers and pharmaceutical companies, could serve as inspiration and an eye-opener to national courts in the OAPI region.

From the above, both primary and secondary sources of information will be used.

The primary sources of information are as follows:

(a) the *travaux préparatoires* of the TRIPS Agreement, national policies and legislation on intellectual property rights and medicines regulation in the OAPI region;

(b) available data about access to medicines in each OAPI member country;

(c) all relevant treaties, such as the Revised Bangui Agreement of 1999, the TRIPS Agreement and subsequent amendments, the Vienna Convention on the Law of Treaties, the Doha Declaration on TRIPS and Public Health and the 30 August 2003 Decision; and

(d) information gathered from interviewing stakeholders from the OAPI countries; and

(e) decided cases from South Africa, Thailand and Kenya.

A list of questions and interviewees is annexed to the thesis.

The secondary sources of information are the following:

(a) text books on intellectual property law, trade law and international law;
(b) journal articles on intellectual property, public health and access to medicines; and
(c) reports from inter-governmental and non-governmental organisations.

1.7 Overview of chapters

The introductory chapter covers the background to the study, the research problem and questions, research methodology, significance of the research and chapter overview.

Chapter 2 examines the problems created by TRIPS in relation to access to medicines. It entails an analysis of some of its patent provisions and discusses the TRIPS Agreement and the stringent conditions that it attached to patents in relation to access to pharmaceuticals, especially by developing countries. It also highlights the criticisms from developing countries that triggered the Doha Declaration and the 30 August 2003 Decision.

Chapter 3 looks at post-TRIPS developments and the flexibilities that emerged from the process. These developments are the Doha Declaration, the August 30 Decision and the WTO Hong Kong Ministerial of 2005.

In Chapter 4, OAPI's patent regime is examined and the reasons why it has not incorporated TRIPS public health flexibilities are investigated, as well as the ways through which OAPI member countries can fully implement TRIPS-compliant flexibilities and what is needed to change the *status quo* are also considered.

In Chapter 5, a concluding analysis is supplemented by recommendations for amending the Bangui Agreement, especially the provisions dealing with patents and compulsory licences, the harnessing of regional approaches, building of a robust domestic legal system, and

establishing an enabling environment that will ensure and enhance access to medicines.

1.8 Scope and delineation of study

The study is limited to the implementation of TRIPS public health flexibilities in OAPI member countries. However, inferences will be drawn from the way leading developing countries, such as Brazil and India, and other sub-Saharan African countries have implemented TRIPS public health flexibilities.

It should be noted that the study is limited to events as of 1 May 2015. However, there have been recent discussions at the level of African Union (AU) countries to harmonise their intellectual property laws. The recommendations proffered in this study are relevant to the patents and access to medicines provisions of the prospective unified African intellectual property law.

CHAPTER 2: AN ANALYSIS OF TRIPS AND ITS PATENT PROVISIONS RELATIVE TO ACCESS TO MEDICINES

This chapter analyses the patent provisions of the TRIPS Agreement relative to access to medicines. The purpose is to examine the letter and spirit of the provisions, the controversies they have created, the manner in which developed, developing and least-developed countries have interpreted them and, lastly, the evolution of the interpretation of these provisions within the WTO.

More precisely, this chapter examines intellectual property standards established by TRIPS and the problems these standards create in relation to access to medicines in developing countries. This entails an analysis of its patent, data protection and enforcement provisions, as well as the flexibilities that exist with respect to these provisions. The chapter also discusses certain instances where intellectual property owners in developing countries brought lawsuits and threats of lawsuits and where developed countries brought trade pressures and other sanctions against countries that tried to use TRIPS-compliant flexibilities to ensure access to more affordable medicines. These pressures resulted in a counter-offensive by developing countries and AIDS activists, triggering the Doha Declaration and the 30 August 2003 Decision, which are explored in chapter 3.

2.1 Background to the adoption of the TRIPS patent regime relative to access to medicines

TRIPS saw its birth in 1995 following the entry into force of the Marrakesh Agreement creating the WTO.[1]

The WTO set in motion new developments with regard to international trade, generally, and intellectual property (IP) rights, in particular, that had not

[1] See Agreement on Trade Related Aspects of Intellectual Property Rights http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 6 December 2011).

been witnessed before. For the first time, the TRIPS Agreement set minimum globally-harmonised standards for IP protection that included strong enforcement provisions. Many arguments have been advanced as to why IP was included in the WTO Agreement, especially as there had already been many treaties[2] on IP and a multilateral UN organisation dealing with the subject – the World Intellectual Property Organization (WIPO). Many would have thought that with the presence of WIPO and the numerous treaties on IP, there would not be any need for another agreement, let alone one making IP a part of what was fundamentally a multilateral, tariff-lowering free trade agreement. However, this was not the case. A number of reasons have been advanced as to why another IP dispensation was created internationally, irrespective of the fact that WIPO already existed.

To begin with, there was pressure from the US for an inclusion of IP in the Uruguay Rounds negotiation. The US was not happy with the progress towards IP protection in WIPO and pointed out the failure of conferences between 1980 and 1984 to revise the Paris Convention on the protection of industrial property.[3] A survey by the US International Trade Commission in 1987 reported that US firms were losing some US $50 billion a year from a lack of overseas intellectual property protection.[4] It should be pointed out that, prior to the above-mentioned conferences of the 1980s and the US Trade Commission Report, there had been a mobilisation for stringent global IP protection from US IP industries, led by Pfizer.[5] In the decades before World War II, several US chemical and pharmaceutical companies had carved a niche for themselves and were making profits locally.[6] Given the increased trade relations between the US and Europe, these companies could have anticipated selling to the broader European and Japanese markets. However, with increasing domestic and international competition, they targeted the large

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2 Eg, the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Work (1886).

3 A Adede 'Origins and history of the TRIPS negotiations' in C Bellman et al (eds) *Trading in knowledge: Development perspectives on TRIPS and sustainability* (2003) 25.

4 As above.

5 P Drahos & J Braithwaite 'Who owns the knowledge economy: Political organising behind TRIPS' http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy (accessed 27 December 2011).

6 As above.

untapped market of developing countries and firmly established themselves in these countries as well.[7] Even though the markets of these countries were relatively small, they were emerging and had large populations and therefore were attractive for future growth. However, a constellation of factors frustrated the pharmaceutical industry, including the failure to achieve harmonisation concerning pharmaceutical and food-related product patents and to prevent discrimination against the fields of technology; the potential of an increased use of compulsory licences; and the passage of IP laws by developing countries designed to suit their development objectives.[8] This frustration gave rise to the fear of losing present and potential business.

More disturbingly, developing countries such as India started exporting generic versions of brand medicines to previously untapped markets in Africa as well as to rich markets, such as Canada. With such a disturbing outlook, members of big businesses became more involved in the Advisory Committee on Trade Negotiations (ACTN), which was a committee created by the US Congress in 1974 with the aim of 'ensuring that US trade policy and trade negotiation objective adequately reflect US commercial and economic interests'.[9] With Pfizer's chief executive officer, Edmund Pratt, at the helm of ACTN, a task force on IP was created which developed a 'trade-based intellectual property strategy' consisting of three parts: multilateralism, bilateralism and unilateralism.[10] Multilateralism was aimed at developing IP standards to be binding on all parties during GATT negotiations and was to have a dispute settlement mechanism; bilateralism was aimed at the US having negotiations with countries that did not sufficiently protect US intellectual property with a view of obtaining agreements from the said countries leading to better protection; while unilateralism was to the effect that the US should threaten or actually impose sanctions on countries that did not adopt or enforce higher standards of IP protection.[11] The outcomes of this approach were that,

7 As above.
8 As above.
9 As above.
10 As above.
11 Drahos & Braithwaite (n 5 above), citing 'Summary of the Recommendations of the Advisory Committee on Trade Negotiations', Task Force on Intellectual Property, undated;

for the first time, the US linked the extension of benefits to countries under the Generalised System of Preference (GSP) scheme[12] to how well the countries seeking benefits protected IP. In addition, the US amended section 301 of the Trade Act in 1984 to give its President powers to withdraw trade benefits from countries that did not provide 'adequate and effective' protection to US IP assets.[13] Under this amendment, the US Trade Representative (USTR) could initiate an action against a country or any interested person could petition the USTR to initiate an action. In 1988, a Special Section 301 was added 'requiring the USTR to identify within six to nine months those countries that denied "adequate and effective protection" of intellectual property rights or that denied "fair and equitable market access" to US intellectual property owners'. Countries were then placed into three categories: watch list, priority watch list and priority foreign country,[14] with countries in the latter category facing the risk of trade sanctions by the US.[15]

The big US companies not only put pressure on their government, but also went international by co-opting European and Japanese companies to join the US in support of IP industries' quest for a stringent global IP regime.[16] In 1986, the Intellectual Property Committee was created, made up of 13 US companies.[17] This Committee sought membership from its European and Japanese counterparts.[18] Initially, the Europeans and Japanese were not keen on joining the Committee.[19] This is because in Europe, most of the countries

'Summary of the Phase II: Recommendations of the Task Force on Intellectual Property to the Advisory Committee for Trade Negotiations', March 1986.

12 Generalised System of Preferences was developed by the UN Conference on Trade and Development (UNCTAD) in 1970. It was an attempt to create real bonds of trade between northern and southern countries. Under this system, a country allowed designated countries to export eligible products into its territory duty free.

13 Trade and Tariff Act of the USA.

14 To put a country on the watch list was to send it a message about its unsatisfactory intellectual property practices. If it did nothing to shut down its piracy, it would be upgraded to the priority watch list. The USTR typically formed a set of precise objectives for the relevant country to work towards. Countries with the worst records on intellectual property were tagged 'priority foreign countries', which led to a US investigation of their laws and practices on intellectual property.

15 S Flynn 'What is a special 301: A historical primer' http://infojustice.org/archives/29465 (accessed 20 December 2013).

16 Drahos & Braithwaite (n 5 above).

17 As above.

18 As above.

19 As above.

had varying standards of IP protection while in Japan, it was difficult to achieve consensus amongst the big corporations.[20] However, industrialists in these countries later took an active position on IP protection, joined IPC and subsequently pressured their respective governments to put IP protection on the trade negotiation agenda.[21]

During the above period, there was a movement advocating for the removal of intellectual property issues from the control of WIPO to another forum. This is because by the mid-1980s, many developing countries had joined WIPO and had started pushing for a development-friendly IP regime. They wanted the Paris Convention to be revised and 'for access to the technology of multinationals to be granted on favourable terms'.[22] For instance, developing countries wanted provisions that would make it easy for governments to authorise someone to use a patented invention without the consent of the patent holder, a move that was considered unacceptable by the US. During the subsequent revision conferences, the US found itself defending the Paris Convention, rather than advocating for a stringent IP regime.[23] As a result, the US and other industrialised countries concluded that WIPO was not the best forum and a new forum was thus appropriate to give effect to their demands.[24]

In addition, prior to and during that same era, there was the rise of newly-industrialised Asian countries such as Taiwan that competed favourably with Western European countries and the US in the production of certain products - especially consumer electronics and high-tech goods - which the US and the Western European countries thought were under their exclusive preserve. The erosion of the technological leadership of US firms coupled with the high US trade deficit was partially attributed to an overly-open technological and scientific system, which allowed foreign countries to imitate and profit from US

20 As above.
21 As above.
22 As above.
23 HP Kunz-Hallstein 'The United States proposal for a GATT agreement on intellectual property and the Paris Convention for the Protection of Industrial Property' (1989) 22 *Vanderbilt Journal of Transnational Law* 265.
24 As above.

innovations.[25] Thus, a major source of declining American competitiveness was conceived to be the losses resulting from overseas weakness or a breach of intellectual property rights.[26] As a result, American patent rights holders took the lead in the formation of an IP alliance advocating for more stringent IP protection.

As a result of the above, there was consensus among Western countries that something had to be done, and the idea of taking up the issue of IP within the GATT framework began to receive support in the US and elsewhere.[27] It is suggested that consensus - if everyone agreed, US could push through and achieve its wish of stringent IP protection - was one of the reasons that motivated the US to advocate for the inclusion of TRIPS in the Uruguay Round negotiations. This is because consensus would usher in the amendments leading to the US's goals of achieving a strong IP regime. However, the inclusion of TRIPS on the agenda of the Uruguay Round did not mean that the developing countries had abandoned their reluctance to have IP rights discussed in the GATT forum.[28] By expanding the scope of issues for discussion, ranging from the TRIPS Agreement and potentially to those aimed at producing a series of agreements in other areas, such as agriculture and textiles, the Uruguay Round was billed as presenting a unique opportunity for developing countries to achieve tangible gains.[29] In fact, US officials had given them the assurance that their jurisdictional arguments of not including IP within the GATT forum would be taken into account during the negotiating process.[30] However, these assurances were not totally met, as is evident from the adoption of the TRIPS Agreement. For instance, although developing countries were able to win concessions on compulsory licensing, articles 7 and 8, transition periods and data protection, in the main, important issues such as

25 CM Correa *Intellectual property, the WTO and developing countries: The TRIPS Agreement and policy options* (2000) 3.
26 As above.
27 Adede (n 3 above).
28 As above.
29 As above.
30 Drahos & Braithwaite (n 5 above).

textile gains were postponed for ten years and some issues, such as agricultural market access, still remain largely unredressed.[31]

Two broad groups - the Group on Negotiation of Goods and the Group on Negotiation of Services - were created and given a mandate to negotiate specific issues as part of the Uruguay Round. These two broad groups had sub-groups. Group 11 was in charge of negotiating IP issues. Western countries held a series of meetings from 1986 to 1990, coming up with many draft texts attempting to define the scope and provisions of TRIPS, submitting a total of 97 working documents. The last of such meetings took place in Brussels from 3 to 7 December 1990, which set the last basis for negotiations culminating in the tabling of the Draft Final Act in December 1991.[32] It should be pointed out that there was opposition from developing countries. Led by Brazil and India, developing countries insisted that GATT was not the proper forum to negotiate a comprehensive IP agreement.[33] The response of the US to this opposition was to invoke amended section 301 of its Trade Act.[34] Brazil, together with other developing countries, found itself listed on the priority foreign country list, making Brazil to finally give up its opposition and accede to the US demand that it would adopt legislation on patent protection for pharmaceutical products.[35] Meanwhile, allegations of India's non-committal to the interests of other developing countries were making the rounds and India's failure to attend a crucial meeting organised by developing countries only served to confirm that rumour.[36] Seeing itself gradually isolated by both developing and Western countries, coupled with a domestic policy shift towards liberalisation, India sent delegates to the negotiations and signed the final act of the Marrakesh Agreement.[37] This could have affected the possibility of having a strong opposition against the negotiation of IP issues during the Uruguay Round.

Some commentators have expressed the view that the process of drafting

31 As above.
32 As above.
33 As above.
34 As above.
35 As above.
36 As above.
37 As above.

TRIPS can hardly be considered as having been a real negotiating process. They have advanced varied reasons, ranging from a fear of retaliation to the influence exerted by powerful multinational companies (MNCs). Shiva holds the view that GATT members did not negotiate TRIPS; it was only imposed by MNCs who used the US government to force it on the other members.[38] He contends that the basic framework for TRIPS was conceived and shaped in a joint statement presented to the GATT Secretariat in June 1988 by the Intellectual Property Committee (IPC)[39] of the US and the industry associations of Japan and Europe. Developing countries could have opted for the bargain/exchange theory whereby they could have concluded the TRIPS Agreement with the promise and expectation to have benefits in current and future negotiations of agreements on agriculture and textiles. However, this was not possible, given the strong pressure of the multinationals exerted through their countries.

In addition to establishing new minimum standards for patents, copyright, trademarks and other IP rights, TRIPS set up a dispute settlement mechanism, which has as objective reviewing cases of alleged breaches of the WTO Agreement and rendering decisions.[40] For the first time, countries could utilise the highly-effective dispute settlement mechanism established by the WTO in instances of alleged breaches of IP rights enshrined in TRIPS. The dispute settlement body has powers to order countries to review policies that are inconsistent with WTO provisions, and could further authorise complainants to impose trade sanctions. It should be noted that prior to the establishment of the WTO, GATT had no such enforceable state/state dispute settlement mechanism.

Developing countries reluctantly negotiated increased standards of protection for IP in the Uruguay Round, and finally acquiesced to making

38 V Shiva *Protect or plunder? Understanding intellectual property rights* (2001) 95.

39 IPC is a coalition of 13 major US corporations dedicated to the finalisation of TRIPS in their favour. The members of IPC are corporations such as Bristol Myers, Dupont, General Electric, General Motors, Hewlett Packard, Johnson and Johnson, Merck, Monsanto, Pfizer, Rockwell and Warner.

40 Art 4-22 of the WTO Dispute Settlement Understanding.

important concessions in terms of reforms of their intellectual property legislation, without obtaining any real compensating concessions from industrialised countries, except for the promises of future textile and agricultural access.[41] The main IP concession gained by the developing world, if it was a concession at all, was the provision in the Agreement for a transition period of five years for developing countries, ten years for countries that did not provide for pharmaceutical patents and 11 years for least-developed countries to bring their legislation in line with the TRIPS Agreement.[42] It should, however, be noted that the transition period for least-developed countries was first extended to 1 July 2013 with respect to TRIPS, generally, which was further extended to 1 July 2021. There is an additional LDC extension until 1 January 2016 with respect to pharmaceutical products, data protection and market exclusivity.[43] Countries also retained certain flexibilities, including standards of patentability, space for pre-grant oppositions, exemptions from patentability, limited exceptions, compulsory and government-use licences, parallel importation, data protection, and other matters discussed further below.

2.2 Basic requirements of the TRIPS Agreement relative to patents, access to medicines and human rights

2.2.1 Meaning of access to medicines: A human rights perspective

Through the adoption of the TRIPS Agreement in 1994, WTO members sought to implement harmonised minimum standards of international protection of

41 Correa (n 25 above) 3.
42 See http://www.southcentre.org (accessed 24 August 2010).
43 Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, Decision of the Council for TRIPS of 27 June 2002 and Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products Decision of the Council for TRIPS of 11 June 2013. See also art 70.9 of TRIPS, which provides that '[w]here a product is the subject of a patent application in a member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that member or until a product patent is granted or rejected in that member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another member and marketing approval obtained in such other member'.

intellectual property rights.[44] It should be pointed out that harmonisation did not entail standardisation, as article 1(1) states as follows: 'Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.' At first glance, one would be inclined to conclude that this provision presupposes countries to be at different development stages and, as such, allows them to comply with certain aspects of TRIPS, taking into consideration their level of development. However, a further reading of the article reveals a different perspective which, unfortunately, makes TRIPS a floor, not a ceiling. This is because article 1(1) provides:

> Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.

Nonetheless, article 1(1) does allow countries a significant degree of interpretive freedom in setting legislative standards for the implementation and enforcement of TRIPS-mandated IP protection.

With respect to flexibilities, article 8(1) of the TRIPS Agreement allows members to 'adopt measures necessary to protect public health and nutrition' so long as they are 'consistent' with other provisions of the Agreement.[45] Article 7 provides that 'the protection and enforcement of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology', to the mutual benefit of rights owners and rights users in 'a manner conducive to social and economic welfare, and to a balance of rights and obligations'.[46] By so providing, countries' health and nutritional requirements and the balancing of owners' and users' interests were recognised as cognisable public interests in the TRIPS Agreement and, by

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44 See Agreement on Trade Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal instruments - Results of the Uruguay Round Vol 31, 33 ILM 81 (1994) (setting minimal standards of protection of intellectual property rights to be recognised by all member countries of the WTO).

45 See art 8 of the TRIPS Agreement.

46 Art 7 TRIPS Agreement.

implication, the WTO Agreement as well, whose overall aim was to promote trade liberalisation. However, there are also strict constructionist, pro-IP interpretations of TRIPS whereby TRIPS should be interpreted to mean that if members' measures were so protective of public interest so as to negatively impact IP rights, specifically, and trade liberalisation, more broadly, then the measures would not pass muster in light of the WTO's spirit, goals and objectives.

It should be pointed out that articles 7 and 8 have been interpreted differently by WTO members. This was highlighted in the case of *Canada - Patent Protection of Pharmaceutical Products*[47] (discussed at length below). In that case, replying to the EC's challenge on its regulatory review and stockpiling exceptions in its patent law, Canada was of the view that articles 7 and 8 of TRIPS

> call for a liberal interpretation of the three conditions stated in Article 30 of the Agreement, so that governments would have the necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies,

adding the following:

> Article 7 … declares that one of the key goals of the TRIPS Agreement was a balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO member governments. Article 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies.

The European Community (EC) took a different view. As the WTO Panel stated in its judgment, the EC was of the view that articles 7 and 8 described the balancing of goals during the negotiating phase of the TRIPS Agreement and were not meant for a liberal interpretation of other national policies. If this were to be the case, it would mean article 30 would give governments the leeway to renegotiate the balance sought and achieved during the negotiations of TRIPS. The EC further argued that article 8(1) of TRIPS obliged members to implement

[47] World Trade Organization (2000) *Canada - Patent Protection of Pharmaceutical Products*, Panel Report, WT/DS114/R.

measures that are consistent with the TRIPS Agreement. A liberal and broad interpretation of article 30 would be beyond what is provided for in the TRIPS Agreement. The WTO Panel took a compromised position by finding as follows:

> In the Panel's view, Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions.[48]

In addition, the Panel was of the view that the words defining the conditions should be carefully analysed and that the objectives of the limitations provided for articles 7 and 8(1) should be taken into consideration as well as the other articles of TRIPS which mention its objects and purposes.[49]

The views of the Panel brought mixed reactions from experts and scholars. Some were of the view that the Panel's findings 'would perpetuate the unfairness of the TRIPS Agreement and take away the member states' needed discretion in developing its public policies'.[50] Others argued that judicial activism and loose interpretation would allow developing countries to achieve their public health policy objectives, although judicial activism might be hurtful, in view of the fact that developing countries, compared to developed counties, have not brought cases on the subject at the level of the WTO.[51]

Despite the above, neither subsequent panels nor appellate bodies have gone any further in coming up with an authoritative interpretation of articles 7

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48 As above.
49 As above.
50 See R Howse 'The Canadian generic medicines panel: A dangerous precedent in dangerous times' (2002) 3 *Journal of World Intellectual Property* 493; R Okediji 'Public welfare and the role of the WTO: Reconsidering the TRIPS agreement'(2003) *Emory International Law Review* 915.
51 P Yu 'The objectives and principles of the TRIPS Agreement' 5 http://www.peteryu.com/correa.pdf (accessed 3 January 2012).

and 8. This inertia was acknowledged by the appellate body in the case of *Canada - Term of Patent Protection*, where it stated that it had yet to determine

> the applicability of article 7 or article 8 of the TRIPS Agreement in possible future cases with respect to measures to promote the policy objectives of the WTO members that are set out in those articles and that [t]hose Articles still await appropriate interpretation.[52]

There is no clear-cut definition of what access to medicines entails. Usually, and in the context of public health and international law and intellectual property, recourse is had to paragraph 12 of General Comment 14 on article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) dealing with the right to the highest attainable standard of health. The ICESCR is binding on countries that have ratified it. In ratifying the ICESCR, states must undertake

> to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.[53]

Ratifying states must also

> guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.[54]

The committee in charge of monitoring compliance with the ICESCR is the Committee on Economic, Social and Cultural Rights (ESCR Committee), which from time to time issues General Comments that serve as interpretative guides

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52 World Trade Organization (2000) *Canada - Term of Patent Protection*, Appellate Body Report, WT/DS170/AB/R, para 101.
53 Art 2(1) ICESCR.
54 Art 2(2) ICESCR.

of the ICESCR provisions. The principal ESCR Committee General Comment with respect to the right to health is General Comment 14.

General Comment 14 paragraph 12 provides that '[t]he right to health in all its forms and at all levels contains the following interrelated and essential elements availability, [a]ccessibility, [a]cceptability and [q]uality'.[55]

Availability implies a functional health care system that delivers the needed supply of medicines. Accessibility implies the availability of medicines to all without any form of discrimination; it also entails the nearness of the health facilities or medicines to the entire population and the affordability of such medicines or health facilities by the population. Acceptability means the respect of cultural and other ethical norms within health facilities or, in the case of medicines, when they are distributed or given out. Quality means that the medicines or health facilities satisfy the purpose for which they are made or provided and meet the required quality and other standards associated with them.[56]

From the above, one can safely say that access to medicines is an amalgam of many obligations – non-discrimination, ensuring quality, ensuring affordability and, above all, ensuring economic, physical and informational access to medicines. One issue worth considering is to what extent the General Comments are binding and whether or not the relevant General Comments will defer to a country's commercial interests and other economic interests, especially when these are in conflict with the right of access to medicines. In the context of the UN, General Comments are 'comments that are directed to all state parties that clarify states' obligations and interpret the substantive provisions of a given treaty or covenant'.[57] Blake is of the view that they 'can be viewed as authoritative interpretative instruments, which give rise to a

55 General Comment 14 The right to the highest attainable standard of health 2000/08/11 E/C.12/2000/4..
56 General Comment 14 (n 55 above) para 12.
57 HJ Steiner 'Individual claims in a world of massive violations: What role for the Human Rights Committee' in P Alston & J Crawford (eds) *The future of UN human rights treaty monitoring* (2000) 21.

normative consensus on the meaning and scope of particular human rights'.[58] According to Marsh,[59] 'they lend a significant degree of legal authority', provide 'an authoritative guidance to a broader group of states' and, lastly, 'reinforce the necessary linkages to other international human rights organs and the international system as a whole'. Some national courts and international tribunals have conferred on them considerable weight. For instance, Japan's Osaka High Court declared in 1994 that 'general comments … should be relied upon as supplemental means of interpretation'.[60] Internationally, the European Court of Human Rights,[61] the African Commission on Human and Peoples' Rights (African Commission),[62] the UN Committee Against Torture (CAT Committee)[63] and the International Criminal Tribunal for the Former Yugoslavia (ICTY)[64] have all applied General Comments in their decisions.

From the foregoing, ensuring access to medicines – while meeting the standard of availability, affordability, accessibility and quality – is thus an international obligation on state parties to the ICESCR. It follows that a country should not pursue strategies or options that are contrary to the spirit and letter of the ICESCR or to the more specific mandates of General Comment 14.

After the above analysis of General Comment 14, it would be instructive to discuss the link between IP and human rights, in order words, answer the question: Are IP rights human rights?

The debate as to whether IP rights are human rights has persisted for a long time. Experts, scholars and academics have divergent views. Scholars

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58 C Blake 'Normative instruments in international human rights law: Locating the General Comment' Center for Human Rights and Global Justice, NYU School of Law, 2002.

59 E Marsh 'Overseeing the refugee convention' http://www.icva.ch/doc00000486.html#4 (accessed 2 September 2011).

60 Y Iwasawa 'The domestic impact of international human rights standards: The Japanese experience' in Alston & Crawford (n 57 above).

61 See, eg, the cases of *Hirst v United Kingdom* (No. 2) Application 74025/01 (2005); and *Öcalan v Turkey* Application 46221/99 (2005).

62 See the case of *Social and Economic Rights Action Centre (SERAC) & Another v Nigeria* (2001) AHRLR 60 (ACHPR 2001).

63 Communication 282/2005; *SPA v Canada*.

64 *Prosecutor v Milosevic*, Case IT-99-37-PT, Decision on Preliminary Motions (8 November 2001).

pointing to IP as a human right usually make reference to international human rights treaties containing provisions on property rights, including IP. The starting point is usually the Universal Declaration of Human Rights (Universal Declaration). Article 17 of the Universal Declaration provides as follows:

> (1) Everyone has the right to own property alone as well as in association with others.
> (2) No one shall be arbitrarily deprived of his property.

More importantly, article 27(2) provides that '[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. Article 15(1)(c) of the ICESCR echoes article 27(2) of the Universal Declaration by recognising the right of everyone '[t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'.

Irrespective of the above provisions, others have pointed out the existing tensions between IP and human rights as such, creating the assumption that they are 'strange bed fellows' and are therefore different.[65] For instance, the UN Sub-Commission on the Promotion and Protection of Human Rights in its Resolution 2000/7 states:

> Since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health … there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS agreement, on the one hand, and international human rights law, on the other.[66]

In addition, it has been argued that, although implicitly mentioned in international human rights treaties such as the Universal Declaration and the ICESCR, IP rights cannot be considered as human rights as they are 'limited in

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65 See *Intellectual Property and Human Rights* CHR Res 2001/21, UN ESCOR, Sub-Commission on Human Rights UN Doc. e/2001/23-e/cn.4/sub.2/res/2001/21 (2001).
66 As above.

time and space', unlike human rights.[67] In addition, while human rights are inalienable, inviolable and irrevocable, IP rights are not.[68] General Comment 17 put it more aptly by providing as follows:

> In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person …[69]

One notes from the foregoing that there is discord as to the question whether IP rights are human rights or not. In my opinion, IP rights should be interpreted in such a way that their protection does not lead to a violation of other human rights and, more specifically, the right to health. It should be pointed out that there are other human rights besides the right to health that may be negatively impacted by IP supremacy, such as the right to education (excessive copyright) and the right to food (excessive IP rights on plant and animal varieties). In the present case, however, I am referring to the right to health and the correlative right to access to medicines. In other words, IP rights should be considered as a special species of human rights, which must give way in situations where strong protection would lead to undesirable results from an access to medicines perspective. Interpreting, linking and limiting IP rights within the human rights discourse could be a 'crucial step in the project of articulating theories and policies that will guide … the adjustment of existing intellectual property rights and the creation of new ones'.[70] In this light, states together with international

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67 Centre for Human Rights, University of Pretoria *Access to medicines course book (Reader)* (2011) (unpublished) 21. For a detailed discussion on IP and human rights, see generally A Chapman 'A human rights approach to health care reform' in A Chapman (ed) *Health care reform: A human rights approach* (1999) 153; A Chapman 'A "violations approach" for monitoring the International Covenant on Economic, Social and Cultural Rights' (1996) 18 *Human Rights Quarterly* 23-66; A Chapman *Human rights perspective on intellectual property, scientific progress, and access to the benefit of science* (1999) 22.

68 As above.

69 ESCR Committee General Comment 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. UN Doc.E/C.12/GC/17, 12 January 2006 para 2.

70 P Drahos *The universality of intellectual property rights: Origins and development* (1999) 24.

institutions should 'ensure that international agreements relating to the protection of intellectual property do not result in violation of the human right to essential medicines'.[71] In addition, states and international institutions should ensure that '[o]n the national and global levels, all policy decisions or agreements likely to have a significant effect on health should be preceded by a transparent and independent health impact assessment'.[72]

2.2.2 Some general obligations of TRIPS: National treatment and most-favoured nation requirements

Part one of the TRIPS Agreement sets out the general provisions and basic requirements. Under article 3, members are obliged to treat nationals of other member states no less favourably than they would treat their own nationals, except in relation to judicial and administrative procedures and

> where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

In addition, article 4 provides that if a member were to accord special treatment to one member, they are obliged to accord such treatment immediately and unconditionally to all other members, except where it was derived from international agreements not directly confined to the protection of intellectual property. This is generally referred to as the most-favoured nation provision.

One of the underlying bases of the two obligations is to promote non-discrimination. Under the TRIPS Agreement and within the context of patents, non-discrimination is provided for in article 27, which states as follows:

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71 Para 13 of the Montreal Statement on the Human Right to Essential Medicines, 2006. See also J Harrington & M Stuttafort (eds) *Global health and human rights: Legal and philosophical perspectives* (2010) 200.

72 Para 13 of the Montreal Statement on the Human Right to Essential Medicines, 2006.

> Subject to para 4 of Art 65, para 8 of Art 70 and para 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Some authors have considered the extent to which article 27 limits the permissible types of exceptions to patentees' rights.[73] They offer two broad interpretations of discrimination within the context of article 27.[74] They contend that 'discrimination' might simply mean to 'differentiate or make a distinction between' or, alternatively, 'discrimination' might be to treat differently 'on a basis other than merit'.[75] The implication of the first interpretation is that any exception that applied to one field of technology but not to another would be impermissible while, with regard to the second interpretation, exceptions would be permissible even if confined to particular technological fields, where there was some 'merit-based' reason to do so.[76]

2.2.3 Patent rights, exceptions to patents, limited exceptions, and compulsory licences

Patents and compulsory licensing are the two major concepts that come into play when one looks at the TRIPS Agreement and access to medicines. A patent can be defined as

> a legal title granted by the state in a specific country that gives exclusive rights over the manufacture and use of an invention to the owner of this invention in that country in exchange for the full disclosure of the invention to the public.[77]

As per article 27(1) of the TRIPS Agreement, patents must be granted on any kind of invention in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application. There are explicit exemptions from patentable subject matter for diagnostic, therapeutic and

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73 L Bently et al *Exclusions from patentability and exceptions and limitations to patentees' rights* (2010) Study prepared for the WIPO Standing Committee on the Law of Patents 40.
74 As above.
75 As above.
76 As above.
77 'Patent situation of HIV/AIDS-related drugs in 80 countries' Joint UNAIDS/WHO publication (January 2000) Geneva.

surgical methods for the treatment of humans or animals and for inventions that would be against public policy.[78] (These exceptions are discussed later in the chapter.) However, there is also other excludable subject matter, exercised differently by different countries, including, for example, discoveries, computer programmes, business methods, abstract ideas and theories, isolated genes and other products isolated from nature, and plant and animal varieties. These exclusions, though not expressly provided for by TRIPS, have been used in certain countries. For instance, in the US, abstract ideas have been excluded from patentability. The exclusion for abstract ideas, among other things, is to prevent patenting 'basic tools of scientific and technological work' because patenting such discoveries 'might tend to impede innovation more than it would tend to promote it'.[79] Recently, the Supreme Court of the US has refused to grant patents on a computer-implemented, electronic escrow service for facilitating financial transactions, stating that that they were invalid because the patented claims were drawn to an abstract idea, and that implementing those claims on a computer was not enough to transform that idea to a patentable invention.[80] It should also be pointed out that the Indian Patent Act (as amended)[81] contains a long list of some of the exclusions to patentability mentioned above. Under section 3 of the Indian Patent Act,[82] the following are excluded from patentability: 'the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature';[83] 'plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and species

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78 Art 27 of TRIPS. Arts 27(2) & (3) provide: 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law' and 'Members may also exclude from patentability:(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'

79 Bently (n 73 above).

80 *CLS Bank Internationalv Alice Corp (Pty) Ltd* 768 F Supp 2d 221, 242-255 (DDC 2011).

81 Indian Patents Act 1970 (as amended in 2005).

82 As above.

83 Sec 3(C) Indian Patents Act 1970.

and essentially biological processes for production or propagation of plants and animals';[84] 'a mathematical or business method or a computer programme *per se* or algorithms'.[85]

Depending on whether the subject matter is a product or a process, a patent confers certain rights on the patent holder. When the subject matter of the patent is a product, the patent holder will have the exclusive right to prevent a third party who does not have the patent holder's consent 'from the acts of making, using, offering for sale, selling or importing for these purposes that product'.[86] Similarly, where the subject matter of a patent is a process, the patent holder will have the exclusive right to prevent third parties who do not have the owner's consent from the act of using the process, and from the acts of 'using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process'.[87] In addition, these rights are to be protected 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.[88] (The way in which the WTO Panel has interpreted this provision is examined later in the chapter.)

These rights of the patent holder are protected for a minimum period of 20 years under article 33 of the TRIPS Agreement. Patent protection under TRIPS has taken a minimum standard approach. The 20-year threshold is the minimum period, but countries are free to incorporate a longer period within their national laws. However, this 20-year threshold was not immediately applicable to least-developed countries (LDCs) because of the TRIPS transition period found in article 66. Nevertheless, a cursory look at some LDCs, especially those in Africa, shows that they have improvidently opted for the 20-year protection period, even though they are at liberty and under no legal obligation to implement the 20-year period within their domestic law. A clear

84 Sec 3(J) Indian Patents Act 1970.
85 Sec 3(K) Indian Patents Act.
86 Art 28 TRIPS.
87 As above.
88 Art 27 TRIPS.

example (as will be discussed in great length in chapter four)[89] are LDCs that are members of the African Intellectual Property Organisation (OAPI), who are signatories to the Bangui Accord, which contains a 20-year period for patent protection in all OAPI countries, including those that are LDCs.

It should be pointed out that there are certain exceptions to patentability. As discussed in chapter three, these exceptions are considered as flexibilities. They are broadly grouped into two categories: 'time-based flexibilities' and 'substantive flexibilities'. Time-based flexibilities consist of three transition periods for the implementation of the TRIPS Agreement, allowed in respect of developing and least-developed countries and a transition period dealing with transitional economies, while substantive flexibilities include implementation flexibilities under article 1(1); exemptions from patentability under articles 27(2) and 27(3); limited exceptions under article 30; compulsory licences/government-use under article 31; parallel importation under article 6, and competition-based flexibilities under articles 8(2), 31(k) and 40. In addition to these explicit textual flexibilities, there are other flexibilities that have been read into or implied from TRIPS because of interpretive ambiguities or implementation flexibilities or because of the absence of prohibition, such as the flexibility to adopt high or stringent standards of patentability (novelty, inventive step, industrial applicability and disclosure), to allow pre- and post-grant opposition procedures, to enact streamlined administrative procedures for compulsory and government-use licences and to allow judicially-granted licences, to adopt data protection rather than data exclusivity. These exceptions are discussed in greater detail in the next chapter.

2.2.4 Article 31(f) and the problems it created

One of the more controversial clauses contained in the TRIPS compulsory licence provision is article 31(f). It provides that 'any such use [of a compulsory licence] shall be authorised predominantly for the supply of the domestic market of the member authorising such use'. This has the practical effect of preventing

89 See ch 4 of this thesis.

exports of predominate portions of generic drugs (more than 49 per cent) to countries that do not themselves have significant pharmaceutical industries.[90]

The limitation imposed by article 31(f) created two inter-linked problems. First, by restricting the quantity of medicines that might be exported pursuant to a compulsory licence, article 31(f) limited access for importing countries that did not have sufficient local capacity to manufacture domestically. Even when such capacity-constrained countries properly exercise a domestic compulsory licence to overcome a domestic patent, they could only import sub-predominant quantities from another country if that country must in turn also issue a compulsory licence to bypass a patent on the medicine. Paradoxically, even where patent protection was not in force in the importing country, article 31(f) could still negatively impact the availability of imported generic drugs produced pursuant to a foreign compulsory licence if those drugs were patented in manufacturing countries. Second, by requiring compulsory licences to supply a predominant part of their production to the domestic market, it limited the flexibility of countries to authorise the export of compulsory-licensed drugs and thereby to exploit economies of scale.[91] (Note, however, that, pursuant to article 31(k), competition-based licences have no such quantity restriction.)

In addition, article 31(f) created more difficulties on the supply side of the generic drug pipeline than on the demand side. With regard to the demand side, if a developing member lacks manufacturing capacity for a particular drug, and there are no members that are able to supply it by export under compulsory licence (or exception), there may be no affordable supply of the drug.[92]

The supply side problem is identified because there are WTO members, including developing members, with the capacity to address the drug import needs of a wide range of developing members under compulsory licence, but who may be inhibited from undertaking this role because of the article 31(f)

90 FM Abbott 'The TRIPS Agreement, access to medicines and the WTO Doha Ministerial Conference' (2001) Quaker United Nations Office, Geneva, Occasional Paper 13.
91 Abbott (n 90 above) 27.
92 As above.

limitation.[93] India is such a country, because it has a large generic industry, but newer medicines, invented post-1995, that are likely to be patented in India and would thus require a compulsory licence if generic competition is desired.

As a result of the problem created by article 31(f), WTO members adopted the 30 August 2003 Decision, which is discussed at length in the next chapter.

2.2.5 Patent and competition law/policy

Although patent rights are monopolistic, especially with regard to the rights conferred to patent owners by article 28, some provisions in TRIPS seek to prevent and redress the abuse of patent rights that adversely impact patent users. TRIPS does this by allowing members to take measures to prevent anti-competitive practices. Implicit and explicit references to the use of competition law/policies can be discerned from articles 7, 8, 31(k) and 40. Article 7 provides that IP enforcement and protection should be to the mutual benefit of rights holders and rights users. Article 8(2) goes further by giving members the leeway to adopt measures to prevent abuse by the patent owner. When read together, articles 7 and 8(1) mean that there should be some balance of rights between rights owners and rights users and, once the balance is unjustly tilted in favour of the rights owner, especially when it is as a result of the said owner abusing rights conferred, then member states might adopt measures to remedy such anti-competitive practices of the rights user. Thus, the significance of article 7 is that 'it provides valuable context for the interpretation of other provisions', while the importance of article 8(2) is that it provides justification for the use of anti-abuse measures.[94] The flip sides of article 8(2) are, firstly, that it gives the

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93 As above.

94 See UNDP *Using competition law and policy to promote access to medicines: A guidebook for low and middle-income countries* http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/ UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf (accessed 7 July 2014); E Ghosh 'Competition law and intellectual property rights with special reference to the TRIPS Agreement' (2010) http://www.cci.gov.in/images/media/ResearchReports/EshanGhosh.pdf. (accessed 12 March 2012); T Avafia et al Sustainability of supply of essential medicines in Sub-Saharan countries using TRIPS and Competition law (2006)

WTO authority to scrutinise anti-competitive measures because such measures must be consistent with the TRIPS Agreement and, secondly, that it contains the word 'may', not the mandatory 'shall', meaning that members are not obliged to adopt competition laws/policies to stop anti-competitive practices by a rights holder. This gives limited room for citizens to force their governments to adopt competition laws/policies, especially if such governments are sympathetic towards a foreign company/national involved in anti-competitive practice with such sympathy stemming from corruption or fear of being in the bad books of the government where the foreign company/national is from.

Article 40 expressly acknowledges the fact that rights owners may be involved in licensing practices and impose licensing conditions that are anti-competitive. If such scenarios were to arise, members may adopt measures regulating anti-competitive terms, such as preventing 'exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing' to remedy the anti-competitive practice and/or condition. Pursuant to article 40, a member whose laws and regulations have been violated as a result of anti-competitive practices may enter into consultation with the member whose national is the subject of the violation. The requesting member shall be accorded full support, opportunity and co-operation from the member addressed. Likewise, a member whose national is the subject of anti-competitive practices that violate the laws and regulations of another member may enter into consultation with the said member.

The significance of article 40 is that it gives 'members the leeway to adopt "appropriate measures" to control anti-competitive practices in addition to a provision for consultation and request-based co-operation to deal with

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http://www.tralac.org/pdf/20061002_Avafia_TRIPsandCompetitionLaw.pdf (accessed 12 March 2012); J Berger *Advancing public health by other means: Using competition policy* (2004) 1-20 http://www.iprsonline.org/unctadictsd/bellagio/docs/Berger_Bellagio3.pdf (accessed 12 March 2012); C Correa *Intellectual property and competition law: Exploring some issues of relevance to developing countries* (2007) http://www.iprsonline.org/resources/docs/corea_Oct07.pdf (accessed 12 March 2012); Essential Action 'Briefing note: U.S. competition policy frequently deployed to remedy anti-competitive practices related to pharmaceutical patents (2008) http://www.essentialaction.org/access/index.php?/archives/144-U.S.-Competition-Policy-and-Pharmaceutical-Patent-Abuse.html (accessed 12 March 2012).

violation of competition laws'.[95] In the African context, the full benefits of this provision might be difficult to achieve because very few countries on the continent have a well-developed competition law/policy and a system in place to monitor and guard against anti-competitive practices, such as collusion by industries to keep prices of goods and services high and monopolistic tendencies. For instance, most of them have neither a competition tribunal nor competition laws. However, a competition policy has been used successfully in South Africa.[96]

2.3 Data protection/exclusivity

Data to be protected under the TRIPS Agreement includes 'test and other data that a pharmaceutical company must provide to a drug regulatory authority (DRA) in order to get first-time registration for any new medicine it wishes to market in a country'.[97] Data protection is provided for under article 39(3) of TRIPS. *Stricto sensu*, TRIPS does not use the word 'exclusivity'; it only uses the verb 'protect'. Article 39(3) of TRIPS provides as follows:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.

In addition, article 39(3) requires members to protect data against disclosure, except 'where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use'.

From the foregoing provision, one notes that data is protected only with respect to 'unfair commercial use' and reasonable 'disclosure'. However, there is great uncertainty with respect to the obligation to protect against 'unfair commercial use', all the more so because TRIPS does not provide any

95 As above.
96 See Hazel Tau & Others v GlaxoSmithKline & Others (Competition Commission of South Africa, Case no. 2002 Sept 22)
97 MSF technical brief May 2004.

definition of the term.[98] This ambiguity has led to two major interpretations. The first, mostly favoured by developed countries and multinational companies, is to the effect that article 39(3) prevents 'regulatory bodies of member states from relying on data submitted by the originator company for a reasonable period of time' when assessing the safety and efficacy of follow-on generic equivalents, while the second, supported by developing countries, is to the effect article 39(3) 'does not prevent regulatory bodies of member states from relying on data submitted by the originator company when deciding whether to register a generic version of the same product'.[99] On the face of it, article 39(3) clearly does not obligate member states to provide 'exclusivity' protection for any particular period of time. Therefore, countries are at liberty both to decide whether or not to provide exclusivity or protection and to establish an appropriate time frame if they do adopt exclusivity.

The US and EU respectively provide five years and 10 years for original exclusivity and three years and one year respectively with regard to successive exclusivity.[100] In fact, most of the provisions on data exclusivity contained in free trade treaties involving the US provide for at least a five-year period for data exclusivity.[101] The implications of data exclusivity for access to generic medicines in countries that have concluded bilateral trade agreements that contain a provision of data exclusivity are significant. This is because even when medicines are not patented, generic manufacturers in the country will have to wait for a period of time from the date of approval of the original medicine before obtaining registration of their own versions of the medicine,

98 *UCTAD resource book on TRIPS and development* (2005).

99 Yu (n 51 above) 166.

100 The European Commission defines data exclusivity as the period during which the data of the original marketing authorisation holder relating to (pre-) clinical testing is protected. Accordingly, in relation to marketing authorisation applications submitted after 30 October 2005 for applications filed in the framework of national procedures or 20 November 2005 for applications filed in the framework of the centralised procedure, 'data exclusivity' refers to the eight-year protection period during which a generic applicant may not refer to the information of the original marketing authorisation holder and 'marketing exclusivity' refers to the ten-year period after which generic products can be placed on the market. However, in relation to marketing authorisation, applications submitted before the above-mentioned dates, the wording 'data exclusivity' refers to the six or ten-year protection period granted to the original MA holder before generic applicants can file their applications for marketing authorisation.

101 See, eg, free trade agreements between the US and the following countries: Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua and Singapore.

because data exclusivity prevents reference to or reliance on the data submitted or the fact of the registration itself in order to establish safety and efficacy.[102] It should be noted that an applicant for generic registration would be free to submit its own clinical trial data so as to register the medicine, but that would be unduly costly, very time-consuming, and probably unethical in terms of repeating clinical trials.[103]

In recent years, the US has linked registration rights of generic manufacturing to the absence of patent protection in what is now referred to as patent-registration linkage. Put simply, linkage means that one cannot register the medicine as long as there is a patent claim on the medicine. Most linkage provisions provide for notice, opportunity to challenge and injunctions while infringement and/or invalidity claims are being heard. It should be pointed out that linkage has negative implications on access to medicines. First, regulatory authorities would have to seek the consent of a patent holder before registering a generic version of a patented medicine, making their work onerous as they might not have the capacity to check the patent status of each product.[104] Second, regulatory authorities would be turned into patent enforcement officers. They might end up enforcing all invalid patents or may fail to enforce valid patents, thereby negatively affecting generic manufacturers.[105]

2.4 Intellectual property enforcement

Part III of the TRIPS Agreement deals with the enforcement of IP rights. It is divided into five sub-sections dealing with general obligations; civil and administrative procedures and remedies; provisional measures; special requirements related to border measures; and criminal procedures. Under article 41, member states have to ensure that private enforcement measures specified in TRIPS are available under their respective legal systems. However,

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102 Abbott (n 90 above).

103 J Reichman 'Rethinking the role of clinical trial data in international intellectual property law: The case for a public goods approach' (2009) 13 *Marquette Intellectual Property Law Review* 51.

104 World Health Organisation (WHO) 'Data exclusivity and other TRIPS plus measures' Briefing note on access to medicines (2006).

105 As above.

there is no obligation on member states to put in place a judicial system solely to enforce IP rights. This minimal requirement is in stark contrast to most of the TRIPS-plus provisions in many bilateral treaties wherein signatories agree to the TRIPS-plus enforcement of IP rights. The recent anti-counterfeiting pieces of legislation[106] that many East African countries are attempting to put in place are eloquent testimony of how states are deviating from the less onerous TRIPS provisions on IP enforcement to a more strict, TRIPS-plus regime.

TRIPS provides for civil and criminal remedies in cases of violations and regulates how evidence shall be collected and tendered. Civil remedies include injunctions and damages, while criminal remedies include terms of imprisonment and monetary fines, seizure and destruction of property. Criminal measures must be available for wilful trademark counterfeiting and copyright piracy on a commercial scale, but are not required for other IP violations, including patent infringements.[107] There are also provisional measures, which are essentially preliminary injunctions or interdicts pending final judicial review. The judiciary is empowered to order prompt and effective provisional measures to prevent an infringement from occurring or the preservation of relevant evidence with regard to an alleged infringement. Once adopted, the court must review the case as soon as possible and decide whether the measures taken should be modified, revoked or confirmed. The defendant is given notice as soon as the measures are adopted. In the context of FTAs, this provision has been interpreted to include almost everyone within the enforcement chain.

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106 Eg, Kenya passed an anti-counterfeit law in 2008 known as the Anti-Counterfeit Act of 2008. Note that this Act was declared unlawful by the Kenyan High Court in Nairobi in the case of *Patricia Ochieng et al v Attorney-General* (Petition 409 of 2009).

107 For a detailed discussion of criminal measures, see the case of *China – Measures Affecting the Protection of Intellectual Property Rights* in which the panel found that '[w]hile China's criminal measures exclude some copyright and trademark infringements from criminal liability where the infringement falls below numerical thresholds fixed in terms of the amount of turnover, profit, sales or copies of infringing goods, this fact alone was not enough to find a violation because art 61 does not require members to criminalise all copyright and trademark infringements'
http://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds362sum_e.pdf
(accessed 29 June 2013).

In certain African countries,[108] for instance, customs and at times the police do play the role of IP enforcement officers. In Cameroon, for instance, the customs have a mandate to check all goods coming into and transiting via Cameroon. In so doing, they have the right to hold and destroy goods that they believe are unlawful or violate internal laws and the public policy of Cameroon.[109] The potential implication of this is that, in practice, a complainant - pharmaceutical company - aware of a shipment of generics may inform the customs about it as he has the right to offer some claim of potential IP violation. Without a proper knowledge of IP and, since IP and health experts hardly get involved in the customs verification process, customs officials thus have a wide discretion to hold, seize and destroy what they consider to be counterfeit, being a fake and fraudulent imitation of some product.[110] Most often, a generic product may be imported with different packaging and colouring, but with a shared international non-proprietary name of the brand medicine. In such cases, the customs officials may treat these generics as trade mark violations of the brand medicines, without knowing that these generics are lawful and legal. In the context of access to medicines and taking into account how complex and difficult it is to handle and deal with medicines, giving customs such a mandate and, more importantly, the possibility of them exercising quasi-judicial functions in the form of collecting evidence and determining sanctions, there is the potential that access to medicines may be negatively impacted. This is so because quality medicines may end up being destroyed as the police could have limited knowledge of the quality and contents and, more disturbingly, bribery and corruption may thrive, rendering the whole operation ineffective and unreliable. Thus, a business dealing with counterfeit products and who pays his or her way may be given the go-ahead, while those dealing in genuine medicines and who refuse to bribe their way may find their medicines impounded and, worst case scenario, confiscated and destroyed.

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108 Eg, Cameroon.

109 See Decree 2005/0528/PM of 15 February 2005 on the creation, organisation and functioning of an *ad hoc* committee in charge of co-ordinating operations against fraud, contraband and counterfeits.

110 *Oxford dictionary* (2011).

The risks of border measures and their misapplication in the case of seizure of medicines in transit came to the fore in 2008 and 2009 when medicines being shipped from India to Brazil and certain African countries were seized for alleged violations of European patent rights – European Union Regulation CE 1383/2003. The Regulation allowed the European Union (EU) to treat goods in transit as if they had been produced in the EU. As a result, India[111] and Brazil[112] filed for consultations at the WTO against the EU. In 2011, India came to an understanding with the EU and decided not to continue with the matter.

Finally, WTO member states can bring an action at the level of the state-to-state WTO dispute settlement mechanism for IP infringement or the non-adoption of national IP laws that are TRIPS-compliant. So far, the WTO Dispute Settlement Body has heard over 30 cases relating to IP.[113]

2.5 Chapter conclusion

This chapter has discussed important TRIPS provisions on patents and data protection that relate to access to medicines. It has examined the letter and spirit of these provisions, the problems and controversies created by the interpretation given to the provisions, and attempts to revise the provisions. In analysing these provisions, the chapter discussed the meaning of access to medicines by first linking it, within the broad definition of the right, to the highest standard of attainable health in line with the explanations of General Comment

111 European Union and a member state - Seizure of generic drugs in transit (IP/D/28 WT/DS408).

112 European Union and a member state - Seizure of generic drugs in transit IP/D/29 WT/DS409). For a detailed discussion of border measures, see B Baker 'ACTA: 'Risks of third-party enforcement to access to medicines' (2011) 26 *American University International Law Review* 579-599; 'Counterfeit medical products: Need for caution against co-opting public health concerns for IP protection and enforcement (2009) *South Centre-CIEL Intellectual Property Rights Quarterly* 1-5; X Seuba 'Free trade of pharmaceutical products: The limits of intellectual property enforcement at border*'* (2010) ICSTD Programme on IPRs and Sustainable Development Series Issue Paper 27.

113 See 'Dispute settlement: Index of disputes by agreement citedhttp://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26#selected_agreement (accessed 29 June 2013). See also L Barsoumian 'India's use it or lose it: Time to revisit TRIPS?' (2010) *The John Marshall Review of Intellectual Property Law* http://www.jmripl.com.php5-10.dfw1-2.websitetestlink.com/articles/Barsoumian_FINAL1.pdf (accessed 29 June 2013).

14 and, second, by examining the interpretations given to and the place of General Comments in international law. Furthermore, it has examined enforcement measures, especially border measures, which by and large have been interpreted to restrict access to medicines.

CHAPTER 3: TRIPS PUBLIC HEALTH FLEXIBILITIES AND POST-1995 DEVELOPMENTS: AN ANALYSIS OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH, THE 30 AUGUST DECISION, HONG KONG MINISTERIAL AND SUBSEQUENT DEVELOPMENTS

The purpose of this chapter is to discuss the public health flexibilities provided for in the TRIPS Agreement, how these flexibilities have been interpreted, adopted and used, and whether or not such adoption and usage have facilitated access to medicines. The chapter also looks at post-1995 developments and the public health flexibilities that emerged after the adoption of TRIPS. These developments are the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration),[114] the Decision of the General Council of 30 August 2003 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 System),[115] the WTO Hong Kong Ministerial of 2005 and post-TRIPS extensions of the LDC transition period. It discusses the salient provisions, their legality, their operationalisation and subsequent developments at the level of the WTO TRIPS Council.

3.1 Definition of concepts: TRIPS public health flexibilities and post-1995 developments

The term 'TRIPS public health flexibilities' has gained prominence in recent years, especially after the Doha Declaration of 2001 became part of the intellectual property and access to medicines vocabulary. In the context of TRIPS, the history and meaning of 'flexibility' can be approached from two perspectives. The first perspective is informed by TRIPS itself, which deals with flexibilities as provided for in the TRIPS Agreement. The second perspective relates to the post-1995 period, which deals with developments after the entry into force of the TRIPS Agreement.

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[114] WT/MIN(01)/DEC/2 20 November 2001 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. (accessed 11 March 2014).

[115] WT/L/540 and Correspondence 1 (1 September 2003). http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 11 March 2014).

The term 'TRIPS flexibilities' is first mentioned in paragraph 6 of the Preamble to the TRIPS Agreement, which makes reference to

> the special needs of the least-developed country members, in respect of maximum flexibilty in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.

However, it should be pointed out that, although used for the first time in paragraph 6 above, the above-mentioned flexibility relates to the LDC transition period which fits within the broader category of flexibilities, which is part of the transition periods. These included transition periods for developing countries, for LDCs, and for countries that had not previously granted pharmaceutical product patents, and countries transitioning from planned economies.

Notwithstanding the above, article 66(1) provides an explanation of the word 'flexibility' as provided for in paragraph 6 of the Preamble to the TRIPS Agreement. It states the following:

> In view of the special needs and requirements of least-developed country members, their economic, financial and administrative constraints, and their need for flexibility to create viable technological base, such members shall not be required to apply the provisions of this Agreement, other than articles 3, 4 and 5 …

The following appears from the above provisions. The Preamble and article 66(1) deal mainly with least-developed countries. More precisely, they deal with a transition period designed to allow time for countries to overcome capacity constraints and to develop a threshold technological base. In addition, 'flexibility', as used in article 66(1), appears to be qualified. This is because the term appears to relate to the creation of a 'viable technological base'. These two references to flexibilities actually connote flexibilities not to implement TRIPS while LDCs develop a technological base. This, of course, is ultimately codified in extended transition periods for LDCs, as will be seen later in the chapter.

Additional policy spaces (flexibilities), which can be discerned from a number of provisions in the TRIPS Agreement, may be divided into two broad groups.

The first group of flexibilities is referred to as 'time-based flexibilities',[116] while the second group may be referred to as 'substantive flexibilities'. The first group of flexibilities consists of three transition periods for the implementation of the TRIPS Agreement, allowed in respect of developing and least-developed countries (LDCs) and a transition period dealing with transitional economies. The first period was from 1995 to 2000,[117] at the end of which most non-least-developed developing countries were obliged to implement TRIPS. The second period was from 2000 to 2005,[118] 'which provided an additional period of five years to put in place product patent protection pharmaceuticals or agro-chemicals for those countries without such protection at the entry into force of the TRIPS Agreement', or countries that were emerging from planned economies.[119] The third period was from 1995 to 2006[120] (later extended to 2013 and later again until 2021) and a special 2016 extension with respect to pharmaceutical products, data protection and market exclusivity,[121] after which least-developed countries would be expected to fully implement the TRIPS Agreement. In the later part of the study, the question will be posed whether LDCs are benefiting from this policy space or whether they have acted prematurely and have actually implemented TRIPS-compliant and TRIPS-plus legislation.

The second class of flexibilities - substantive flexibilities - includes implementation flexibilities under article 1(1); exemptions from patentability

116 As above.
117 Art 65(2) TRIPS Agreement.
118 Art 65(4) TRIPS Agreement.
119 n 1 above.
120 Art 66(1) TRIPS Agreement.
121 See Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the 4th WTO Ministerial Conference, Doha, Qatar. Para 7 of the Doha Declaration provides that least developed countries 'will not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 and 7 Part II of the TRIPS Agreement or to enforce rights provided under these sections until 1 January 2016, without prejudice to the rights of least developed country members to seek other extensions of the transition periods as provided for in article 66.1 of the TRIPS Agreement'.

under articles 27(2) and 27(3); limited exceptions under article 30; compulsory licences/government-use under article 31; parallel importation under article 6, and competition-based flexibilities under articles 8(2), 31(k) and 40. In addition to these explicit textual flexibilities, there are other flexibilities that have been read into or implied from TRIPS because of interpretive ambiguities or implementation flexibilities or because of the absence of prohibition. These flexibilities include the flexibility to adopt high or stringent standards of patentability (novelty, inventive step, industrial applicability and disclosure); to allow pre- and post-grant opposition procedures; to enact streamlined administrative procedures for compulsory and government-use licences; and to allow judicially-granted licences, to adopt data protection rather than data exclusivity.

Article 1(1) of the TRIPS Agreement provides for substantive flexibilities. It states as follows:

> Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

From the foregoing, it may be concluded that laws on intellectual property can be tailored – at least to a certain extent – to local conditions. Countries have a significant discretion to determine how TRIPS-compliant IP law is crafted and implemented so long as so-called minimum standards apply. By so providing, the drafters of TRIPS might have had in mind the principle of sovereignty, respecting each country's right to determine its own domestic affairs as to what minimum standards are – subject to potential WTO dispute resolution review – and to what extent, if any, the country wants to exceed those minimum standards. The significant portion of article 1 provides:

> Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement …[122]

Although the sovereignty argument appears simplistic as it is now construed differently,[123] the traditional view of sovereignty as being independent and autonomous from outside influence may have guided the TRIPS drafters.

Article 1(1) has not been the subject of interpretation by the WTO dispute settlement body. It has, however, been mentioned in passing. For instance, in *Canada-Patent Protection of Pharmaceutical Products,* the European Community (EC) in one of its arguments against Canada, and in a bid to emphasise the obligations of WTO members, interpreted article 1(1) of TRIPS as 'demonstrating that the basic purpose of the TRIPS Agreement was to lay down minimum requirements for the protection and enforcement of intellectual property rights'.[124] It should be noted that the interpretation of article 1(1) was not in contention in the dispute. However, although article 1(1) was not in contention, it is submitted that it is highly likely that article 1(1) will be relevant in many disputes where countries disagree about what exactly 'minimum standards' are.

Article 27(2) contains key flexibilities as it provides for exemptions from patentability, in the following terms:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

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122 Art 1 TRIPS Agreement.

123 See eg S Krasner *Sovereignty: Organised hypocrisy* (1999), where Krasner argues that sovereignty does not only entail supreme power or autonomy and independence, but takes various formats depending on the context and situation. He contends that the different formats are 'domestic sovereignty' (which envisages a superior being charged with making and enforcing laws); 'international sovereignty (when states recognised others as equals); and Westphalian sovereignty, which is based on 'territoriality and the exclusion of external actors from domestic authority structures'.

124 WT/DS114/R 17 March 2000.

So far, the interpretation of article 27(2) has not really been tested by the WTO dispute settlement system. However, there are very important questions whether excludable subject matter is limited to what is listed in article 27. There are strong arguments to the contrary, because many countries have other kinds of excludable subject matter, including discoveries, abstract ideas, laws of nature, software, business methods, plants and animals, methods of human cloning, isolated genes, etc. For instance, while some developed countries grant patents on life forms, developing and least-developed countries regard this as morally and ethically incorrect.[125] In fact, some countries specifically exclude patents from their local legislation on the basis that they do not constitute inventions.[126]

Notwithstanding these additional exclusions, it appears that the interpretation and exact meaning of article 27(2) may pose a problem, particularly with respect to the public order/morality clause, if it becomes the centre of a dispute. Doane contends that the article is vague and may lead to protectionist abuse 'without a narrowing interpretation or interpretative statement'.[127] Harper states that, although WTO members may under article 27(2) withhold the granting of patents involving risky inventions that may have a negative impact on health and the environment, the standard to be used for this exception to apply is not clear.[128] In addition, countries would be justified to use article 27(2) as a precautionary principle, for instance to ensure quality and safety standards.[129] Thus, under article 27(2), a country may protect itself by doing one of the following if it has concerns that a particular invention may be risky. First, it may require a determination from both domestic and foreign producers that an invention is safe and, if the burden is not carried at all, then it could declare the invention unsafe.[130] Second, if an invention fails to meet a

125 C Guneratne *Genetic resources, equity and international law* (2012) New Horizons in Environmental and Energy Law Series 12.
126 Sec 3(j) Indian Paten Act, 1970 (as amended).
127 M Doane 'TRIPS and international intellectual property protection in an age of advancing technology' (1994) 9 *American University Journal of International Law and Policy* 465.
128 B Harper 'TRIPS Article 27.2: An argument for caution' (1997) 21 *William and Mary Environmental Law and Policy Review* 381.
129 Harper (n 15 above) 417.
130 Harper 418.

lesser standard of safety, a country may stop its development and subsequently refuse to patent it.[131] Harper argues that his interpretation can be supported by international environmental law and other aspects of the WTO Agreements, such as the technical barriers to trade agreements (TBTs).[132]

From the above, one might be tempted to conclude that article 27(2) could thus be used as a shield to ensure that a particular class of medicines that can be patented must meet certain safety and quality standards, or is not against public policy or morality, which is determined by national law.

Additional exclusions from patentability are couched in article 27(3) of the TRIPS Agreement. This article provides as follows:

> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

With regard to the exclusions mentioned above, article 27(3)(b) has been somewhat contentious. First, it was the first provision in an international IP instrument to require IP on life forms[133] and, secondly, it 'blurs the distinction between inventions, which are patentable under traditional patent law, and discoveries, which are not'.[134] In fact, article 27(3)(b) was a compromise provision resulting from attempts by huge industries in the West to impose monopolistic rights over biological resources and attempts by developing countries to prevent the extension of private monopoly rights over biological resources from which food and medicines are derived.[135]

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131 As above.
132 As above.
133 C Oh 'Article 27.3(b) of the TRIPS Agreement: Review options for the South' http://www.twnside.org.sg/title/oh1-cn.htm (accessed 22 July 2013).
134 C. Correa 'TRIPS and the protection of community rights' in *Signposts to Sui Generis Rights* (1997) Resource Materials from the International Seminar on *Sui Generis* Rights, December 1997.
135 Oh (n 20 above).

It should be pointed out that the obligations imposed by article 27(3)(b) can be broken down into three major components: (i) a country *may*[136] exclude from patentability plants, animals and essentially biological processes for the production of plants and animals; (ii) a country *must*[137] allow patents for microorganisms and non-biological and microbiological processes for the production of plants or animals; (iii) a country *must* provide protection for plant varieties, either by patents or by an effective *sui generis* system or a combination thereof.[138]

There are still disagreements as to the interpretation and scope of article 27(3)(b). Certain developed countries favour a narrow interpretation in the implementation process of article 27(3)(b), while most developing countries are 'for a broader approach which would examine the scope and rationale of the provision itself'.[139] A review of article 27(3)(b) started in 1999, but was soon caught up by the Doha Declaration. The review at the level of the TRIPS Council has proceeded with the debate now focusing on the relationship between TRIPS and the UN Convention on the Protection of Biodiversity.[140]

3.2 Limited exceptions under article 30

Article 30 is referred to as the limited exception to the rights of a patent holder. It provides as follows:

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

As was held by the WTO Panel in the *Canada - EC* case, for this exception to apply, three conditions must be fulfilled:

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136 My emphasis.
137 My emphasis.
138 L Das 'Proposals for improvements in the Agreement on TRIPS' (1998) 2 *Bridges Weekly Trade News Digest* 5.
139 Oh (n 20 above).
140 J Linarelli 'Trade-related aspects of intellectual property rights and biotechnology: European aspects (2002) 6 *Singapore Journal of International and Comparative Law* 410.

(i) The exception must be 'limited'.

(ii) The exception must not 'unreasonably conflict with normal exploitation of the patent'.

(iii) The exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.[141]

According to the Panel, these three conditions are cumulative, each being a separate and independent requirement that must be satisfied and that 'failure to comply with any one of the three conditions results in the article 30 exception being disallowed'.[142] It has been suggested that the language of article 30 leaves greater room to maneuver as it does not list specific exceptions, rather the conditions under which any exception falling under it should be construed.[143] Over the years, as documented by scholars such as Correa[144] and Garrison[145] and organistions such as Third World Network,[146] the following, amongst others, have been used as exceptions to the rights of a patent owner: academic and commercial research and experimentation on or with an invention; educational use; prior use; acts done privately for non-commercial purposes; the preparation of medicines under individual prescription; parallel importation; and Bolar or early working exception. In view of their potential relevance in promoting access to medicines, especially in developing and least-developed countries, the Bolar exception and the research exception will be discussed below.

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141 World Trade Organisation (2000), *Canada - Patent Protection of Pharmaceutical Products*, Panel Report, WT/DS114/R.

142 As above.

143 P Yu 'The objectives and principles of the TRIPS Agreement' http://www.peteryu.com/correa.pdf 5 (accessed 3 January 2012).

144 Correa (n 21 above) 76.

145 Exceptions to Patent Rights in Developing Countries (2006), http://www.iprsonline.org/resources/docs/Garrison%20-%20Patent%20Exceptions%20DC%20-%20Blue%2017.pdf (accessed 7 January 2013).

146 Third World Network: Manual on good practices in public-health-sensitive policy measures and patent laws 66, http://www.twnside.org.sg/pos.htm (accessed 7 January 2013).

3.2.1 Bolar exception

One of the most commonly-accepted limited exceptions under article 30 is what is referred to as the Bolar or early working exception. This exception stems from the US case of *Roche v Bolar.*[147] In that case, Bolar used experiments to determine whether its product had the bio-equivalent of Valium, a drug that was patented to Roche. Roche brought an action for patent violation. Bolar argued that there was no infringement as it was involved in experimentation, which was an exception to patent law. Bolar also argued that public policy allowed the making of generics to be used once the patent term expired so as to safeguard against monopoly and that seeking tentative regulatory approval before the expiration of the patent was important to prevent a *de facto* extension of monopoly control. The Court of Appeals for the Federal Circuit rejected the arguments on the grounds that Bolar had a business intention and because public policy decisions were under the ambit of Congress, not Bolar. After the *Bolar* decision, the US Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the 'Hatch-Waxman Act',[148] which allows the use of existing clinical trial data for purposes of obtaining US Food and Drug Administration (FDA) approval, subject to a term of so-called data exclusivity (discussed later). In addition, under the Act, the use of patented product was permissible even during the patent term in order to prepare the regulatory dossier. Internationally, many, but not all, countries have acknowledged the use of the Bolar exception either through acts of parliament[149] or decisions of national courts.[150] US court decisions have extended the Bolar exception to include getting approval from a foreign government before importation, creating

147 *Roche Products Inc v Bolar Pharmaceutical Co Inc* 733 F 2d 858 (Fed Cir 1984).

148 Public Law 98-417, 1984.

149 Eg, see Canada Patent Act, (RS 1985, c.P-4), sec 55.2(1), European Union: Agreement Relating to Community Patents (1989) (89/695/EEC), Argentina: Law 24.766, 1996 art 8.

150 UK: *Monsanto v Stauffer Chemical Co & Another* (1985) RPC 675; Germany: *Boehringer Ingelhiem Int GmbH v Dr Rentschler Arzneimittel GmbH & Others* (1995); *Klinishe Versuche Clinical Trials II* (1998) RPC 423; France: *Welcome Foundation Ltd v Parexel International & Others,* Tribunal de Grande Instance de Paris, 20 February 2001; Japan: *Otsuka Pharmaceutical Co Ltd v Towa Yakuhin KK* Case 1998 (ju) l2 (Supreme Court).

stock-piles, carrying out consumer studies, and explaining clinical trials and technics to the public.[151]

At the level of the WTO, the Bolar exception was tested in the case of *Canada – Patent Protection for Pharmaceutical Products*.[152] In that case, the European Community argued that Canada's legislation was incompatible with its obligations under the TRIPS Agreement, because it did not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by articles 27(1), 28 and 33 of the TRIPS Agreement. The EC took issue with certain provisions under Canada's Patent Act (1989), especially the regulatory review as provided for under section 55(2)(1) and the stockpiling provisions of section 55(2)(2), which allowed general drug manufacturers to override, in certain situations, the rights conferred on a patent owner. Section 55(2)(1) states that

> [i]t is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product

Section 55(2)(2) states that

> [i]t is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the

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151 B Coggio & D Cerrito 'The safe harbour provision of the Hatch-Waxman Act' Present scope, new possibilities and international considerations (2002) 57 *Food and Drug Law Journal* 162. Bolar has also been extended to 'using the drug product to raise capital; authorising publications describing product features; circulating study results to potential licensees; demonstrating features of the drug product at scientific meetings and trade shows; acquiring import approval from a foreign government; performing clinical studies for foreign regulatory agency clearance as long as the trials also relate to obtaining FDA approval; obtaining foreign patents; manufacturing a product to generate data and creating stock-piles; selling a product to clinical investigations at a hospital; selling a product to international distributors; testing of a product in a foreign country by a clinical investigator; testing by a foreign company; demonstrating the drug to physicians and non-physicians; conducting consumer studies; describing clinical trials to investors and journalists; promoting a product to consumers and shipping a product to a potential commercial partner'.

152 WT/DS114/R 17 March 2000.

> manufacture and storage of articles intended for sale after the date on which the term of the patent expires.

The WTO Panel did not find the regulatory review provision to be inconsistent with article 27(1) of the TRIPS Agreement since it was covered by the exception in article 30 of the TRIPS Agreement and, as such, not inconsistent with article 28(1) of the TRIPS Agreement. In that case, Canada asserted that the regulatory review exception of section 55(2)(1) could be regarded as limited because the rights given to third parties did not deprive the patent holder of his right to exclude all other 'commercial sales' of the patented product during the term of the patent.[153] Canada was taking the position that an exception is limited as long as the exclusive right to sell to the ultimate consumer during the term of the patent is preserved.

Canada used two main arguments to support its position. First, it pointed out that in 1984, the United States had enacted a regulatory review exception similar to section 55(2)(1) of Canada's Patent Act, known as the Bolar exemption. This exception was well-known during the negotiation of article 30, and that governments were aware that the US intended to secure an exception that would permit it to retain its 'Bolar exemption'. Canada further asserts that it was known that the US agreed to the general language of article 30 on the understanding that the provision would do so.[154]

Second, Canada also used subsequent practice under TRIPS to support its position. With regard to subsequent practice, Canada pointed out that, after the conclusion of the TRIPS Agreement, four other WTO members[155] adopted legislation containing similar regulatory review exceptions, and that both Japan and Portugal adopted interpretations of existing patent law which confirmed exemptions for regulatory review submissions.[156] Canada argued that these actions were subsequent practices by parties to the agreement, within the meaning of article 31(3)(b) of the Vienna Convention, which confirmed its

153 As above.
154 As above.
155 Argentina, Australia, Hungary and Israel.
156 n 39 above.

interpretation that regulatory review exceptions were authorised by article 30 of TRIPS.[157]

The WTO Panel concluded that Canada's regulatory review exception was a 'limited exception' within the meaning of article 30 of TRIPS because of the narrow scope of its curtailment of article 28(1) rights.[158] The Panel maintained:

> As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded.[159]

Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products.[160]

With regard to the stockpiling exception, the WTO Panel held that it was inconsistent with article 28(1) of the TRIPS Agreement and could not be considered to be a limited exception within the meaning of article 30 of the TRIPS Agreement as Canada had claimed.[161]

3.2.2 Research exception

The research exception has long been recognised as an exception to patent rights as far back as the nineteenth century, with the determining factor in some countries being whether the said research was for commercial or non-commercial use. The first known recorded case where the research exception

157 As above.
158 As above.
159 As above.
160 As above.
161 As above.

was highlighted was in the case of *Whittemore v Cutter*.[162] In that case, the defendant challenged a jury instruction that 'the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right'. Justice Story, in approving the jury instruction, stated:

> it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiment, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

In other words, using the machine for profit other than for philosophical (in this case research) purposes was tantamount to a patent infringement.[163]

Nowadays, an important issue which has arisen is whether the research is for commercial or non-commercial use. In some jurisdictions, the research exception can be upheld if it is for non-commercial use only.[164] In other jurisdictions, research is interpreted broadly and a distinction is not made as to commercial or non-commercial use.[165] This is the case with the Bangui Agreement establishing the Africa Intellectual Property Organisation (OAPI), which provides that 'the rights deriving from the patent shall not extend ... to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research'.[166]

Irrespective of the above, it is sometimes difficult to draw a fine line between commercial and non-commercial use. It could be difficult to ascertain any one of the two, especially the way research is conducted 'since applied

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162 29 F Cas 1120 (CCD Mass 1813) (No 17,600).

163 S Michel 'The experimental use exception to infringement applied federally funded inventions' *Berkeley Technology Law Journal* http://www.law.berkeley.edu/journals/btlj/articles/vol7/Michel.pdf (accessed 8 July 2014).

164 Eg, the US, where the courts have limited research exceptions to cases of non-commercial use. See the cases of *Sawin v Guild* (21 F Cas 554 (CCD Mass 1813) (No 12, 391), *Peppenhausen v Falke* (19 F Cas 1048, 1049 (CCSDNY 1861) and *Madey v Duke University*, 307 F 3d 1351 (Fed Cir 2002), cert denied 539 US 958, 123 SCt 2639, 156 LEd2d 656 (2003).

165 See eg art 43(II) of Brazil's Law 9279/96, as amended, and art 8(1)(c), Annex I of the Agreement Revising the Bangui Agreement of 2 March 1977, on the Creation of an African Intellectual Property Organisation (1999).

166 Art 8(1)(c), Annex I of the Agreement Revising the Bangui Agreement of 2 March 1977, on the Creation of an African Intellectual Property Organisation (1999).

commercial research relies on basic research done in universities and other research institutions'.[167]

Another distinction should be made between research 'on' or 'with' the patent product or process. 'A patented invasion may be primarily research subject matter permitting others to research "on" the compound in order to advance further the knowledge about the compound.'[168] On the other hand, in the case of research 'with' the compound, 'the use of the invention could be a "research tool" or simply an ingredient in the new drug formulation'.[169] It should be noted that in both cases, the research could be conducted in relation to scientific experiments that could have commercial or non-commercial benefits.[170]

3.3 Parallel importation

Parallel importation is one of the substantive flexibilities provided for in the TRIPS Agreement. Maskus defines parallel import as 'goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorisation of the local owner of the intellectual property right'.[171] Although this is the widely-acceptable definition, Correa is of the view that parallel importation should be permitted whenever a product has been lawfully produced and placed on the market, regardless of the right holder's consent.[172] Thus, according to Correa, if a medicine is produced generically pursuant to a compulsory licence, it can be regarded as parallel importation. Kenya has in fact adopted such a provision. Article 58(1) provides that the patentee's right does not extend to 'acts in respect of articles which have been put on the market

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167 E Misati & K Adachi 'The research and experimentation exceptions in patent law: Jurisdictional variations and the WIPO Development Agenda' UNCTAD - ICTSD Project on IPRs and Sustainable Development policy brief Number 7, March 2010 2.

168 As above.

169 As above.

170 As above.

171 K Maskus 'Parallel imports in pharmaceuticals: Implications for competition and prices in developing countries' (2001) Final Report to World Intellectual Property Organisation 2 http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf (accessed 2 September 2012)

172 C Correa *Trade-related aspects of intellectual property rights. A commentary on the TRIPS Agreement* (2007).

in Kenya or in any other country or imported in Kenya'. OAPI member countries could follow the Kenyan example by amending the Bangui Agreement to allow parallel importation whenever the product has been lawfully produced. As seen above, this may not be in violation of TRIPS.

Parallel importation is permitted by article 6. However, it should be pointed out that article 6 neither defines nor expressly mentions parallel importation – it references the concept of exhaustion of rights instead:

> [F]or the purposes of dispute settlement under this Agreement, subject to the provisions of articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Thus, countries have the right to adopt the exhaustion regime when they want to use parallel importation if they adopt international exhaustion. Under international exhaustion, once a 'good', in this case medicine, is sold, the rights of the patent owner is deemed to have been 'exhausted', meaning the patent holder cannot control the resale and further distribution of the medicine. The implication of article 6 of TRIPS is that, once there is exhaustion, patented medicines can be imported into countries even though the patent holder is selling the same medicine at a higher price.

Note should be taken of the fact that, depending on the intellectual property regime in place, exhaustion could be national, regional or international. It is national when the exhaustion right is only limited to a particular country, meaning that cheaper versions of drugs can only be resold within the particular country where the right has been exhausted. When exhaustion is regional, it means that, once sold in the delineated region, cheaper versions could be exported or imported to other countries within the particular region where the right has been exhausted. The European Union, for example, has regional exhaustion. International exhaustion means that once sold in any market, it could be exported or imported and traded anywhere in the world where international exhaustion applies.

Exhaustion can be contractual whereby the product is put on the market with the permission of the patent holder, either through direct sale by the patent holder or through a voluntary licence. However, it is not quite settled whether a post-sale limitation clause inserted by the patent holder is valid and enforceable. This issued has been raised in US courts and, to date, there has been no conclusive answer. The first case in which the issue came to the fore was the case of *Mallinckrodt Inc v Medipart Inc*[173] in which case the Federal Court held that such post-sale restriction clause was valid. However, in *Static Control Components Inc v Lexmark International Inc*,[174] the Federal Court held that post-sale restriction was invalid. Thus, it will depend on the national law of the country whether such post-sale restrictive clauses would be enforceable.

The disparity between markets may bring the issue of parallel import to the fore. Pharmaceutical companies sometimes get involved in tier pricing, where there are different prices for countries depending on their levels of development. Most companies often fear that once there is tier pricing, there is the risk of medicines sold more cheaply in developing and least-developed countries to make their way to developed markets, which may lead to a loss of profit. This may be especially true when the developing or least-developed markets are not well regulated, increasing the possibility of drugs being sold there at a cheaper price to be transported to more developed and richer markets.[175]

The use or non-use of parallel importation continues to divide opinion. The main disagreement is that it undermines tiered pricing schemes, meaning that companies would be unwilling to sell at highly-discounted prices to low-income countries. In addition, sometimes there is disagreement about parallel importation in relation to counterfeiting. On the one hand, opponents of parallel importation are of the view that it limits the rights of the patent owner and can lead to trade in counterfeits and pirated goods, thereby leading to consumer

173 976 F2d 700, 708 (Fed Cir 1992).
174 615 F Supp 2d 586 (ED Ky 2009).
175 M Han 'Trademark and parallel importation in Europe' (1998) 1 *Journal World Intellectual Property* 621.

deception.[176] On the other hand, proponents of parallel importation are of the opinion that counterfeits and pirated goods, unauthorised and illegal goods, are different from the concept of parallel importation and that 'consumer deception would only occur if low-quality and substandard versions of parallel import were sold as legitimate versions of the products'.[177]

As mentioned in the preceding chapter, the effectiveness and interpretation of article 6 was invoked in South Africa.[178] One of the arguments by the US was that 'article 6 of TRIPS does not authorise parallel importation' because it 'does not alter the substantive obligations of the TRIPS Agreement, particularly those contained in Part II of the Agreement'.[179] This argument has been ridiculed by non-governmental organisations (NGOs) and some scholars. As stated in a South African government report, the Treatment Action Campaign, an NGO which was actively involved by mobilising support against pharmaceutical companies during its case against the South African government, at the time stated that article 6 of TRIPS implied that the TRIPS Agreement did not cover parallel importation and that many countries in the European Union used it.[180] In the EU, for instance, the European Court of Justice ruled in favour of regional exhaustion, holding that 'the free circulation of goods within the European Union trumps individual intellectual property rights'.[181] Some scholars, such as Fisher and Rigamonti, are of the view that

> some rules in GATT may be read as mandating the adoption of an international exhaustion regime because outlawing parallel imports may be viewed as a non-tariff trade barrier in violation of article XI:1 of GATT 1994 and as a form of discrimination that violates national treatment rule.[182]

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176 Maskus (n 58 above) 4.
177 As above.
178 See *Pharmaceutical Manufacturers Association & Others v President of the Republic of South Africa & Others* (Transvaal Provincial Division Case 4183/98) 2.4.1 of chapter two above.
179 W Fisher & C Rigamonti 'The South Africa AIDS controversy: A case study in patent law and policy' (2005) Harvard Law School 11.
180 Public Protector of the Republic of South Africa, Report on the Propriety of the Conduct of Members of the Ministry and Department of Health Relating to Statements in Connection with the Prices of Medicines and Utilisation of Generic Medicines in South Africa, Special Report 6 (1997).
181 See the case of *Merck v Stephar* (C-187/80).
182 As above.

3.4 Compulsory licences

A compulsory licence with respect to a patent is defined as 'a licence for a patented product issued by government to a third party without the patent holder's permission in return for what government considers reasonable compensation'. *Black's law dictionary* defines it as the 'granting the use of a patent to a third party without the authorisation of the patent holder'.

Article 31 refers to 'other use', that is to say, use other than that permitted under article 30. Therefore, although not expressly referred to as a compulsory licensing provision, article 31 allows for 'use without authorisation', in effect a compulsory licence granted by the competent government authority to allow the manufacture of a patented product or the use a patented process without the authorisation of the rights holder. In this respect, the public interest goal of achieving broader access to the patented invention is considered more important than the private interest of the rights holder in fully exploiting his exclusive rights. What this means in the context of public health is that compulsory licensing is intended to permit countries to produce or import generic drugs that are more affordable than patented proprietary medicines. Since compulsory licences grant an exception to the exclusive rights of the patent holder, article 31 also sets out restrictive conditions that must be satisfied before a compulsory licence may be awarded. These conditions include the following:

1 Authorisation for compulsory licences must be determined on a case-by-case basis.[183]

2 The scope and duration of such use must be limited to the purpose for which it was authorised.[184]

3 Such use shall be non-exclusive[185]; such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use.[186]

183 Art 31(a).
184 Art 31(c).
185 Art 31(d).
186 Art 31(e).

4 Any such use must be authorised predominantly for the supply of the domestic market of the member authorising such use.[187]

5 Authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorised, is to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur.[188]

6 Prospective licencees must negotiate for commercially reasonable terms for a commercially reasonable period of time. Countries may define both. It should be pointed out that the mandatory negotiation requirement may be waived by a member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use as well as in competition-based licences.

7 The right holder must be paid adequate remuneration taking into account the value of the authorisation.[189]

8 There shall be rights of review before a distinct higher authority both with respect to the authorisation and the amount of remuneration.[190]

9 There are special rules allowing compulsory licences in order to allow the exploitation of a second dependent patent that involves an important technical advance of consideration economic significance.[191]

Despite these explicit procedural requirements, member states have significant policy space under article 31 to simplify and expedite the process of issuing a compulsory licence. They can:

(i) specify the grounds upon which CLs may be issued, including, but not limited to, excessive pricing, refusals to licences, inadequate supply, blockage of fixed dose combinations, lack of local working, and public health/public interest more broadly;

(ii) define what is a national emergency or matter of extreme urgency;

(iii) establish a short time limit for the duration of efforts to secure a voluntary licence on reasonable terms;

(iv) adopt easy-to-use administrative procedures, including administrative appeals procedures; and

(v) adopt remuneration guidelines.

187 Art 31(f).
188 Art 31(g).
189 Art 31(h).
190 Art 31(j).
191 Art 31(l)(i).

A number of African countries have issued compulsory licences in order to alleviate the health plights of their nationals. Mozambique and Zambia both authorised the use of compulsory licences in 2004. Mozambique's declaration was triggered by the country's HIV/AIDS situation which it considered to have reached emergency levels. In the words of the declaration, Mozambique considered itself to be among the ten countries in Africa worst hit by HIV/AIDS,[192] which was having a negative impact on the country's development efforts. Mozambique amended article 70 of its Industrial Property Code through Decree 18/99 of 4 May 2004, enabling it to make this declaration. The declaration reads as follows:

> The government of Mozambique, conscious that the HIV/AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, underdevelopment and misery and, taking into consideration that high rates of morbidity and mortality have put Mozambique among the ten countries in Africa worst hit by the disease. Current estimates are that at the end of 2002 over 1,5 million Mozambicans were infected by HIV, of whom more than 100 000 are suffering from full-blown AIDS. The AIDS death toll is far well over 200 000 and about 360 000 children have been orphaned by the pandemic, and that, in spite of multiplication and diversification of vigorous prevention campaigns the spread of the virus is still on a climbing trend as shown by the high number of infections, considering further that, anti-retroviral drugs are already available, which prolong lives of those infected with HIV/AIDS, and that until now, at this day, the international patent owners have failed to make such drugs accessible at affordable prices to most of the Mozambican people, and for such reason on 14 November 2001 the World Trade Organization declared the right of each member state to protect public health and in particular to promote access to medicines for all, by granting compulsory lincences in cases which constitute national emergency or other circumstances of extreme urgency and of public health crisis, including those relating to HIV/AIDS tuberculosis, malaria or other epidemics can represent a national emergency or other circumstances of extreme urgency. Considering further that a triple compound of Lamivudine, Stavudine and Nevirapine has proved, in the last few years, to be one of the most effective and economical anti-retroviral treatments, but the three different international owners of such single drugs failed to reach an agreement to produce this combination …[193]

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192 At the end of 2002, it was estimated that over 1,5 million Mozambicans were infected by HIV, of whom more than 100 000 were suffering from full-blown AIDS. See Decree 18/99 of 4 May 2004 below.

193 Mozambican compulsory licencing 01/M10/04. Mushayavanhu (n 7 above) 154, quoting http://www.cptech.org/ip/health/. The operative part of the declaration reads as follows:

Zambia also declared granting compulsory licences to alleviate the country's HIV/AIDS situation. The operative part of the declaration allowed the Ministry of Commerce, Trade and Industry to grant a compulsory licence to Pharco Ltd, a local company, to manufacture generic versions of Normavir 30 and Normavir 40.[194]

'The Ministry of Commerce and Industry of the Republic of Mozambique, making use of the provision of art 70 no. 1 point (b) of Decree no. 18/99 of 4 May, has decided to grant the compulsory licence no 1/MIC/04 to the company Pharco Moçambique Lda, which has already presented a project for local manufacture of the mentioned triple compound under the names of Pharcovir 30 and Pharcovir 40. Communication of this decision will be given to the applicant and to the patent owners. In consideration that the mentioned product, a triple combination of drugs, is not marketed in Mozambique by the international patent owners and that it is in the national interest to keep the final price as lowest as possible, to the total amount of royalties due to the patent owners shall not exceed 2% of the total turnover of the mentioned products, at the end of each financial year of Pharco Moçambique Lda. This Ministry of Industry and Commerce, in accordance to provisions of Art. 70 point 6 of Decree no. 18/99will notify the concerned parties of the expiration of the present compulsory licence as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end. The Government of the Republic of Mozambique reserves the right to review this compulsory licence, in case the conditions in which it was issued are changed.'

194 The Preamble to the Zambian Declaration provides as follows: 'The government of Zambia, conscious that the HIV/AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under-development and misery, and taking into consideration that high rates of morbidity and mortality have put Zambia among the ten countries in Africa most hit by this disease. Current estimates are that, at the end of 2003, over 917 218 Zambians are infected by HIV, of whom an unestimated number are suffering from full-blown AIDS. The AIDS death toll is so far in excess of 835 904 and about 750 504 children have been orphaned by this pandemic, creating a situation where 75% of households in Zambia are caring for at least one orphan, and that children aged below 14 years headed more than 130 000 poverty stricken households out of a total of 1,905 000, and that, in spite of the multiplicity and diversity of vigorous prevention campaigns, the spread of the virus is still on an upward trend as shown by the high number of infections; taking into account the gravity of the situation being faced by most African countries, including Zambia, the need to ensure access to drugs at affordable prices, while respecting the protection of intellectual property, is well recognised. For this reason; on 14 November 2001, the World Trade Organization, while recognising members' commitment to the TRIPS Agreement, declared the right of each member state to take measures aimed at protecting public health and in particular to promote access to medicines for all, by utilising to the full the flexibilities in the TRIPS Agreement relating to, among others, the granting of compulsory licences, in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crisis including those relating to HIV/AIDS, tuberculosis, malaria, or other epidemics which can represent a national emergency or other circumstances of extreme urgency. Considering further that a triple compound of Lamivudine, Stavudine and Neverapine has proved, in the last few years, to be one of the most effective economical anti-retroviral treatments, but that the three different international owners of such single drugs failed to reach an agreement to produce this combination.' The operative part provided that '[t]he Ministry of Commerce, Trade and Industry of the Republic of Zambia, making use of the provisions of sec 40 of the Patent Act, Chapter 400 of the Laws of Zambia, and Statutory Instrument No 83 of 2004 titled The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004 Regulation 3, has decided to grant a Compulsory Licence No. DC 01/2004 to PHARCO, LTD, a company incorporated in Zambia, which has already presented a project proposal for the local manufacture of the mentioned triple compound under the names of Normavir 30 and Normavir 40. It is further understood that the use of vending of the above mentioned drugs is subject to Regulation 4 of Statutory

It should be pointed out that compulsory licences have also been used to good effect outside of Africa. Compulsory licences have been issued in other developing countries, including Thailand,[195] Brazil,[196] India,[197] Indonesia[198] and Ecuador.[199] From 2006 to 2008, the government of Thailand famously issued a number of licences to help alleviate its plight of access to medicines. The issuance of these licences was very contentious inside and outside of Thailand, as many thought that the negative consequences of their issuance, such as problems with the US and EU, might outweigh the benefits of the issuance in terms of improved access to affordable medicines.[200] Nevertheless, the Thai

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Instrument No 83 of 2004, titled the Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation), Regulations, 2004, and therefore cannot be exported to any place outside Zambia. Communication of this decision will be given to the applicant and to the patent right holders. In consideration that the mentioned product, a triple combination of drugs, is not marketed in Zambia by the international patent owners and that it is in the national interest to keep the final price as low as possible, the total amount of royalties due to the patent owner shall not exceed 2.5% of the total turnover of the mentioned products at the end of each financial year of PHARCO LTD. The Ministry of Commerce, Trade and Industry, shall in accordance with sec forty one of the Patent Act notify the concerned parties of the expiration of the present Compulsory License as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end, or upon the expiry of the period of national emergency stipulated in Statutory Instrument No 28 of 2004 titled The Patent (Manufacture of Patented Antiretroviral Drugs) (Authorization) Regulations, 2004, and therefore cannot be exported to any place outside Zambia. Communication of this decision will be given to the applicant and to the patent right holders. In consideration that the mentioned product, a triple combination of drugs, is not marketed in Zambia by the international patent owners and that it is in the national interest to keep the final price as low as possible, the total amount of royalties due to the patent owner shall not exceed 2.5% of the total turnover of the mentioned products at the end of each financial year of PHARCO LTD. The Ministry of Commerce, Trade, Industry, shall in accordance with sec forty one of the Patent Act notify the concerned parties of the expiration of the present Compulsory Licence as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end, or upon the expiry of the period of national emergency stipulated in the Statutory Instrument No 38 of 2004 titled The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004. The Government of the Republic of Zambia reserves the right to review this Compulsory Licence should the conditions and circumstances under which it is granted should change.'

195 In 2010, Thailand renewed compulsory licences for HIV medicines Efavirenz and Lopinavir+ritonavir.

196 In 2007 Brazil granted a compulsory licence on the HIV medicine Efavirenz for five years. See P Maybarduk 'US Government Special 301 "watchlist" and developing country use of compulsory licences for healthcare' http://infojustice.org/archives/29493 (accessed 8 July 2014).

197 India issued a compulsory licence this year for Sorafenib, a treatment for kidney and liver cancer. See Maybaduk (n 83 above).

198 Decree of the President of the Republic of Indonesia 76 of 2012 regarding the exploitation of patent by the government on antivirals and antiretroviral medicines.

199 S Catherine 'Ecuador grants first compulsory licence for HIV/AIDS drug' *Intellectual Property Watch*. 22 April 2010. http://www.ip-watch.org/weblog/2010/04/22/ecuador-grants-first-compulsory-licence-for-hivaids-drug/. (accessed 8 July 2014).

200 I Yamabhai 'Government use licences in Thailand: An assessment of health and economic impacts' http://www.globalizationandhealth.com/content/7/1/28 (accessed 23 July 2013).

government issued compulsory licences for the production of generic versions of seven essential medicines relating to HIV, cardio-vascular disease and cancer, namely, Efavirenz, Lopinavir/Ritonavir combination, Clopidogrel, Letrozole, Docetaxel, Erlotinib and Imatinib.[201] The justification of the Thai government was the substantial burden of the diseases, the clinical importance of the medicines and the affordability of the generic prices and compliance with the TRIPS flexibilities and Thai Patent Act.[202] The main implication of the policy was the reduction in prices of the drugs and, more importantly, an increase in their accessibility to many Thais who were in need of those medicines.[203]

In addition to allowing compulsory licences for the manufacture and sale in all economic sectors, article 31 of the TRIPS Agreement also provides for public, non-commercial use of patents (government use). One of the most important features of public non-commercial use is that it does not require prior negotiation with the rights holder. It should be pointed out that TRIPS does not provide a definition of 'public, non-commercial use'. Musungu and Oh maintain that government or public, non-commercial use licences are different from compulsory licences in that ordinary compulsory licences 'would cover commercial [and non-commercial] use'.[204] Thus, the difference appears in the nature and purpose for which the patent is used.[205] The consequence of taking this difference into consideration, especially when formulating policies, is that developing countries have ample policy space in interpreting government use to include a vast array of measures aimed at safeguarding their public health needs.[206] It is clear that government use can include use by and for the government and, thus, government-use licences can be granted to commercial, for-profit entities that are producing products for public, non-commercial purposes by government.

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201 As above.
202 As above.
203 A Mohra et al 'Impact of the introduction of government use licences (GUL) on the drug expenditure of seven drugs in Thailand.' http://www.ispor.org/consortiums/asia/ViH/3rdIssue/Impact-of-the-Introduction-of-Government-Use-Licenses.pdf (accessed 22 July 2013).
204 S Musungu & C Oh *The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?* (2005) 22.
205 As above.
206 As above.

Finally, a number of recommendations have been advanced for developing and least-developed countries to make proper and better use of government-use provisions. Any government-use system should be simple and straightforward, not overly legalistic. Second, government-use provisions should be strong by giving governments broad powers to issue government-use licences and, lastly, the system of compensation should be straightforward and easy to administer.[207]

The above shows the importance of compulsory and government-use licences as a positive response to the health plight faced by many developing countries. Most developing countries are not wealthy enough to provide brand name medicines to their citizens. In addition, many do not possess the technical and human resources to manufacture new medicines to cure diseases affecting most of their citizens.

3.5 Competition-based flexibilities

Competition-based flexibilities are provided for under articles 8(2), 31(k) and 40. Article 8(2) gives member countries the authority to take measures to stop practices adopted by IP holders that may be anti-competitive and may act as a restraint of international trade. However, any such measure must be consistent with the TRIPS Agreement. As pointed out in chapter two, the importance of this provision is, firstly, that 'it provides justification for the use of anti-competitive measures',[208] while the shortcoming is that it gives the WTO the authority to scrutinise anti-competitive measures because such measures must be consistent with the TRIPS Agreement and, secondly, that it contains the word 'may', not the mandatory 'shall', meaning that members are not obliged to

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207 J Love 'Compulsory licences: Models for state practices in developing countries, access to medicines and compliance with WTO TRIPS Accord' 6-7 *Third World Network* 2004 http://www.twnside.org.sg/title2/IPR/pdf/ipr06.pdf (accessed 23 July 2013).

208 E Ghosh 'Competition law and intellectual property rights with special reference to the TRIPS Agreement' (2010) http://www.cci.gov.in/images/media/ResearchReports/EshanGhosh.pdf (accessed 2 September 2012).

adopt competition laws/policies to stop anti-competitive practices by a rights holder. [209]

Article 31(k) states that in cases where anti-competitive practices have been found, either through judicial or administrative investigation, WTO Members need not follow the requirements of articles 31(b) and 31(f) when issuing a competition-based compulsory licence. Additionally, when determining the amount to be paid to the patent holder as remuneration, WTO member states may factor in the need to cure anti-competitive practices.

In order to analyse and interpret article 31(k), it is necessary to look at the provisions of articles 31(b) and 31(f) because article 31(k) creates competition-based exceptions to articles 31(b) and 31(f). Article 31(b) lays down the conditions to be followed before the issuance of a compulsory licence. These conditions include 'unsuccessful efforts made to obtain authorisation from the right holder on reasonable commercial terms and within a reasonable period of time'; promptly informing the patent holder in instances of 'public non-commercial use'; and, lastly, compulsory licences can be granted expeditiously in cases of 'emergency or extreme urgency'. Article 31(f) also provides another condition to be fulfilled before the issuance of a compulsory licence. It provides that a compulsory licence 'shall be authorised predominantly for the supply of the domestic market of the member authorising such use'. Because of article 31(k), the conditions set forth in articles 31(b) and 31(f) need not be followed in instances where the patent owner is found to have been involved in anti-competitive practices. In such a scenario, article 31(k) can be triggered to issue a competition-based compulsory licence that allows unlimited export, and that does not require prior negotiations for a voluntary licence.

One issue with article 31(k) is the absence of the definition of anti-competitive practice or, better still, what will constitute anti-competitive practices. Some scholars have pointed out that in the absence of a definition, countries would have the lee-way in determining what constitutes anti-

209 See ch 2 of this thesis.

competitive practices. Baker, for example, argues that, given the absence of any definition or guidance on what constitutes anti-competitive practices, countries can frame definitions on the subject under their national laws.[210] This is because article 1 of TRIPS gives Members the authority to 'determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice'.[211] This is an important flexibility as countries would have the policy space to determine what constitutes anti-competitive practice. According to Baker:

> Super-monopoly power, profits, excessive prices, patent holders discriminating between prices offered in the public and private sector and the practice of price differentiation among countries can be held to constitute anti-competitive practices.[212]

Article 40 gives member states the right to adopt measures regulating anti-competitive terms in licensing agreements. Under this provision, countries can prescribe legal and anti-competitive licensing terms and also require the submission and regulatory approval of proposed licensing agreements .Article 40 also obligates states to co-operate and to give full support to requesting states that intend to address anti-competitive practices.[213]

Competition law thus provides a good mechanism to promote access to medicines. It has been used with great success in South Africa. In the case of *Hazel Tau & Others v GlaxoSmithKline SA (Pty) Ltd & Others*,[214] two pharmaceutical companies were challenged for anti-competitive practices that made it difficult for certain medications to be accessed in the private sector. In 2002, Hazel Tau, a group of individuals and civil society organisations, submitted a complaint to the South African Competition Commission against

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210 B Baker 'Producing HIV/AIDS medicines for export/import under TRIPS, articles 31(F), (K), and 30' (2001) *Trans-Atlantic Consumer Dialogue (TACD) briefing paper* 9.

211 As above.

212 As above. See UNDP 'Using competition law and policy to promote access to medicines' http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf (accessed 7 July 2014).

213 See ch two above for an analysis of this provision.

214 Competition Commission of South Africa, Case No 29 of September 2003).

Boehringer Ingelhiem (BI) and GlaxoSmithKline (GSK) for collusion and involvement in anti-competitive practices. The complainants alleged that GSK and BI were responsible for 'premature, predictable and avoidable loss of life' by charging excessive prices of their anti-retrovirals (ARVs) to private-sector patients. The complaint was predicated on section 49B(2)(b) of South Africa's Competition Act 89 of 1998, which stipulates that any person may 'submit a complaint against an alleged *prohibited practice* to the Competition Commission in the *prescribed* form'.[215] The South African Competition Commission held that

> [b]oth companies had charged excessive prices for their patent-protected anti-retroviral medicines; had unlawfully refused to issue voluntary licences to generic companies, thereby unreasonably restricting access to an essential facility preventing fixed-dose combination medicines.[216]

The actions of the two companies were found to be in violation of section 8 of the South African Competition Act which prohibits 'a dormant firm to refuse to give a competitor access to an essential facility when it is economically feasible to do so'. The two companies were also found to have violated section 8(b) of the Act, which defines 'essential facility as an infrastructure or resources that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers'.

The Competition Commission subsequently referred the matter to the Commission Tribunal by virtue of section 50 of the Competition Act, which allows for the submission of complaints by the Competition Commission within a year if the commissioner at the Competition Commission determines that a prohibited practice exists.

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215 Note that the emphasis in italics of the words 'prohibit practice and prescribed' is provided for in the Act.

216 Ghosh (n 95 above) 159.

Faced with the possibility of adverse publicity, bad precedent, disclosure of their actual R&D costs, and long drawn-out litigation,[217] BI and GSK decided to settle the matter with the complainants. With regard to the granting of voluntary licences, the settlement agreement provided that

> all licensees and applicants for licences contemplated in this agreement should be strongly encouraged, so far as practicable, to manufacture and/or formulate relevant anti-retrovirals in South Africa in the interests of developing local pharmaceutical manufacturing capacity and job creation. GSK will accordingly convey this view to all such licensees and applicants for licences. For the sake of clarity, it is recorded that GSK will not delay, refuse or withhold a licence as contemplated above on the basis that the applicant will not agree or will not be able as a licensee to manufacture or formulate relevant anti-retrovirals (whether in combination with other anti-retroviral medicines or otherwise) in South Africa.[218]

Following the settlement agreement, the two companies went ahead to grant voluntary licences to a South African company, Aspen Pharmacare, so as not to be bound by the decision.[219]

The *Hazel Tau* case shows the effectiveness of using competition law to promote access to medicines. This success notwithstanding, a cautious approach is called for. Competition law may be complex and difficult to understand and use, especially by litigants with limited means to hire an expert or limited capacity to understand certain specialised concepts, for instance, market dominance. In a bid to get BI and GSK to react positively to their complaint, the complainants treaded carefully and stuck with the excessive prices argument rather implicating other aspects of the Competition Act.[220] The complainants linked the excessive price argument to the grave HIV/AIDS

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217 T Avafia et al *The ablility of select sub-Saharan African countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: A study of producing and importing countries* (2006) 32.

218 Clause 2.2.5 of the settlement agreement between Hazel Tau and Others and GlaxoSmithKline South Africa (2003).

219 As above.

220 Avafia et al (n 104 above) 29.

problem prevailing in South Africa at the time, as well as to South Africa's Bill of Rights.[221]

Despite the complainant's cautious approach, the Competition Commission expanded its analysis beyond the excessive pricing argument and also adopted an 'essential facilities' theory. In fact, the Competition Commission found that the practices of the pharmaceutical companies had violated the Competition Act by refusing access to essential facilities as spelt out in section 8(b) of the Competition Act. Menzi Simelane, commissioner of the Competition Commission, expressed the following view:

> Indeed the very goals of our Competition Act - promoting development, providing consumers with competitive prices and product choices, advancing social and economic welfare and correcting structural imbalances - have been made difficult in this context by the refusal of the respondents to license patents.[222]

To facilitate the effective use of competition law in promoting and protecting access to medicines, most African countries would have to craft laws that are clear and would have to avoid ambiguities as much as possible. In addition, such laws should provide for effective relief in the form of, for instance, the issuing of compulsory licences in cases involving anti-competitive practices. One way would be to interpret and domesticate TRIPS provisions against anti-competitive practices into local law.

However, as mentioned in chapter two, the importance of using competition law to promote access to medicines may be difficult to gauge in many African countries. Many African countries, except South Africa, are still in the process of adopting competition legislation. Thus, the use of competition

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221 Specifically sec 39(2) of the South African Constitution, which obligates every court, tribunal or forum to interpret pieces of legislation by promoting 'the spirit, purport and objects of the Bill of Rights'.

222 Competition Commission of South Africa Media Release (29 of 2003): Competition Commission finds pharmaceutical firms in contravention of the Competition Act, 16 October 2003 http://www.compcom.co.za.(accessed 24 September 2013).

principles has therefore been minimal. In addition, even in countries that have adopted competition laws, there has been limited use, perhaps due to capacity constraints or, more likely, a culture of not using competition laws. For instance, Cameroon passed a Competition Law in 1998,[223] but it has not been used as widely as in South Africa. This may be because, unlike South Africa, in Cameroon there is limited domestic capacity to enforce competition law.

3.6 Additional public health flexibilities

3.6.1 Standards of patentability

Setting the proper standards of patentability is an additional TRIPS flexibility. Article 27 of TRIPS lays down the baseline standards of patentability. It provides that inventions are patentable if they are 'new, involve an inventive step and are capable of industrial application'. Chisum is of the view that the provisions of article 27(1) that '[f]or the purposes of this article, the terms "inventive step" and "capable of industrial application" may be deemed by a member to be synonymous with the terms "non-obvious" and "useful" respectively' was to accommodate the United States' 'non-obviousness' and 'utility' requirements.[224]

The TRIPS Agreement does not expressly define novelty and inventive step. To cover this void, countries have further defined them either through statutes, regulatory guidance or case law.

Regarding inventive step, the European Patent Convention defines it as follows: 'An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.'[225] The European Patent Organisation further states in its manual on invention that '[t]o be regarded as an invention, an idea needs to include an

223 Law 98/013 of 14 July 1998.
224 D Chisum 'Patentability under TRIPS: The need for uniformity' (2006) 2 *Indian Journal of Law and Technology* 2-3.
225 Art 56 European Patent Convention.

inventive step. An inventive step must be non-obvious - that is, it would not readily occur to an expert in the relevant technology.'[226] In order words, the inventive step must not be obvious to a person skilled in the arts. In the case of *Polymer Powders/Allied Colloids Limited*, the Board of the European Patent Organisation described the person skilled in the art in the following words:

> Whilst such generally accepted definitions of the notional 'person skilled in the art' do not always use identical language to define the qualities of such a person, they do have one thing in common, namely that none of them suggests that he is possessed of any inventive capability. On the contrary, it is the presence of such a capability in the inventor which sets him apart from the notional skilled person.[227]

In the US, for a long time the teaching, suggestion and motivation (TSM) test was used to determine non-obviousness. The TSM test arose from a corpus of cases built over the years by US courts.[228] Under the TSM test, 'an invention was non-obvious if the prior art failed to provide teaching, suggestion, or motivation to combine known elements to reach the claimed invention'. [229] However, in *KSR v Teleflex*,[230] the US Supreme Court overruled the TSM test, stating that 'a person of ordinary skill is also a person of ordinary creativity, not an automaton',[231] and dwelled on the 'need to consider common sense and the degree of predictability of the results or advantages obtained by the proposed combination'.[232]

The Revised Bangui Agreement of 1999 does not define all the patent standards. It only lists them as TRIPS does. As discussed further in a subsequent chapter, it is recommended that OAPI, in receiving patent applications, apply a strict standard on inventive step. One way would be to

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226 http://www.epo.org/topics/innovation-and-economy/handbook/novelty/idea.html (accessed 9 July 2014).
227 T39/93 [1997] OJ EPO 134.
228 J Richards 'Obviousness and inventive step - New differences?' http://fordhamipconference.com/wp-content/uploads/2010/08/John_Richards_Obviousness_and_Inventive_Step_New_Differences.pdf (accessed 9 July 2014).
229 T Calame et al 'The patentability criteria for inventive step/non-obviousness' http://www.aippi-us.org/docs/WGL_Q217_final_E_211210.pdf (accessed 9 July 2014).
230 550 US 398 (2007).
231 As above.
232 Calame et al (n 116 above).

require that the 'invention is obvious to a person highly skilled in the art'.[233] It is submitted that the more expertise considered when evaluating the non-obviousness of an invention, the higher the possibility of that invention to be deemed obvious.[234]

As with inventive step, TRIPS also does not define novelty. Member states have had to give their own definitions in their respective IP laws. Under section 2 of the UK 1977 Patent Act, an invention shall be taken to be new if it does not form part of the state of the art. The section goes on to define state of the art as to be taken to comprise all matter which has at any time before the priority date of the invention been made available to the public, whether in the UK or elsewhere, by written or oral description, by use or in any other way.[235]

As with inventive step, the Revised Bangui Agreement of 1999 does not expressly define novelty. Some African countries have not only linked novelty to prior art, but have actually defined it. Under the IP laws of Kenya, prior art comprises matters which before the invention have been made 'worldwide written or oral disclosure use, exhibition or other non-written means'.[236] Under the IP laws of Tanzania (Zanzibar), prior art comprises matters which before the invention have been

> made worldwide and disclosed in tangible or oral form including patent applications; everything that can be derived from a combination of patents; use; information disclosed in any other way, including material in any deposit institution.[237]

From the foregoing and in order to promote and protect access to medicines, it is submitted that African countries broadly define prior art as widely as possible, including

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233 East African Community Regional Intellectual Property *Policy on the utilisation of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation* (2001) 13.

234 As above.

235 Secs 2(1) & 2(2) of the UK Patent Act (1977). This is similarly provided for in sec 54 of the European Patent Convention.

236 Sec 23.2 Kenyan Industrial Property Act of 2001.

237 Sec 4.2 Zanzibar Patents Act 4 of 2008.

> everything disclosed to the public, whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be actually or theoretically accessed by the general public.[238]

Notwithstanding the above and in the context of access to medicines, the question is whether to grant patents on minor variations in chemical compounds, new formulations and dosages, or new uses of existing products, generally referred to as ever-greening. Some countries, such as India, have adopted high standards of patentability. Article 3(d) of Indian Patent Act provides that the following are not patentable:

> [t]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

In contrast, most developed countries are loosely defining patent standards to include some new forms and new uses of products and are seeking to impose that looseness on trading partners. For instance, consistent with its own domestic practice, the US proposed text in the Trans-Pacific Partnership Agreement (TPPA) is to the following effect:

> The parties confirm that patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.[239]

To really benefit from the TRIPS flexibility to adopt stringent patentability standards and to prevent ever-greening and the proliferation of secondary patents of dubious quality, developing and least-developed countries should limit the definition of patent standards, especially not granting patents on new

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238 East African Community (n 120 above).

239 See http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf (accessed 2 January 2014).

forms and uses of existing medicines. In fact, the UN Special Rapporteur on the Right to Health has recommended:

> Developing countries and LDCs should establish high patentability standards and provide for exclusions from patentability, such as new forms and new or second uses, and combinations, in order to address ever-greening and facilitate generic entry of medicines.[240]

As mentioned above, patenting of new forms has generated tremendous debate all over the world. Until recently, it was not possible to patent living organisms, which were always regarded as discoveries of nature and therefore not patentable. In 1980, however, all this changed. In the landmark case of *Diamond v Chakrabarty*,[241] the issue was whether a living organism, a bacterium that could digest oil, could be patented. The US Supreme Court ruled in the affirmative with Chief Justice Warren Burger declaring that the 'relevant distinction is not between animate and inanimate things but whether living products could be seen as human-made inventions'. This decision marked an important turning point in IP history, as it opened the floodgates towards the patenting of gene pool of plants, animals and humans as well as long-drawn litigation between pharmaceutical companies.[242] However, this position has changed following the case of *Association for Molecular Pathology v Myriad Genetics Inc*,[243] where the US Supreme Court held that merely isolating genes that are found in nature does not make them patentable. Generally, the following negative consequences on access to health care have been noted if new forms are patented:

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240 See http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf (accessed 2 January 2014).

241 447 U.S. 303 (1980).

242 Eg, the long drawn-out legal battle between Hoffman La Roche and Chiron over a patent on genes and proteins of the AIDS (HIV) pathogen granted to Chiron by the European Patent Agency in 1993. The dispute ended with an out-of-court settlement of over US $78 million in favour of Chiron. See D Levine 'Chiron wins $78M in dispute with giant Hoffmann-La Roche' http://www.bizjournals.com/sanfrancisco/stories/2004/09/20/newscolumn1.html?page=all (accessed 8 July 2014).

243 USSC 12-398

(i) considerable increase in the burden on patients and health insurance funds;
(ii) protracted litigation that may also severely impede research and development;
(iii) a blockade of research and development by whole bundles of patents to be observed for individual technical innovations;
(iv) hindrance to medical institutions, particularly in the field of diagnosis;
(v) obstruction of current proteomics research by hastily granted and too extensive gene patents;
(vi) impediment of research and development, particularly in the field of infectious diseases; and
(vii) unacceptable dependence of patients with hereditary diseases on individual companies.[244]

It should be pointed out that recent debates on intellectual property have also focused on additional patentability criteria, namely, industrial applicability and disclosure. Some developed countries have favoured a broad interpretation of industrial applicability with the aim of easing patent standards, whereas developing countries want a strict interpretation. In the US, for instance, 'the approach to the utility requirement is that the requirement is met so long as the specified utility is reasonable and not an attempt'.[245] In the EU, with regard to industrial applicability, the European Patent Office (EPO) Examination Guidelines state that '[t]he description should indicate explicitly the way in which the invention is capable of exploitation in industry'.[246] The EPO has given the following example to show the applicability of the industrial application provision:

> [I]n most cases, the way in which the invention can be exploited in industry will be self-evident, so that no more explicit description on this point will be required; but there may

244 'The true cost of gene patents: The economic and social consequences of patenting genes and living organisms http://www.greenpeace.org/international/PageFiles/24248/1Study_True_Costs_Gene_Patents.pdf (accessed 8 July 2014).
245 J Erstling 'Usefulness varies by countries: The utility requirement of patent law in the United States, Europe and Canada' (2012) http://web.wmitchell.edu/cybaris/wp-content/uploads/2012/06/Erstling-Salmela-Woo.pdf 10 (accessed 1 November 2014).
246 EPO Examination Guideline C, ch II, para 4.12.

> be a few instances, eg, in relation to methods of testing, where the manner of industrial exploitation is not apparent and must therefore be explicitly indicated.[247]

The above definition and interpretations given suggest a broad and less stringent approach to the industrial application standard by certain developed countries. However, developing and least-developed countries should not follow the above approach. They should adopt a strict approach in interpreting industrial applicability as well as demanding full disclosure from the patentee.

3.6.2 Disclosure

Disclosure requirement is couched in article 29 of TRIPS, which provides:

> 1 Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
>
> 2 Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

From the above, TRIPS members will require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. In addition, TRIPS members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

Under US law, the patent application must 'set forth the best mode contemplated by the inventor of carrying out his invention'.[248] As was pointed out in the case of *Eli Lilly & Co v Barr Laboratories Inc*,[249] the reason behind the best mode requirement is that it

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247 As above.
248 US Patent Laws, 35 USC 112.
249 *Eli Lilly & Co v Barr Laboratories Inc* 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed Cir 2001).

> creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practising the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practising the claimed invention.[250]

Furthermore, it has been submitted that, in the absence of strict standards for disclosure, there could be an unwillingness for patent applicants to not fully disclose the details of their invention. As such, they might keep the knowledge of the 'best mode' undisclosed, 'so that they retain a competitive advantage even after the patent expires'.

Article 29(2) of TRIPS gives members the right to require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants. This could be helpful for countries with limited capacity as it would enable their patent officers to know the status of the patent application in other countries.

3.6.3 Pre- and post-grant opposition application

Generally, a patent opposition refers 'to the ways in which it is possible to challenge the validity of a patent – both during the period when a patent application is being reviewed, and after the patent has been granted'.[251] When the opposition is done during the period when the patent application is reviewed, it is referred to as pre-grant opposition. When the opposition takes place after the patent has been granted, it is referred to as post-grant opposition. Post-grant opposition is best understood as involving administrative procedures rather than judicial revocation or invalidation procedures.

As discussed above, article 27 of TRIPS generally sets out patentability standards to be met before patents are granted. Specific implementation,

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250 As above.

251 See http://patentoppositions.org/how_to_build_an_opposition (accessed 2 January 2014).

however, is dependent on the provisions of national laws. This is provided for in article 62(4) of TRIPS, which provides:

> Procedures concerning the acquisition or maintenance of intellectual property rights and, where a member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of article 41.

Opposition, especially those that are against questionable patent monopolies, if successful, can lead to a price decrease since the patent will be rejected, thereby allowing the production of low-priced generics. This will in turn facilitate access to medicines.[252]

One of the first cases where a patent was opposed by those promoting access to medicines was tested was the case of *AIDS Access Foundation & Others v Bristol Myers Squibb & the Department of Intellectual Property.*[253] In May 2001, a law suit was filed by the AIDS Access Foundation, a Thai AIDS foundation, and two people living with HIV/AIDS, against Bristol-Myers Squibb (BMS) and the Thai Department of Intellectual Property (later added as a co-defendant). The law suit challenged the grant of a patent on the anti-retroviral drug Didanosine (also known as DdI).

The US government held the rights to the original DdI invention, but later BMS licensed the rights to DdI from the US government and filed a secondary patent application in Thailand intended to protect a specific dosage formulation. In this patent application, the invention was limited to a specified dosage range of 5mg to 100mg per dosage unit.

During the examination of the patent application, the Thai Department of Intellectual Property allowed BMS to remove the limitation in the dosage range.

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252 See 'MSF welcomes Brazil Parliamentary Committee recommendation to reform patent law' http://www.msfaccess.org/about-us/media-room/press-releases/msf-welcomes-brazil-parliamentary-committee-recommendation-reform (accessed 11 April 2015).

253 Black Case Tor Por 34/2544 The Central Intellectual Property and International Trade Court, October 2002.

Subsequently, the Thai patent office granted a patent for this unlimited invention. The effect of this unlimited patent was to prevent the Thai Government Pharmaceutical Organisation (GPO) from manufacturing any sort of DdI tablet. Faced with this block on local production of the tablets they needed, the AIDS Access Foundation and two individuals challenged the grant of the patent itself. The plaintiffs demanded that BMS amend their patent claim back to the limited dosage range originally asked for. BMS tried to oppose their application on the ground that the complainants had no right under Thai law to challenge a patent.

In its judgment, the court clearly confirmed that the two individuals and the AIDS Access Foundation had the right to challenge the BMS patent. The court ordered this, quoting the Doha Declaration and emphasising that the TRIPS Agreement should be implemented and interpreted in a manner supportive of Thailand's right to protect public health and, in particular, to promote access to medicines for all.[254] The court noted that the plaintiffs had the right to challenge the patent and that 'those in need of medicines are interested parties to the granting of a patent'.[255]

The court also found that the amendment BMS made was unlawful because the removal of the dosage limitation of 5mg to 100mg expanded the scope of protection beyond what was described in the patent document.[256] The judgment ordered BMS and DIP to amend the patent by reinstituting the limitation. This meant that the non-patented DdI dosage forms could then be produced by generic manufacturers.[257]

Relying on judicial proceedings could cause delays and may be costly.[258] In order to fully benefit from pre-grant and post-grant opposition to patent

254 As above.
255 As above.
256 As above.
257 India is another country where opposition has been used to good effect. For a comprehensive discussion on opposition systems, see, generally, World Intellectual Property Organisaition 'Opposition systems and related mechanisms' http://www.wipo.int/patents/en/topics/opposition_systems.html (accessed 10 July 2014).
258 See WIPO: Standing Committee on the Law of Patents Report 24-29 January 2010: http://www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_5.pdf (accessed 13 May 2015).

application, developing and least-developed countries should not only allow pre- and post-grant opposition applications at the administrative level in their respective national laws, but they also need to put in place clear legislation that adopts easy-to-use procedures for submitting and deciding pre-grant and post-grant opposition applications. In this light, the UN Special Rapporteur for Health has recommended that '[d]eveloping countries and LDCs should establish liberal pre-grant, post-grant opposition and revocation procedures, which can be taken advantage of by all concerned stakeholders, including patients' groups'.[259]

3.6.4 Post-1995 extensions of the LDC transition period

Article 66(1) provides for another type of flexibility in the application of the TRIPS Agreement. This relates to the transition period for the implementation of TRIPS by LDCs. Article 66(1) provides:

> In view of the special needs and requirements of least-developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this Agreement, other than articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country member, accord extensions of this period.

This provision was followed by paragraph 7 of the Doha Declaration, which provided:

> We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in article 66.1 of the TRIPS Agreement.

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259 See http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf (accessed 2 January 2014).

Following the Doha Declaration, the TRIPS Council granted the first extension in 2002 that precluded LDCs from implementing or enforcing patent and test data obligations with respect to pharmaceutical products until 1 January 2016.[260]

The second extension, approved by the TRIPS Council in 2005, provided that LDCs would not have to apply the provisions of TRIPS (in general, not just as they apply to pharmaceuticals), other than articles 3, 4 and 5, until 1 July 2013.[261] Unfortunately, this extension had a stay-put provision that would not allow LDCs that had already adopted TRIPS IP protection to eliminate those protections. The 2013 extension has been further extended until 2021, but without the stringent stay-put provision.[262]

The primary benefit of these extension periods is to provide LDCs the policy space and ability 'to determine appropriate development, innovation, and technological promotion policies, according to local circumstances and priorities'.[263] Unfortunately, many LDCs, including those in OAPI, have not availed themselves of the flexibilities under the transition clause as extended.

3.7 Analyses of laws, cases and controversies surrounding the application of the TRIPS Agreement relating to access to medicines

3.7.1 The pharmaceutical companies' law suit against the government of South Africa[264]

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260 WTO Document IP/C/25 http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm (accessed 1 December 2014).

261 WTO document IP/C/40. http://www.wto.int/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf. (accessed 1 December 2014).

262 WTO: Extension of the transition period under article 66.1 for least developed country members. Decision of the Council for TRIPS of 11 June 2013.

263 TRIPS transition period extensions for least-developed countries, http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2474_TRIPS-transition-period-extensions_en.pdf (accessed 2 January 2014).

264 The legal suit was *Pharmaceutical Manufacturers Association & Others v President of the Republic of South Africa & Others* (Transvaal Provincial Division case 4183/98).

The potential impact of the TRIPS Agreement on access to essential medicines was brought into focus in February 1998 in South Africa, when 42 pharmaceutical companies (applicants) brought an action before the High Court of South Africa (Transvaal Provincial Division) against the government of South Africa (composed of ten respondents) to challenge the constitutionality of some of the provisions embodied in the Medicines Amendment Act 90 of 1997.[265] Prior to the legal action, there had been tension brewing between the Pharmaceutical Manufacturers Association of South Africa (PMA) and the Department of Health. This was evident when the PMA filed a complaint with the Public Protector of South Africa, stating that officials of the Department of Health had 'created a perception in the minds of the general public that medicines in South Africa are unreasonably expensive and moreover that the blame for such expensive medicines lies with the manufacturing and primary importing companies'.[266]

It should be noted that the legal action brought, but subsequently abandoned by the PMA, concerned, in particular, section 10 of the South African Medicines and Related Substance Control Amendment Act of 1997, which added section 15C to the 1965 Medicines and Related Substances Control Act.[267] In terms of the TRIPS Agreement, the law suit challenged section 15C, alleging that it allowed the Minister of Health to abrogate patents and to allow parallel imports of pharmaceutical products in order to increase availability and lower the cost of medicines.[268] The Medicines Act also

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265 T Kongolo 'Public interest versus the pharmaceutical industry's monopoly in South Africa' (2001) 4 *Journal of World Intellectual Property* 616. See also 'Notice of motion in the High Court of South Africa' Transvaal Provincial Division Case 4183/98, http://www.cptech.org/ip/health/sa/pharmasuit (accessed 25 August 2011).

266 Public Protector of the Republic of South Africa, Report on the Propriety of the Conduct of Members of the Ministry and Department of Health Relating to Statements in Connection with the Prices of Medicines and Utilisation of Generic Medicines in South Africa, Special Report 6 (1997).

267 Sec 15C states: 'The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and, in particular may (a) notwithstanding anything to the contrary contained in the Patent Act 1978 (Act 57 of 1978), determine that the rights with regards to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine …' D Matthews 'The WTO decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: A solution to the access to essential medicines problem?' (2004) 7 *Journal of International Economic Law* fn 22, quoting Amendment Act, reprinted in Kongolo (n 152 above) 605.

268 Matthews (n 154 above) 79.

introduced a number of other elements with the aim of containing the health care cost to both the government and the private sector, but in a way that was alleged to unconstitutionally diminish the property rights of innovator pharmaceutical companies.[269] In the subsequent paragraphs, three such elements will be discussed, including reactions from pharmaceutical companies.

First, the Act provided for generic substitution of medicines that were no longer patented. Pharmacists were required by law to inform everyone who bought prescribed medicines of generic alternatives and their benefits, unless the patient expressly refused the substitution, the doctor had written 'no substitution' on the prescription, or the Medicines Council had declared the product 'not substitutable'.[270] By so providing, pharmacists would have had to offer generic versions of brand name medicines. With regard to this provision, the CEO of GlaxoSmithKline, Beecham, remarked that 'it will remove the ability of my company to retain profits from its pharmaceutical operations to which it is entitled as a result of substitution by default'.[271]

It was hypocritical for companies to criticise the South African government for inserting a provision on generic substitution, when rich countries did the same. In an extract of a US official report on generic substitution released by the Treatment Action Campaign, it is stated that in 1996, 43 per cent of prescription drugs sold in the US were generics and, since they cost less, they played an important role in reducing US national spending on prescription drugs: For instance, generics enabled purchasers to save between $8 billion and $10 billion in 1994.[272] The report stated that the rise in generics was, amongst other things, influenced by the Drug Price Competition and Patent Term Act of 1984, which made it easier and cheaper for companies to enter the market for generic drugs. Most states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even

269 As above.
270 Sec 22F.
271 See http://www.tac.org.za/Documents (accessed 31 August 2011).
272 As above.

when the prescription called for a brand name drug and, lastly, some government health programmes, such as Medicaid, and many private health insurance plans have actively promoted generic substitution.[273]

Second, the Medicines Act provided for the appointment of a pricing committee[274] that would recommend that the Minister of Health pass regulations to ensure transparency and accountability in medicine pricing.[275] The impact of this is that pharmaceutical companies would have to justify medicine prices they charged the public. The drug companies argued that this provision was unconstitutional as it would intervene with their constitutional right to trade.[276] It should be noted that other countries, such as The Netherlands, Germany, Sweden and Denmark, had implemented direct control mechanisms, such as having a fixed price for a certain group of pharmaceuticals and indirect price control mechanisms, such as global prescribers' budgets, to resolve their citizens' health plight.[277] It is submitted here that, by providing for price control and a price control committee, the South African government was merely following the example of other countries. In addition, a pricing committee would be able to establish the real cost of what a company spent to produce a particular medicine.[278] This will go a long way towards ensuring that companies do not hide behind the oft-cited mantra that they spend billions on research and development, which is the reason why they charge high prices. Thus, a price control mechanism would allow the government to ascertain the real cost incurred in the cost of production and a reasonable rate of return.

Thirdly, section 15C of the amended Medicines and Related Substances Act gave the Minister of Health the authority to prescribe conditions for the supply of more affordable medicines in certain instances to protect the health

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273 As above.

274 It should be noted that some countries have medicine review boards. In the US, it is called the Food and Drug Administration. In Canada, there is the Patented Review Board that was created in 1987. Irrespective of the many legal challenges about the Board's constitutionality, it has managed to keep prices of patented medicines lower.

275 Secs 22G & 35.

276 See n 158 above.

277 As above.

278 As above.

of the public.[279] Specifically, the law allowed the Minister to import the same medicines made by the same company or someone they had licensed if it is sold at a cheaper price in another country.[280] As a riposte to this provision, the drug company held that it conflicted with and violated the patent owner's rights as provided for in article 28 of the TRIPS Agreement and that it was not covered by the exceptions provided for in articles 30 and 31 of TRIPS.[281] The US government shared the industry's view, albeit in a different way, by stating that 'article 6 of TRIPS does not authorise parallel importation'[282] because it 'does not alter the substantive obligations of the TRIPS Agreement, particularly those contained in Part II of the Agreement'.[283] Another issue that arose concerning section 15C was that of compulsory licences. Generally, in terms of the TRIPS Agreement, South Africa had legislation[284] which complied with TRIPS. The problem was that at the time the PMA feared that South Africa could resort to the granting of compulsory licences as an option to solve its AIDS crisis, especially as Brazil had enacted a law in 1996[285] that allowed for compulsory licences. Similarly, WHO had adopted a resolution urging members to put public health over commercial interest in looking at measures to improve access to essential medicines.[286]

South Africa defended the law on two grounds, namely, that section 15C was constitutional as it did not grant the Minister broad powers to abrogate patent rights via compulsory licences and, secondly, that it was right under TRIPS to use parallel importation.[287] South Africa even believed that the law

279 Sec 15C.
280 As above.
281 W Fisher & C Rigamonti 'The South African AIDS controversy: A case study in patent law and policy' (2005) *Harvard Law School* 11.
282 As above.
283 See Statement by the US Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (10 July 2001) 40.
284 South African Patent Act 57 of 1978.
285 SICE, Intellectual Property Rights National Legislation-Brazil; Industrial Property Law 9.279 of 14 May 1996, http://www.sice.oas.org/int_prop/nat_leg/Brazil/ENG/L9279eI.asp (accessed 10 July 2014).
286 Fisher & Rigamonti (n 168 above).
287 As above.

suit was an attempt by the PMA and the US government to force it to enact TRIPS-plus laws.[288]

It should be noted that the US government also exerted trade pressure on South Africa to abolish section 15©. It used both domestic and international efforts to pressurise South Africa. Domestically, one of the first indications of the US government's discontent came from its then ambassador to South Africa, who wrote to the South African government, stating the following: 'My government opposes the notion of parallel importation of patented products anywhere in the world.'[289] In 1998 and 1999, the US put South Africa on its Special 301 watch list (as discussed above), withheld trade benefits on a range of South African goods under the GSP scheme and conditioned US development assistance to South Africa to the repeal, suspension or termination of section 15(C).[290]

Internationally, the US co-opted certain European countries to join in putting pressure on South Africa. For instance, the US Embassy in Pretoria contacted the Swiss and EU member embassies to join them in protesting against the provisions of section 15(C).[291]

The law suit and the subsequent US pressure was met with intense and widespread international condemnation and sympathy from human rights groups, NGOs and civil society organisations (CSOs).[292] In South Africa, the Treatment Action Campaign (TAC) played an important role in mobilising civil society and airing out its views on the impact a triumph by the PMA would have on access to medicine initiatives in South Africa, especially in the context of anti-retroviral medicines. Their curtain raiser was using the 2000 World AIDS Conference in Durban, South Africa, as a platform to spearhead national and

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288 Statement by the South Africa Delegation, Minutes of the Council for TRIPS Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/31 (10/July/2001) 27.

289 Fisher & Rigamonti (n 168 above) 7.

290 As above.

291 P Bond 'Globalisation, pharmaceutical pricing and South African health policy: Managing confrontation with US firms and politicians' (1999) 29 *International Journal of Health Services* http://www.iatp.org/files/Globalization_Pharmaceutical_Pricing_ and_South.htm (accessed 1 July 2013).

292 Eg, Oxfam and Treatment Action Campaign.

international opposition against the PMA.[293] In addition to its advocacy efforts, during the case, TAC sought and obtained permission from the High Court to intervene and file an *amicus curiae* brief.[294]

Meanwhile, during the case, NGOs in the US, led by Health Global Access Project (GAP) led a struggle against the US Global HIV/AIDS Policy under the Clinton administration. In a senatorial hearing in 1999, Eric Sawyer, one of the activists, summed up the NGOs' views on President Clinton's administration's AIDS Policy as follows:

> The administration is establishing international trade policy in a moral and intellectual vacuum – where the only thing that matters is the economic impact of trade on Western multinationals … The global village is much more than a global market. Disowning anyone in the village – because they don't buy enough of our merchandise, because they are weak, because they don't look like us, because we are too apathetic to work for their well-being as well as our own – is not just immoral, it is a threat to public health and humanity.[295]

Subsequently, the activists took a more robust campaign against the Clinton administration. They disrupted the kick-off of Al Gore's presidential campaign, held a protest against the United States trade representative, Charlene Barshefsky, and even travelled to Seattle to protest during the World Trade Organization ministerial meeting.[296]

The campaigns against Pharma's case in South Africa and President Clinton's policies fostered a strong moblisation between NGOs in both developed and developing world and developing country governments, culminating in the creation of the Global Treatment Access Group (GTAG), a network of NGOs including, among others, Treatment Action Campaign South

293 E Cameron 'Patents and public health: Principle, politics and paradox' inaugural British Academy law lecture held at the University of Edinburgh, 19 October 2004, 536.
294 As above.
295 P Siplon *AIDS and the policy struggle in the United States* (2002) 121.
296 Siplon (n 182 above) 123 124.

Africa, Act UP, *Medecins Sans Friontières* and Oxfam.[297] This moblisation, protests and the ensuing criticism caused the US President, Clinton, to 'back down on South Africa'[298] and he later signed the Executive Order on Access to HIV/AIDS Pharmaceutical and Medical Technologies 'directing the US government to refrain from seeking the revocation of any law or policy imposed by a beneficiary sub-Saharan government to promote access to essential medicines'.[299]

It should be pointed out that the case against the South African government proved particularly emotive and because access to anti-retroviral drugs for the treatment of HIV/AIDS, such as AZT (Zidovudine), was constrained in South Africa by the prohibitively high price of those medicines. In April 2001, the pharmaceutical companies that, since 1998, had challenged the constitutionality of the 1997 Amendment Act, announced the withdrawal of their action.

The above is a clear example of how a country was pressurised because it attempted to use a fully TRIPS-compliant flexibility. It is estimated that 400 000 people died of AIDS-related illnesses from the time the Act was passed and the time the pharmaceutical companies withdrew their law suit.[300] This was because it took almost three years for the case to be heard.

An argument could be made from this case that countries were not going to be permitted to use the limited flexibilities that they had been expressly granted in the TRIPS Agreement. This is because, irrespective of the fact that articles 7 and 8 tried to provide a compromise for countries to use flexibilities consistent with other TRIPS provisions to solve their health crises and to protect the public, Big Pharma and the US opposed the actual use of such flexibilities in order to preserve profits and to enhance the US's balance of trade. For

297 A Weber & L Mills 'A one-time-only combination: Emergency medicine exports under Canada's access to medicines regime' http://www.hhrjournal.org/index.php/hhr/article/view/209/303 (accessed 1 July 2013).
298 Siplon (n 182 above) 124.
299 President of the United States, Executive Order 13155, Access to HIV/AIDS Pharmaceutical and Medical Technologies.
300 Fisher & Rigamonti (n 168 above).

instance, it might have been that the pharmaceutical companies feared that they would not only lose business in South Africa, but, *a fortiori,* South Africa's example would have opened the floodgates for other countries to follow suit, as such limiting the market for brand name medicines.

3.7.2 Pharmaceutical companies' law suit against the government of the Philippines

The difficulty of having a parallel importation regime incorporated into domestic law came to the fore in the Philippines in November 2000. This was evident in the case of *Pharmaceutical and Healthcare Association of the Philippines Inc v The Government of the Philippines*.[301] The facts of the case were as follows: The Filipino Department of Health and Department of Trade and Industry had, through order AO No 85, used a state-owned enterprise called Philippines Trading Corporation to buy medicines at cheaper prices in India to the tune of 1,5 million Philippines dollars. The same medicines sold in the Philippines would have cost the government 5 million Philippines dollars. The petitioner, the Pharmaceutical and Healthcare Association of the Philippines Inc, brought an action for the issuance of a temporary restraining order against the respondent, the Department of Health, Director of Bureau of Food and Drugs and the Philippines Trading Corporation, claiming that the action 'violated existing laws and intellectual property rights of the members of the association and that its implementation would cause proliferation of adulterated drugs and medicines and would damage the reputation of the member pharmaceutical companies'.[302] The respondent, on the other hand, contended that granting such a restraining order would not hold muster from a technical and substantive viewpoint. From a substantive viewpoint, the respondent argued that the temporary restraining order would cause irreparable damage while, from a technical viewpoint, it posited that the verification of the petition was defective as well as the fact that the petitioner was not a party with a real interest.

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301 Civil case 00-1374 Regional Trial Court, National Capital Judicial Region, Branch 64 City of Makati, 28 November 2000.

302 As above.

The trial court of the city of Makati (the Court) held that the petitioner had satisfied the technicalities. On the substantive issue, the Court held that the petitioner had failed to convince the Court that

> the implementation of order AO No 85 will neither caused injustice nor irreparable damage. Instead, the importation of the medicines would be beneficial to patients of government hospitals by making these drugs available to them at a price lower than the prevailing price of the same drugs dispensed by the members of the petitioner's association.[303]

From the foregoing, it transpired the government of the Philippines was allowed to proceed with its parallel importation scheme as the Court ruled that it would be for the benefit of the public - the patients and people of the Philippines - rather than for the benefit of a few individuals - the pharmaceutical industries. By holding that 'neither injustice nor irreparable damage' would be caused by allowing parallel importation, the Court might have been motivated by the absence of tangible evidence that parallel importation presented danger to the business, reputation and profits of pharmaceuticals, as has always been claimed by pharmaceutical industries. In addition, the Court made a strong case that the public interest as a whole - healthcare and wellbeing - trumps 'the super profit' interests of pharmaceutical companies.

3.7.3 The case of article 68 of the Brazilian Industrial Property Act

US opposition to the use of the compulsory licensing provisions contained in the TRIPS Agreement was again highlighted in June 2001, when the US government initiated a complaint against Brazil in the WTO.[304] Brazil had taken legislative action that permitted the granting of compulsory licences to generic producers of, among others, anti-retroviral drugs to combat HIV/AIDS. Article 68 of the Brazilian Industrial Property Act provides as follows:

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303 As above.

304 Request for the Establishment of a Panel by the United States, Brazil – Measures Affecting Patent Protection, WT/DS199/1, 8 June 2001.

> A patent shall be subject to compulsory licensing if the owner exercises rights therein in an abusive manner or if it uses it to abuse economic power under the terms of an administrative or judicial decision.[305]

It further provides the following as grounds for compulsory licences: (i) failure to work the subject-matter of a patent on the territory of Brazil, failure to manufacture, or incomplete manufacture of, the product, or failure to completely use a patented process, except for failure to work due to lack of economic viability, in which case importing shall be admitted; or (ii) marketing that does not satisfy the needs of the market.

The US had also questioned the compatibility of article 68(4) of the Brazilian Industrial Property with TRIPS. Article 68(4) provides as follows:

> In the event of importation, in order to exploit a patent or importation in the preceding paragraph, third parties shall also be allowed to import a product manufactured according to a process patent or a product patent, provided it has been placed on the market directly by the patent owner or with his consent.[306]

The US complained that article 68(1)(1) was in violation of articles 27(1) and 28(1) of the TRIPS Agreement by imposing a 'local working' requirement which stipulates that a patent shall be subject to compulsory licensing if the subject matter of the patent is not 'worked' in the territory of Brazil. In addition, if a patent owner chooses to exploit the patent through importation rather than 'local working', then article 68 will allow others to import either the patented product or the product obtained from the patented process.

Article 27(1) of the TRIPS Agreement provides:

> Subject to paragraph 4 of article 65, paragraph 8 of article 40 and paragraph 3 of this article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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305 Law 9279 of 14 May 1996; effective from May 1997.
306 As above.

Article 28(1) gives the patent holder the right to prevent third parties without the patent holder's consent from selling, making, offering for sale or importing a patent-protected product. In instances where a process was patented, article 28(1) gives the patent holder the right to prevent third parties without the patent holder's consent from using for sale, selling, or importing a product which was directly obtained from the said process.[307]

In response to the US complaint, Brazil counter-complained against articles 204 and 209 of Title 35 of the US Patent Code, stating that those provisions discriminated against foreign producers. However, the US ultimately dropped its action against Brazil on 25 June 2001. The US withdrew its challenge and Brazil in turn agreed to hold prior talks with the US under the US-Brazil Consultative Mechanism before issuing any compulsory licence against patents held by US companies.[308] A joint communication to the WTO by the US and Brazil provided as follows:

> Without prejudice of the US and Brazil's different interpretations of the consistency of article 68 with the TRIPS Agreement, the US government will withdraw the WTO Panel against Brazil concerning the issue, and the Brazilian government will agree, in the event it deems necessary to apply article 68 to grant compulsory licences on patents held by US companies, to hold prior talks on the matter with the US. These talks would be held within the scope of the US-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject.[309]

One of the reasons for the US to withdraw the case was the widespread criticism from various civil society organisations, such as US Consumer Project on Technology, *Medecins Sans Frontières*, Oxfam and Third World Network advocating the increase of access to drugs in developing countries.[310] The US

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307 'This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of gods, is subject to the provisions of article 6 [of the TRIPS Agreement].'

308 'US beats a (tactical) retreat over Brazil's patent law' http://www.trnside.org.sg/title/tactical (accessed 1 September 2011).

309 As above.

310 M Lang 'What a long, strange 'TRIPS' it's been: Compulsory licencing from the adoption of TRIPS to the agreement on implementation of the Doha Declaration' (2004) 3 *John Marshall Review of Intellectual Property Law* 337.

was unwilling to receive more negative publicity following the case in South Africa.

Although the withdrawal was a major achievement for public health and access to medicine initiatives, the provision in the joint communication that prior talks had to be held with the US was somewhat disturbing. James Love, a leading campaigner against the US complaint, is of the opinion that it was against states' sovereignty, a *jus cogens* principle under international law. He stated the following:

> But the agreement to give the US government the right to be consulted on each compulsory licensing request is not helpful and it is reminiscent of the Gore proposal to South Africa that would have had the US government supervise each parallel import license. At some point, we have to respect national sovereignty, and in the case of Brazil, let Brazil continue its difficult and costly effort to treat poor AIDS patients.[311]

Some analysts have said that article 68 of the Brazilian Industrial Property Act did not *stricto sensu* violate the TRIPS Agreement.[312] Shanker is of the view that the US complaint was part of a 'strategy to test the provisions of TRIPS through use of the dispute settlement mechanisms'.[313] He points out that the local working provision of article 68 of the Brazilian Industrial Property Act was not in violation of article 27(1) of TRIPS, as it was in line with article 5 of the Paris Convention[314] which, by virtue of article 2 of the TRIPS Agreement, is applicable in its totality to the TRIPS Agreement. Article 5A(2) of the Paris Convention provides:

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311 Siplon, (n 182 above) 123 124.

312 See, eg, D Shanker 'Brazil, the pharmaceutical industry and the WTO' (2005) 5 *Journal of World Intellectual Property* 99.

313 As above.

314 The Paris Convention for the Protection of Industrial Property of 20 March 1883, as revised and amended up to 29 September 1979 (Legislative Texts): WIPO Database of Intellectual Property. For further discussions on local working condition as grounds for a compulsory licence, see M Halewood 'Regulating patent holders: Local working requirement and compulsory licences at international law' (1997) 35 *Osgood Hall Law Journal* 243-287; C Lee 'The legality of local patent working requirements under the TRIPS Agreement (2013) 2 *National Taipei University of Technology Journal of Intellectual Property Law and Management* 39-48; P Champ & A Attaran 'Patent rights and local working under the WTO TRIPS Agreement: An analysis of the Brazil patent dispute' (2002) 27 *Yale Journal of International Law* 365-293.

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, *failure to work*.

Even the UK in section 48(3) of its Patent Act of 1977 also contains a local working provision. In addition, Berger argues that it is permissible under article 27(1) of TRIPS for a compulsory licence to be designed 'solely in relation to pharmaceutical products' because the WTO panel in the Canada case held that the term 'discrimination in article 27(1) means "the unjustified imposition of differential disadvantageous treatment" and not mere discrimination'.[315] Mercurio and Tyagi are of the view that 'when viewed holistically', the objectives and principles of TRIPS as provided in articles 8 and 9, the incorporation of WIPO Agreements by the TRIPS Preamble as well as subsequent guidelines such as the Doha Declaration which allows members to take measures to promote their public health initiatives make the absolute interpretation of the term discrimination unwarranted.[316] An absolute interpretation of discrimination will be against the 'context of article 27(1) and the guidance of object and purpose'.[317] From the foregoing observations, the Brazilian Industrial Property Act was thus not in violation of article 27(1) of the TRIPS Agreement.

In addition, a further reading of the other articles of the Brazilian Industrial Property Act shows that it safeguarded the interests of patent holders, not whittling it down as the US had appeared to suggest. For instance, article 69 of the Act provides:

> A compulsory licence shall not be granted if, at the date of the request, the patent owner:
> (i) justifies failure to use legitimate reasons;
> (ii) proves that serious and effective preparations for exploitation have been made; or
> (iii) justifies failure to manufacture or to market on grounds of legal obstacles.

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315 J Berger 'Tripping over patents: AIDS, access to treatment and the manufacturing scarcity' (2002) 17 *Connecticut Journal of International Law* 199.

316 B Mercurio & M Tyagi 'Treaty interpretation in WTO dispute settlement: The outstanding of the legality of local working requirements' (2010) 19 *Minnesota Journal of International Law* 175-316.

317 As above.

With regard to the argument that the Act violated the parallel import provision of article 28(1) of TRIPS, Shanker is of the view that the argument does not hold water and that 'article 28.1 would not come into the picture at all'.[318] This is because the footnote on article 28(1) provides that the said article is subject to article 6, which provides:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of articles 3 [national treatment] and 4 [most-favoured treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.[319]

The Brazilian case demonstrated how far developed countries, in this case the US, could go in trying to block access to medicine initiatives. In my opinion, Brazil had the right to adopt the measure in view of its AIDS crisis. The Brazilian case is significant in the context of TRIPS, IP and access to medicines.

First, it set in motion a new wave of developed countries exceeding international rules by entering into bilateral agreements containing TRIPS-plus provisions. For instance, in the joint communication, Brazil intimated that it would consult the US on a bilateral basis prior to issuing any compulsory licence against US companies. Brazil had no obligation, either under international law or under WTO law, to consult the US before enacting a piece of legislation. This provision was, therefore, some kind of harbinger to the numerous TRIPS-plus provisions that would follow in the many bilateral treaties that the US would conclude after 2000.

Second, even though civil society advocacy organisations played a significant role in highlighting the potential public health consequences should the US make Brazil repeal the law, this, in my opinion, was not the definitive factor. Brazil had a valid counter-claim against certain provisions in the US Patent Act, which it found discriminatory. This is so because, as Brazil claimed,

318 Shanker (n 199 above) 81.
319 Shanker (n 199 above) 78.

> [a]rticle 204 requires small business firms and universities which claim a patent on an invention backed by government subsidies to 'manufacture substantially' their invention in the United States, while article 209 requires goods covered by federally-owned patents (those of US government agencies) to be 'substantially produced' in the United States in order to ensure patent protection were in violation of the non-discrimination principle under articles 27.1 and 28.1 of TRIPS.[320]

The US was probably found beaten at its own game and wanted to limit any potential complaints against its own regime. An eloquent testimony of the fact that humanitarian consideration may not have been at the forefront of the withdrawal is the statement of the then US trade representative, Robert Zoellick. In the aftermath of the withdrawal, he was of the view that the requirement that a patent included a local manufacturing component was a stumbling block to free trade and that '[t]he US government will *aggressively*[321] engage other countries that impose or maintain such requirements and, if appropriate, pursue WTO dispute settlement'.[322]

Third, the Brazilian case added impetus to the call that the African Group had made to the WTO TRIPS Council meeting on prioritising public health and access to medicines. The Brazilian case was the second example, after the South African case where the US was bent on challenging local pieces of legislation that were friendly to public health measures. No doubt, after the Brazilian case, WTO members adopted the Doha Declaration on TRIPS and Public Health which, amongst other things, gave WTO member states leeway to implement the TRIPS Agreement in a manner supportive of their public health initiatives and, in particular, promoting access to medicines to all.

3.7.4 US pressure against Thailand

320 G Yerkey & D Pruzin 'United States drops WTO case against Brazil over HIV/AIDS patent law' http://cptech.org/ip/health/c/brazil/bna06262001.html (accessed 3 January 2012).
321 My emphasis.
322 Siplon (n182 above).

In 1999, many Thai activists urged their government to issue compulsory licences for Didanosine (Ddl), the patent of which was held by Bristol Myers Squibb (BMS). At the time, Thailand was facing a major HIV/AIDS pandemic because most people could not afford the drug. In response to the threatened compulsory licence, the US threatened Thailand with trade sanctions. As a matter of fact, the US linked the issuance of the compulsory licence to Thailand's jewelry access to US markets.[323] Consequently, Thailand backed down and grudgingly refused the issuance of the compulsory licence on 16 January 2000.[324]

Notwithstanding the cases above, it appears that not as much use has been made of compulsory licences as one would have expected, especially by African countries. There are a couple of practical limitations in the use of compulsory licences. For instance, there is a lack of co-ordination between countries of the various regions that results in sub-optimal market size. In the case of the Central African sub-region, although the countries have the same intellectual property laws, and have harmonised many other pieces of business and foreign exchange control regulations, there have been very few efforts, if any, to co-ordinate health initiatives and medicine regulations so as to have a united approach. Another practical problem limiting the use of compulsory licences in Francophone West and Central Africa is the buying power needed to incentivise generic entry and robust competition. Of the 14 countries of the OAPI, only four are considered as non-LDC developing countries.

3.8 Developed countries and compulsory licences: Who is watching the 'big brothers'?[325]

The cases analysed above have one common denominator: Western countries' persistent quest for IP protection and resistance to use TRIPS flexibilities,

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323 C Raghavan 'NGO denounce northern pressures against compulsory licence' http://www.twnside.org.sg/title/1879-cn.htm (accessed 17 January 2012).

324 http://www.thailawforum.com/articles/hivdrugs2.html#40 (accessed 17 January 2012).

325 Sub-title sourced from J Oloka-Onyango 'Who's watching "Big Brother"? Globalisation and the protection of cultural rights in present-day Africa' (2005) 27 *Human Rights Quarterly* 1245.

whether or not it is detrimental to other countries, especially developing countries' access to medicine initiatives. The desire to ensure stringent IP protection is achieved either by developed countries bringing trade complaints against laws in developing countries that they perceive to be against their interests, or by big pharmaceutical companies bringing law suits and using their home countries – developed countries – to put pressure on developing countries to repeal a particular piece of legislation which, they contend, is against their commercial interests.

However, it is not always developing countries that take measures that utilise or even exceed TRIPS flexibilities. There have indeed been instances where developed countries have enacted legislation, which arguably violated TRIPS.[326] For example, the US has, for example, on several occasions used or threatened to use compulsory licences.[327] A clear example was in 2001 when the US threatened to issue a compulsory licence on Ciprofloxacin without consulting Bayer, the patent holder, although it later withdrew the threat.[328] By threatening to issue a compulsory licence, the US was somewhat hypocritical. This is because the US had often been at the forefront of pressurising countries not to enact legislation which might give them power to issue compulsory licences, as is evident in the Brazilian case above.[329] Weber and Mills have observed that

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326 Eg, in response to the US complaint, Brazil counter-complained against arts 204 and 209 of Title 35 of the US patent code, stating that they discriminated against foreign producers.

327 Eg, in 1997, a march-in rights petition by Cell-Pro was denied, and ultimately their infringing device was pulled from the market despite its clinical advantages and lack of a licenced alternative. In 2004, DHHS and NIH refused to grant march-in rights in a case brought by Essential Inventions involving patents on the AIDS drug Ritonavir/Norvir; in 2006, the Centre for Disease Control threatened to use march-in rights to issue compulsory licences on patents on reverse genetics, which are needed to manufacture vaccines for avian flu. For more examples, see J Love 'Recent examples of the use of compulsory licences on patents' http://accessvector.org/oldkei/content/view/41/ (accessed 3 January 2012).

328 A Harmon & R Pear 'Canada overrides patent for Cipro to treat anthrax' *New York Times* 9 October 20001 http://www.nytimes.com/2001/10/19/business/19CANA.html?pagewanted=1 (accessed 5 September 2011).

329 See sec 2.5 above.

> the US action [of threatening to issue compulsory licences] in the face of a relatively minor threat undermined its moral authority to demand concessions from developing countries faced with the HIV/AIDS pandemic and other severe health problems.[330]

Apart from NGOs, most developing countries, especially African countries, rarely complained officially against laws enacted by the 'big brothers' - Europe and the US - especially laws that by their implementation allegedly violated TRIPS. To date, no sub-Saharan African country has brought a claim at the WTO Dispute Settlement Mechanism. A number of reasons have been advanced as to why African countries have not used the WTO Dispute Settlement Mechanism. First, the system is too expensive and resource-constrained African countries have so many priorities as far as their finances are concerned that bringing a law suit is, to say the least, not a priority.[331] Secondly, the law suits are usually very long and technical, requiring significant expertise and close attention to detail.[332] Many African countries do not have such expertise. In addition, many African countries are accustomed to using a less litigious approach to solving disputes.[333]

From the foregoing, it appears that a violation of the TRIPS provisions is both an issue of developing and developed countries. Such violations are sometimes driven by countries' specific interests, which for some developing countries would be to ensure access to medicines. It is submitted here that it is counter-productive for certain countries such as the US, as discussed above, to threaten countries enacting laws which it considers to be in violation of TRIPS, whereas they themselves sometimes have laws that violate TRIPS.

3.9 Doha Declaration clarification of TRIPS public health flexibilities

As a result of the problems encountered in the interpretation and use of some of the TRIPS provisions (in particular article 31) and in response to concerns

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330 Weber & Mills (n 184 above).
331 For a detailed discussion on the subject, see V Mosoti 'Africa in the first decade of WTO dispute settlement' (2006) 7 *Journal of International Economic Law* 427-453.
332 As above.
333 As above.

about high prices for patented drugs and the use of compulsory licences, WTO members met in the Qatari capital of Doha, from 9 to 14 November 2001 and adopted the Declaration on the TRIPS Agreement on Public Health. This Declaration, which marks a turning point in the political and legal relations at the WTO,[334] was primarily a response to punitive actions against the use of flexibilities undertaken by the US, as demonstrated in the cases discussed above.

As mentioned above, the Doha Declaration sheds more light on the meaning and implications of the word 'flexibility'. To begin with, paragraphs 1 and 2 provide the following:

> We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
>
> We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

In essence, the two paragraphs stressed the importance of prioritising public health and access to medicines for all.

Furthermore, paragraph 4 provides:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Paragraph 5 then explains the meaning of the term 'flexibilities' as used in paragraph 4. It provides as follows:

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334 F Abbott 'The Doha Declaration on the TRIPS Agreement and public health: Lighting a dark corner at the WTO' (2002) 5(2) *Journal of International Economic Law* 469.

Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.'

Before examining the main provisions of the Doha Declaration relating to access to medicines, it will be necessary to discuss events leading to the Declaration. This is because these events throw light on the diametrically diverse positions of developing and developed countries on the way TRIPS should be interpreted, especially in the context of access to medicines.

Following the South African case of *PMA v the Government of South Africa*, there was consensus, especially within the African group, on the need for a clarification of the relationship between the protection of IP rights and countries' policy objectives of promoting access to medicines.[335] In the special TRIPS Council meeting on the subject in June 2001, the Africa Group, together with other developing countries such as Brazil, had a common goal: the need for legal security and certainty and a common legal interpretation of TRIPS; that a restrictive interpretation of TRIPS would negatively affect their access to medicine efforts and ability to solve access to medicine problems, especially in

335 TRIPS and Public Health, submission of the Africa Group and other developing countries to the Special TRIPS Council Meeting of June 2001, 5 http://www.twnside.org.sg/title/twr131d.htm (accessed 29 January 2012).

the context of HIV/AIDS.[336] In addition, developing countries made submissions, including the following points: (i) Developing countries have a broad spectrum of public health concerns, not only HIV/AIDS, and they are particularly concerned about the lack of research on so-called neglected diseases. (ii) Patents raise prices and thus impede *access* to *medicines*. (iii) Developing countries should be free to use existing TRIPS *flexibilities* including compulsory licences and parallel importation without being threatened by developed countries. (iv) Least-developed members need an extension of transitional periods beyond 2006. (v) Developing countries need to be able to source generic *medicines* from exporting countries despite the predominately *for* domestic use rule in article 31(f) of the TRIPS Agreement, preferably through an article 30 limited exception. (vi) Developing countries need assurances that the data protection rules in article 39(3) would not impede the registration of generics.[337]

The US was of the view that there was a link between strong IP protection and innovation and thus access to medicines, and that the TRIPS Agreement accommodated the interests of developing countries by providing them 'longer transition periods for compliance'. In addition, the US argued that articles 7 and 8 were not the basis of interpreting the TRIPS Agreement and that any granting of a compulsory licence, provided for in article 31(f), should be made in conjunction with the provisions of article 27(1).[338] Furthermore, the US stated that a 'comprehensive approach' in tackling access to medicines, for example addressing the problems created by inadequate health infrastructures and the inadequate number of health professionals, was key rather than linking TRIPS and HIV/AIDS.[339]

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336 J Gathii 'The legal status of the Doha Declaration on TRIPS and public health under the Vienna Convention on the Law of Treaties' (2002) 1(2) *Harvard Journal of Law and Technology* 296.

337 See Developing Country Group's Paper, IP/C/W/296 (29 June 2001); Draft Ministerial Declaration - Proposal from a Group of Developing Countries, IP/C/W/312 (4 October 2001).

338 As above. See also C Oh 'US opposed to moves to address public health concerns about TRIPS http://www.twnside.org.sg/title.twr131f.htm (accessed 23 January 2012).

339 As above.

Developing countries countered the last US argument by stating that the issue raised by the US was a matter of domestic concern and policy and proposed a number of elements to be included in the forthcoming TRIPS Council meeting in Doha, Qatar.[340] The elements proposed by the Africa Group included the following: using articles 7 and 8 of TRIPS in the interpretation of all provisions of the TRIPS Agreement; flexibility for countries to determine when they may grant the issuing of compulsory licences; flexibility in determining parallel importation; a moratorium on all actions against access to medicine initiatives; and, lastly, the extension of the transition periods for developing and least-developed countries.[341]

During the same period when there were ongoing discussions at the TRIPS Council, public health concerns became mainstreamed into US political discussions.[342] This is because during the same period, the US and Canada had threatened Bayer to issue compulsory licences on Ciprofaxin used to cure anthrax, which had killed a number of people in the US.[343] WTO members reached consensus on the way forward for an agreement when they met in Doha, paving the way for the Doha Declaration.

As discussed above, originally an initiative of the African Group, joined thereafter by a number of developing countries,[344] the Doha Declaration acknowledges the gravity of the public health problems afflicting many developing and least-developed countries, especially problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[345] According to the same line of reasoning, the Declaration sets out that intellectual property protection is important for the development of new medicines, and recognises its effects on

340 As above.
341 The Africa Group's Proposal's http://www.tenside.org.sg/title/twe131g.htm (accessed 29 January 2012).
342 B Baker 'Arthritic flexibilities for accessing medicines: Analysis of WTO action regarding paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (2004) 14 *Indiana International and Comparative Law Review* 613.
343 As above.
344 T Kongolo 'WTO Doha Declaration and intellectual property: African perspectives' (2002) *African Yearbook of International Law* 201.
345 Para 1 of the Doha Declaration on the TRIPS Agreement and Public Health.

prices.[346] Furthermore, the Doha Declaration reaffirmed the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for public health purposes and it confirmed that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and, in particular, to promote access to medicines for all.[347] In addition, the Declaration recognised the flexibilities contained in the TRIPS Agreement with respect to the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; the right of each member to determine what constitutes a 'national emergency' or other circumstances of extreme emergency, it being understood that public health crises can represent a national emergency or other circumstances of extreme emergency; and the effect of the provisions of the TRIPS Agreement that allow each member the freedom to establish its own regime for the exhaustion of intellectual property rights.[348]

However, as stated above, one of the main problems was that the compulsory licensing provisions of the TRIPS Agreement were of little practical use to countries with little or no pharmaceutical manufacturing capability, since developing countries could not import from other members with manufacturing capacity until the second member had also invoked a compulsory licence and that, even then, the second member would fall foul of article 31(f) because the compulsory licence would have to be 'predominantly for the supply of the domestic market' of the member granting the licence.[349] In recognition of this problem, paragraph 6 of the Doha Declaration explicitly recognised that WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of the compulsory licence regime under the TRIPS Agreement. Paragraph 6 set the deadline at the end

346 Kongolo (n 231 above).
347 Para 4 of the Doha Declaration on the TRIPS Agreement and Public Health.
348 D Matthews 'WTO decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: A solution to the access to essential medicines problem?' (2004) 7 *Journal of International Economic Law* 82.
349 S Bartelt 'Compulsory licences pursuant to TRIPS article 31 in the light of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6(*Journal of World Intellectual Property* 286.

of 2002, by which time the TRIPS Council was instructed to find an expeditious solution to this problem and to report to the General Council of the WTO.[350] Overall, then, the text of the Doha Declaration was interpretive in nature and designed to reaffirm the flexibilities already contained in the provisions of article 31 if the TRIPS Agreement.[351]

In recent times, concerns as to the legal status of the Doha Declaration have been raised. This is another area in the intellectual property and access to medicine debates where legal opinions differ. According to the World Intellectual Property Organisation (WIPO), many different opinions have been expressed as to the functions and, *ipso facto*, the implications of the term 'flexibilities' clarified in the Doha Declaration. According to the WIPO, some experts and policy makers are of the view that flexibilities 'should not be an excuse to avoid compliance' with TRIPS obligations, while others hold that 'flexibilities are not always the solution for problems in the field of intellectual property', because of member countries' divergence in 'economic development levels'. Vandoren claims that when disputes arise over measures taken by members on public health grounds, the Declaration can be used to argue that the Panel should interpret the TRIPS Agreement in a manner supportive of a member's right to protect public health.[352] Bartelt also suggests that, by virtue of article 31(3) of the Vienna Convention, the Doha Declaration should be regarded as 'subsequent practice in application of the treaty' because paragraph 5(a) of the Declaration gives clear guidelines for interpretation, stating that the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular its objectives and principles.[353] However, Reichman offers a word of caution. He acknowledges that, although article 31(3) of the Vienna Convention may apply, the precise legal status of the Doha Declaration still remains inconclusive and uncertain.

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350 See World Trade Organization *Declaration on the TRIPS Agreement and Public Health,* WT/MIN (01)/DEC/2 (20 November 2001) (recognising the gravity of public health problems afflicting developing countries and the need for internal action to help combat these problems).

351 Matthews (n 235 above) 82.

352 P Vandoren '*Medicaments sans frontières*? Clarification of the relationship between TRIPS and public health resulting from the WTO Doha Ministerial Declaration' (2002) 5 *Journal of World Intellectual Property* 8.

353 Bartelt (n 236 above) 286.

This is because future WTO panels and the appellate body may only draw guidance from the Declaration when interpreting complaints rather than basing their entire judgment on the Declaration.[354]

Gathii offers three possibilities regarding the legal status of the Doha Declaration. First, it can be interpreted as 'a subsequent agreement under article 31(3)(a) of the Vienna Convention on the Law of Treaties regarding the interpretation of the TRIPS Agreement'.[355] This is because, among other things, 'the Declaration proposes a balancing approach' in cases where there are divergent interpretations by both developing and developed countries.[356] In addition, 'it interprets specific provisions of the TRIPS Agreement', such as article XX, as well as 'the TRIPS Agreement itself in the light of its objectives and principles' spelt out in articles 7 and 8 of the TRIPS Agreement.[357] It also provides an elaboration of terms not defined in the TRIPS Agreement, such as defining and explaining the meaning of what constitutes a national emergency or circumstances of extreme urgency, words mentioned in article 31 but not defined in that article.[358] A second possibility is that the Doha Declaration could be interpreted as 'evidence of subsequent practice under the TRIPS Agreement'.[359] This is because it constitutes a common understanding between WTO members in the 'interpretation of specific provisions of the TRIPS Agreement', for instance, the provision of flexibilities and the defining of terms such as national emergency by the Doha Declaration.[360] Finally, a third possibility is that the Doha Declaration could be interpreted as a 'legally non-binding statement of intent and commitment'.[361] This is because the general acceptance and endorsement of the Declaration by all WTO members could be likened to 'codification under customary international law' as it signalled the subsequent practice of WTO member states.[362]

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354 As above.
355 Gathii (n 223 above) 299.
356 As above.
357 As above.
358 Gathii (n 223 above) 301-307.
359 As above.
360 Gathii (n 223 above) 311.
361 As above.
362 Gathii (n 223 above) 314.

At present, there has not been a case at the WTO Dispute Settlement Body in which the persuasive effect of the Doha Declaration has been tested. A recent assessment of the impact of the Doha Declaration by the UNDP concluded that

> [t]he Doha Declaration has contributed significantly to providing legal clarity on the flexibilities contained in the TRIPS Agreement, and to provide some certainty on the space available to pursue public health policies while observing the Agreement's substantive and enforcement provisions even though much remains to be done to give full force to the Declaration and to develop other policies that ensure that access to medicines by all becomes a reality.[363]

Nevertheless, it would be interesting to see how the WTO Panel will interpret the legal nature of the Declaration should a case bearing on the legal nature come before it.

3.9.1 Panorama of unsuccessful attempts to implement paragraph 6 of the Doha Declaration

The euphoria created by the Doha Declaration, especially its paragraph 6 which urged members to find expeditious solutions to TRIPS, was soon to disappear as members persistently failed to arrive at a compromise in finding an expeditious solution as provided for in the Doha Declaration. In fact, the December 2002 deadline was missed. To adequately understand why this happened, it is necessary to undertake a chronological analysis of the failed negotiations aimed at implementing paragraph 6 of the Declaration.

To begin with, a number of solutions were advanced and discussed at the level of the TRIPS Council. These solutions were (i) a moratorium on dispute settlement; (ii) a waiver of article 31(f); (iii) the possibility of amending article 31(f); and (iv) an authoritative interpretation of article 30.

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363 'The Doha Declaration ten years on and its impacts on access to medicines and the right to health' http://www.undp.org/content/dam/undp/library/hivaids/Discussion_Paper_Doha_Declaration_Public_Health.pdf (accessed 22 July 2013).

Negotiations on the implementation of paragraph 6 began in June 2002 during the meeting of the TRIPS Council. The Africa Group proposed a moratorium on bringing complaints against low-income developing countries before the dispute settlement body of the WTO relating to article 31(f) of the TRIPS Agreement.[364] This solution was also recommended by the US in one of its submissions to the TRIPS Council.[365] One of the advantages of a moratorium was that it would set aside any WTO dispute settlement proceeding that might otherwise arise for a breach of article 31(f) of the TRIPS Agreement through the production and export of pharmaceutical products to a third country in order to address a public health crisis in this country. However, this idea was discarded for two reasons. First, since there was arguably no sound legal basis for not applying the dispute settlement procedure in instances of a moratorium, there was a risk that, even as a temporary arrangement, a moratorium on disputes against members who take action to address public health crises in countries with insufficient or no manufacturing capacity was likely to present the inherent problem of lacking legal certainty as to the behaviour of potential complainants, particularly developed country WTO members.[366] Second, there was the problem that, implicit in the moratorium was the proviso that it would apply only if developing countries compensated patent holders for compulsory licences, and only until the expected end date of the Doha development round of multilateral trade negotiations in January 2005, when the transitional arrangements for developing countries under article 65(4) of the TRIPS Agreement would also come to an end. With the prospect of a temporary solution of the kind offered by a moratorium lasting only until the end of the Doha round, the likelihood was that trade-offs and package deals would emerge. Such trade-offs could be similar to those that emerged during the original TRIPS negotiations. It will be recalled that during the TRIPS negotiations, developing countries were offered trade advantages and market

364 Joint Communication from the African Group in the WTO Proposal on Paragraph 6 of the Ministerial Declaration on TRIPS Agreement and Public Health, IP/C/W/351, 24 June 2002, para 6(g).

365 Communication from the United States 'Moratorium to address needs of developing and least developed members with no or insufficient manufacturing capacities in the pharmaceutical sector' IP/C/W/396 14 January 2003.

366 J Bourgeois & TJ Burns 'Implementing paragraph 6 of the Doha Declaration on TRIPS and Public Health: The waiver solution' (2002) 5 *Journal of World Intellectual Property* 839.

access in areas like agriculture, in return for agreeing to the more restrictive interpretation of article 31(f) proposed by developed countries.[367]

The second solution recommended by the US[368] was aimed at examining the possibility for a waiver of article 31(f) of the TRIPS Agreement to be granted to WTO members facing public health crises, but lacking domestic manufacturing capacity. This could be achieved under article IX(3)-(4) of the WTO Agreement.

The third solution explored included examining the possibilities of amending article 31(f) of the TRIPS Agreement to allow exports of products produced under compulsory licences and broadly interpreting the limited exceptions clause of article 30. This solution was recommended by the Africa Group[369] and was temporarily championed in two EC submissions.[370]

The fourth solution recommended by the United Arab Emirates[371] and some developing countries in Asia and South America[372] was for an authoritative interpretation of article 30. Europe was initially also open to an article 30 approach.

The solution aimed at amending article 31(f) of TRIPS failed due to the divergent views of WTO members, especially the EU and the US. The EU proposed that any solution allowing an exemption to the article 31(f) requirement that generic drugs produced under compulsory licence to be

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367 As above.

368 Second Communication from the United States, para 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/358, 9 July 2002.

369 Joint Communication from the African Group in the WTO 'Proposal on Paragraph 6 of the Ministerial Declaration on TRIPS Agreement and Public Health,' IP/C/W/351, 24 June 2002, para 3(e).

370 Communication from the European Communities and their Member States, Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/339, sec III.1, 4, 4 March 2002; Communication from the European Communities and their Member States, 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', IP/C/W/352, 20 June 2002.

371 Communication from United Arab Emirates 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,' IP/C/W/354 24 June 2002.

372 Communication from Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, 'Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,' IP/C/W/355 24 June 2002.

'predominantly' for domestic use should be limited to the production of medicines where the gravity of public health problems afflicted developing and least-developed countries, especially problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[373] However, the US adopted a more restrictive position. The view of the US was that broadening the exception to cover any 'other epidemics', in keeping with the wording of the Doha Declaration, would risk the inclusion of 'lifestyle' illnesses, such as obesity and the common cold, which should not be exempted from the compulsory licensing provisions of the TRIPS Agreement.[374]

In its subsequent submission to the TRIPS Council meeting, the US proposed another set of solutions. It wanted export licences to be limited to addressing certain diseases, such as HIV and malaria, and to pharmaceutical products only.[375] In addition, it wanted the benefits of any such licences to go to a limited number of countries that must show insufficient technical and financial capacity to manufacture the medicines covered by the licences.[376] Such countries, the US argued, should show proof and should ensure that medicines covered by the licence will not be re-exported and, lastly, there should be compensation to the patent holder after negotiations based on reasonable commercial terms.[377]

Differences in opinion led to the failure of the second attempt because of the broad interpretation of the limited exception clause. As has been pointed out, the US for the most part consistently argued for a strict interpretation of

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373 Communication from the EC and their Member States to the TRIPS Council 'Concept paper relating to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and public health' IP/C/W/339, 4 March 2002. See also F Abbott 'The WTO medicines decision: World pharmaceutical trade and the protection of public health' (2005) 99 *American Journal of International* Law 317; V Bradford Kerry & K Lee 'TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the remaining steps for protecting access to medicines' (2007) *Globalisation & Health* http://www.globalizationandhealth.com/content/pdf/1744-8603-3-3.pdf (accessed 17 July 2013).

374 See 'Drugs for the poor' http://www.washingtonpost.com (accessed 7 September 2011).

375 Baker (n 229 above). See also Communication from the United States, IP/C/W/340 (14 March 2002); Second Communication from the United States, IP/C/W/358 (9 July 2002).

376 As above.

377 Baker (n 229 above). See also Communication from the United States, IP/C/W/340 (14 March 2002); Second Communication from the United States, IP/C/W/358 (9 July 2002).

article 30,[378] while the EC and its member states questioned its legal merits due to doubts about whether the criteria of article 30 offer sufficient scope for an authoritative interpretation.[379] The problems created by this difference in opinion was exacerbated by the WTO Dispute Panel decision in the case of *Canada-Patent Protection of Pharmaceutical Products,* where it indicated that a limited exception allowable under article 30 must meet three cumulative conditions which must all be satisfied for the exception to fall within the scope of article 30. First, the exception must be of limited nature; second, it may not unreasonably conflict with a normal exploitation of the patent; and, third, it may not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties.[380]

Following the Panel decision in *Canada-Patent Protection,* Bartelt maintains that there are doubts as to whether a compulsory licence to manufacture and supply generic drugs to another WTO member could be justified under article 30, since it would be unlikely to meet the requirement of not conflicting with the normal exploitation of the patent, since compulsory licensing could be described as being 'diametrically opposed to the subject-matter of the patent, which is to reward the inventor for his creative efforts'.[381] Bartelt's doubts whether compulsory licences in the context above could be justified under article 30 can be easily assuaged. First, if one were to take a more territorial view of the risk of commercialisation, there would be no real commercialisation as such in the country of production, but rather in the country of import and consumption. Second, using article 30 as a solution could have required a compulsory licence in the importing country if a blocking patent existed there.[382]

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378 Second Communication from the United States Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health, IP/C/W/358, 9 July 2002.

379 TA Hagg 'TRIPS since Doha: How far will the WTO go toward modifying the terms of compulsory licencing?' (2002) 84 *Journal of the Patent and Trademark Office Society* 969.

380 WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted on 17 March 2000.

381 S Bartelt 'Compulsory licences pursuant to TRIPS Article 31 in the light of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6 *Journal of World Intellectual Property* 300.

382 I am grateful to Prof Brook Baker for this remark.

The subsequent paragraphs will discuss the evolution of attempts to find a successful solution to the problem created by article 31(f).

3.9.2 Motta text

The solution that was almost adopted under tight pressure of time is now popularly referred to as the 'Motta text'. The text attempted to strike a compromise by which the TRIPS Agreement would be amended so that any country with manufacturing capacity could export, while developing countries without manufacturing capacity in the pharmaceutical sector would be allowed to benefit from the system in the face of public health problems.[383]

As mentioned above, the Motta text contained an attempted solution to the paragraph 6 problem. For instance, under this text, countries importing generic pharmaceutical products and using the paragraph 6 mechanism would be expected to take measures to prevent re-exportation, provided such measures were 'reasonable', 'within their means' and 'proportionate' to their administrative capacities and the risk of trade diversion. Exporting countries are obliged to require of the beneficiary company of the compulsory licence (i) to export their entire production to the countries needed; and (ii) to clearly identify the products through labelling or marking and through special colouring or shaping of the products themselves.

However, when the TRIPS Council met on 20 December 2002, the deadline for reaching an agreement on the conclusion of paragraph 6, there was a deadlock. The US blocked an agreement on the grounds that the text was too broad and went beyond the focus of HIV/AIDS, tuberculosis and malaria. This caused the negotiations to be halted and the Chairperson to convene another meeting, which was held in February 2003. The February 2003 meeting was a dismal failure as no party was willing to relinquish its key

383 'Main elements of the Chair's 16 December 2002 Draft Compromise Decision (Perez Motta Text)' European Commission (Trade and Development) Press Release, 9 January 2003, available at http://www.europa.eu.int/comm/trade/csc/memo090103_en.htm, (accessed 7 September 2011).

demand. The next TRIPS Council meeting, held on 4 and 5 June 2003, ended without any substantial progress towards a solution.

Earlier on in the process, on 9 January 2003, the EC had come up with a proposal aimed at removing WTO constraints requiring compulsory licences to be 'predominantly' for domestic supply in the case of medicines to combat a limited list of 22 infectious diseases (including HIV/AIDS, tuberculosis and malaria) that are generally recognised by health experts as having the most damaging impact on developing countries.[384]

Due to these intransigencies on the part of the various governments, no solution could be reached as to how the system could be improved to give a clear and firm interpretation of article 31(f). The US intransigence was one of the main reasons for the prolonged negotiations.[385] There was thus a clarion call by developing countries, NGOs and other interested stake holders for the TRIPS Council to find an expeditious solution, as required by paragraph 6 of the Doha Declaration. After two years of wrangling, negotiations and diametrically-opposed positions, WTO members finally came to a consensus on 30 August 2003. On this date, they announced that they had found a solution, albeit a temporary one, to the article 31(f) problem.

The long negotiation process once more shows, on the one hand, the role powerful countries play in doing everything in their power to stall any progress that might impact on their economic interests and, on the other hand, how unity by countries facing similar developmental and health challenges can bring positive gains in international politics and the negotiations of international treaties. Patience, tact and consistency are often evident when countries display a strong sense of unity. These may have been major factors in orchestrating the outcome of the August 2003 Decision. Such unity is really needed by African countries in the context of intellectual property rights and

384 'EU seeks to break the current deadlock on WTO access to medicines: A multinational solution is needed' European Commission (Trade and Development) Press Release, 9 January 2003 http://www.europa.eu.int/comm/trade/csc/pr090103_en.htm (accessed 7 September 2011).

385 Baker (n 229 above).

access to medicines, more broadly. This is because, as will be pointed out in subsequent chapters, the negotiations of bilateral treaties often pit countries one-to-one at the negotiating table, usually with disproportionate results, mostly in the best interests of the more advanced, developed and powerful countries, which unfortunately are usually not African countries.

3.9.3 August 2003 Decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and the Hong Kong Ministerial Meeting of 6 December 2005

Almost two years after the Doha Declaration had urged the Council to find an 'expeditious solution' to the problem of implementation of TRIPS, WTO members finally adopted an agreement on the interpretation of the ambiguous TRIPS articles (Implementation Decision) on 30 August 2003.[386]

The final breakthrough was achieved when Ambassador Motta's successor as Chairperson of the TRIPS Council, Vanu Gopala Menom of Singapore, met with a small group of WTO members to negotiate a solution to paragraph 6.[387] This group, comprising the United States, Kenya, Brazil, South Africa and India, succeeded in producing a draft decision on 21 August 2003, followed by a revised draft, almost identical to the original Motta version, on 26 August. Following approval by the TRIPS Council on 28 August, the General Council of the WTO was then presented with a final draft of the decision on implementation of paragraph 6 of the Doha Declaration, which it adopted on 30 August 2003.[388]

386 World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights, Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405 (30 August 2003) (discussing the availability of compulsory licensing under art 31 of the TRIPS Agreement).

387 Matthews (n 235 above) 95.

388 As above.

Developing[389] and developed countries[390] alike reacted positively to the 30 August Decision on the implementation of paragraph 6 of the Doha Declaration. However, some countries permanently opted out of utilising the provisions of the agreement,[391] while others maintained that they would use the system only in urgent emergency situations.[392] This was mainly due to the strong-arm tactics of the US.[393]

The implementation agreement defines numerous terms, including 'pharmaceutical product', 'eligible importing member' and 'exporting member'.[394]

Furthermore, the implementation agreement makes compulsory licensing easily accessible to least-developed countries by defining an eligible importing member as 'any least-developed country member', without any

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389 See statement made by Kenyan Ambassador to the WTO, Amina Chawahir Mohamed, after the deal had been concluded: 'All people of good will and good conscience will be very happy today with the decision that the WTO members made … it's especially good news for the people of Africa who desperately need access to affordable medicine' available at http://www.washingtonpost.com (accessed 7 September 2011).

390 See European Trade Commission, 'Access to essential medicines: EU strongly welcomes WTO deal on generic medicines' http://www.europa.eu.int (accessed 7 September 2011).

391 World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights, Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405 (30 August 2003) (discussing the availability of compulsory licencing under art 31 of the TRIPS Agreement). Within the meaning of 'exporting members', the agreement notes that certain countries will not use the system in this decision. These countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxemburg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

392 These countries consist of Chinese Hong Kong, Israel, Korea, Kuwait, Chinese Macao, Mexico, Qatar, Singapore, Taiwan, Turkey, and United Arab Emirates. Others, such as the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia, stated that they would only use the benefit of the decision in the event of a national emergency; and after their accession to the EU, they would opt out of using the system as the 23 countries mentioned above.

393 Baker (n 229 above) 14.

394 Implementation Agreement. For the purposes of this decision, 'pharmaceutical product' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised in para 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; 'eligible importing member' means any least developed country member, and any other member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a member may notify at any time in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use and lastly, 'exporting member' means a member using the system set out in this decision to produce pharmaceutical products for, and export them to, an eligible importing member.

further requirements. In addition, it waives the requirement of article 31(f) of the TRIPS Agreement that, when a compulsory licence is used, it must predominantly be for the supply of the domestic market. For this waiver to occur, both the eligible importing member and the exporting member must meet a number of conditions. On the one hand, the importing member must specify the name and expected quantities of the product needed; establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex of the Implementation Decision; and, lastly, must have granted or intended to grant a compulsory licence in accordance with article 31 of the TRIPS Agreement and the provisions of the Implementation Decision, whenever the pharmaceutical product is patented in her territory. On the other hand, the exporting member shall notify the TRIPS Council of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. In addition, the notification shall also indicate the address of the website referred to.

Moreover, the Implementation Agreement sets out numerous conditions that the compulsory licence itself must incorporate.[395] The Implementation Agreement also clears up some prior concerns of double compensation to the patent holder that a member would encounter under the requirement of adequate remuneration in article 31(h). In addition, the Implementation

395 World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights, Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/405 (30 August 2003) (discussing the availability of compulsory licencing under art 31 of the TRIPS Agreement): '[T]he compulsory licence issued by the exporting member under this decision shall contain the following conditions: (i) only the amount necessary to meet the needs of eligible importing member(s) may be manufactured under the licence and the entirety of this production shall be exported to the member(s) which has notified its needs to the Council of TRIPS; (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the product themselves, provided that such distinction is feasible and does not have a significant impact on price; and (iii) before shipment begins, the licencee shall post on a website the following information: the quantities being supplied to each destination as referred to in indent (i) above; and the distinguishing features of the product(s) referred to in indent (ii) above.'

Agreement states that importing members are to take reasonable measures to prevent the re-exportation of products that they have imported under a compulsory licence. It also provides that members shall assist one another in preventing re-exportation from occurring and, if a member has a problem with another member's compliance with this requirement, that member may bring the issue before the TRIPS Council for review.

At the insistence of the US,[396] the WTO's 30 August Decision was supplemented by a separate statement from the WTO General Council Chairperson, Carlos Perez del Castillo. This statement clarifies that members are to implement the decision in good faith to protect public health problems and not for industrial or commercial policy objectives, and that issues such as preventing medicines from getting into wrong hands are important.[397] Furthermore, it suggests that any disputes arising between members are to be resolved 'expeditiously and amicably'. One may question the legality and effectiveness of Carlos Perez's statements. The first issue is whether he was reaffirming the spirit of the decision and whether his statement can be considered as such. Another issue is whether his statement might be binding or provide guidance to a WTO Panel should a dispute arise as to the implementation of the decision. In my view, the statement might provide guidance and might be used as *travaux préparatoires*, as such, and help to interpret the Decision should a dispute arise. My opinion is given credence by article 32 of the Vienna Convention which provides, inter alia, as follows: 'Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning' of the said treaty. This view is supported by Baker, who contends that the Chairperson's statement may well influence the interpretation and enforcement of the TRIPS Agreement at the WTO.[398]

396 Baker (n 229 above) 7.

397 World Trade Organization The General Council Chairperson's Statement on implementation of paragraph 6of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), available at <http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm>, (accessed 7 September 2011).

398 Baker (n 229 above).

It should be noted that the August 2003 Decision finally led to the proposed amendment of the TRIPS Agreement on 6 December 2005 during the Hong Kong Ministerial with the inclusion of article 31*bis*. In that Ministerial meeting, the August Decision was adopted and submitted to WTO members for acceptance.[399] Members were given until March 2007 or some later date to accept the amendment.[400] However, successive TRIPS Council meetings kept postponing the final date. For instance, during its December 2007 meeting, the deadline was extended to December 2009.[401] In its 17 December 2009 meeting, the deadline was extended for the second time (second extension) to 31 December 2011.[402] In a subsequent meeting, which took place in December 2011, the date was extended (third extension) to 31 December 2013.[403] In its last meeting which took place in November 2013, the deadline was again extended to 31 December 2015.[404] For the past seven years, the final date of accepting the proposed amendment has been postponed three times. This begs the question of how serious WTO members are to make the amendment part and parcel of TRIPS. A cursory look at countries that have submitted notifications of their acceptance to WTO shows that the number of these countries is fairly balanced between developed and least-developed countries. Besides Zambia and a few other states, there is a conspicuous absence of least-developed countries. This is probably due to the fact that they have until 2016 to become TRIPS-compliant and may not want to spend time and energy on the proposed amendment. However, given the fact that 2016 is only a year away, it might make sense for least-developed countries to notify their

399 Amendment of the TRIPS Agreement http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (accessed 24 October 2011).
400 Baker (n 229 above).
401 Decision of the General Council, Amendment of the TRIPS Agreement - Extension of the Period for the acceptance by members of the Protocol Amending the TRIPS Agreement, WT/L/711 (18 December 2007).
402 Decision of the General Council, Amendment of the TRIPS Agreement—Second extension of the period for the acceptance by members of the Protocol Amending the TRIPS Agreement, WT/L/785 (21 December 2007).
403 Decision of the General Council, Amendment of the TRIPS Agreement—Third extension of the period for the acceptance by members of the Protocol Amending the TRIPS Agreement, WT/L/829 (5 December 2012).
404 Decision of the General Council Amendment of the TRIPS Agreement – Fourth Extension of the period for the acceptance by members of the Protocol Amending the TRIPS Agreement, *WT/L/899* (26 November 2013).

acceptance so that they at least have something in place before the 2016 transition period comes to an end.

However, many activists and commentators recommend against the ratification/adoption of the paragraph 6 system as it would lock in a labyrinth and to this point largely-unused mechanism.[405] Instead, people want a full study of the effectiveness of the mechanism and consideration of alternatives if it is found wanting. It is recommended that countries should not adopt article 31*bis* of TRIPS, but instead should argue that it is ineffective and needs to be revised.

From the above it is evident that the original article 31(f) is not abrogated. The 2005 proposed amendment is not yet in force. In essence, it is a consolidation of the August 2003 Decision, which is applicable until the entry into force of the amendment. According to paragraph 1 of article 10 of the WTO Agreement, once two-thirds of members have formally accepted it, the amendment will take effect for those members and will replace the 2003 waiver for them.[406] For the time being and for the remaining members, the waiver will continue to apply until a sufficient number of members have accepted the amendment, causing it to take effect. As at June 2014, 55 countries have notified the WTO of their acceptance.[407]

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405 TAC and sec 27urge parliament not to ratify WTO decision on para 6 of the Doha Declaration on TRIPS and Public Health http://www.section27.org.za/2011/05/04/tac-and-section27-urge-parliament-not-to-ratify-wto-decision-on-paragraph-6-of-the-doha-declaration-on-trips-and-public-health/ (accessed 22 July 2013).

406 Art X, para 1 provides that '[a]ny Member of the WTO may initiate a proposal to amend the provisions of this Agreement or the Multilateral Trade Agreements in Annex 1 by submitting such proposal to the Ministerial Conference. The Councils listed in paragraph 5 of Article IV may also submit to the Ministerial Conference proposals to amend the provisions of the corresponding Multilateral Trade Agreements in Annex 1 the functioning of which they oversee. Unless the Ministerial Conference decides on a longer period, for a period of 90 days after the proposal has been tabled formally at the Ministerial Conference any decision by the Ministerial Conference to submit the proposed amendment to the Members for acceptance shall be taken by consensus. Unless the provisions of paragraphs 2, 5 or 6 apply, that decision shall specify whether the provisions of paragraphs 3 or 4 shall apply. If consensus is reached, the Ministerial Conference shall forthwith submit the proposed amendment to the Members for acceptance. If consensus is not reached at a meeting of the Ministerial Conference within the established period, the Ministerial Conference shall decide by a two-thirds majority of the Members whether to submit the proposed amendment to the Members for acceptance. Except as provided in paragraphs 2, 5 and 6, the provisions of paragraph 3 shall apply to the proposed amendment, unless the Ministerial Conference decides by a three-fourths majority of the Members that the provisions of paragraph 4 shall apply.'

407 United States, 17 December 2005, WT/Let/506; Switzerland, 13 September 2006, WT/Let/547; El Salvador, 19 September 2006, WT/Let/548; Republic of Korea, 24 January 2007, WT/Let/558; Norway, 5 February 2007, WT/Let/563; India, 26 March 2007, WT/Let/572;

(a) Legal status of the August 2003 Decision

Having analysed the provisions of the decision on the implementation of paragraph 6 of the Doha Declaration, it is necessary to consider its legal status and effect. As stated above, the WTO's August 2003 Decision provides temporary waivers to the obligations contained in article 31(f) of the TRIPS Agreement.

In accordance with article 57 of the Vienna Convention on the Law of Treaties, a waiver does not imply any change in substantive treaty obligations, but it temporarily suspends their operation. In the context of the WTO, a waiver means that a member shall not initiate a complaint against another member if the latter acted under the terms of the adopted waiver. However, to the extent that a member's national law is not revised to implement the terms of the waiver, patent owners may invoke the provisions of national law to block the predominant exportation of a patented drug produced pursuant to an ordinary compulsory licence (not a competition-based one).[408] Nevertheless, the extent

Philippines, 30 March 2007, WT/Let/573; Israel, 10 August 2007, WT/Let/582; Japan, 31 August 2007, WT/Let/592; Australia, 12 September 2007, WT/Let/593; Singapore, 28 September 2007, WT/Let/594; Hong Kong, China, 27 November 2007, WT/Let/606; China, People's Republic of, 28 November 2007, WT/Let/607; European Communities, 30 November 2007, WT/Let/608; Mauritius, 16 April 2008, WT/Let/619; Egypt, 18 April 2008, WT/Let/617; Mexico, 23 May 2008, WT/Let/620; Jordan, 6 August 2008,WT/Let/630; Brazil, 13 November 2008, WT/Let/636; Morocco, 2 December 2008, WT/Let/638; Albania, 28 January 2009, WT/Let/639; Macao, China, 16 June 2009, WT/Let/645; Canada, 16 June 2009, WT/Let/646; Bahrain, 4 August 2009, WT/Let/652; Colombia, 7 August 2009, WT/Let/650; Zambia, 10 August 2009, WT/Let/651; Nicaragua, 25 January 2010, WT/Let/663; Pakistan, 8 February 2010, WT/Let/664; Former Yugoslav Republic of Macedonia, 16 March 2010, WT/Let/671; Uganda, 12 July 2010, WT/Let/678; Mongolia, 17 September 2010, WT/Let/684; Croatia (6 December 2010); Senegal (18 January 2011); Bangladesh (15 March 2011); Argentina (20 October 2011); Indonesia (20 October 2011); New Zealand (21 October 2011); Cambodia (1 November 2011); Panama (24 November 2011); Costa Rica (8 December 2011); Rwanda (12 December 2011); Honduras (16 December 2011); Togo (13 March 2012); Saudi Arabia (29 May 2012); Chinese Taipei (31 July 2012); Dominican Republic (23 May 2013); Chile (26 July 2013); Montenegro (9 September 2013); Trinidad and Tobago (19 September 2013); Central African Republic (13 January 2014);Brunei Darussalam (10 April 2015);Turkey (14 May 2014) Botswana (18 June 2014) and Uruguay (31 July 2014).

408 CM Corea 'Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' Buenos Aires, 24 April 2004, http://www.who.int/medecines/organisation/mgt/wto_Doha Decision Para 6 f I (accessed 7 September 2011).

to which generic drug makers may actually be able to export under the August 2003 decision will depend on how far national laws allow for it.

(b) A critical analysis of the WTO August 2003 deal on medicines

Much criticism has been levied against the WTO's August 2003 Decision on the implementation of paragraph 6 of the Doha Declaration. While some critics feel that the deal did nothing to change the *status quo*,[409] others hold the view that the deal is nothing more than a 'gift bound tightly in a red tape'.[410] The following arguments may, however, be advanced to support the above views.

Most importantly, the deal brought in complicated bureaucratic processes that need to be followed. For instance, in the case of patents in both countries, there is the requirement for the issuance of two compulsory licences, one by the exporting state and the other by the importing state, in order for the implementation decision to be used. This may be more problematic in many developing countries, especially in sub-Saharan African countries, where there may be administrative and other bottlenecks for an importing country to persuade the exporting country to grant a compulsory licence for a medicine which is needed by the latter country.

In addition, in restraining importing countries' eligibility of effectively using the decision, the US and EU placed certain limitations on the use of compulsory licences by these countries under the decision. Baker lists four of

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409 C Raghavan 'Medicine won't be cheaper under TRIPS and the public health decision' Geneva: Third World Network, 31 August, 2003, http://www.twnside.org.sg/title/5409b.htm (accessed 7 September 2011). See also the statement of Oxfam's Head of Advocacy, Celine Charveriat :'The proposed deal is largely cosmetic and will not make a significant difference to the millions of sick people who die unnecessarily in the Third World every year.' http://www.cptech.org (accessed 7 September 2011).

410 A 'gift bound in a red tape' is the term which has been used to describe the August 2003 WTO deal on medicines. This phrase was used in a joint NGO statement released on 10 September 2003, by 14 NGOs: ACT Up Paris; Consumer Project on Technology; Consumer International; Essential Action; European AIDS Treatment Group; Health Action International; Health GAP; International People's Health Council; *Medicins sans Frontières*; OXFAM International; People's Health Movement; SEATINI; Third World Network; and Women in Development; http://www.lists.essential.org/pipermail/ip-health/2003-september/005245.html, (accessed 7 September 2011).

these limitations.[411] First, the US and EU entered into a deal with 23 countries that had agreed not to issue compulsory licences under the system; the US and EU entered into another deal with 12 countries to the effect that these countries would only use the system in cases of national emergency; furthermore, the US and EU pressured ten countries on the verge of joining the EU not to use the system except in cases of national emergency; and, lastly, the EU and US insisted on the provision that developing countries may only grant compulsory licences under the system after showing that they lack domestic capacity.[412]

Besides, many constraints have been added to the business practices of the generic companies. Concerns remain that the added costs associated with altering packaging, pill size and colour will have a detrimental effect on the availability of essential medicines in developing countries, reducing the incentives for generic drug companies, who will find it less cost-efficient to produce identifiable pills. [413]

Furthermore, there may be some ambiguity with regard to the implementation of the deal. This is because it introduced an extra layer of uncertainty by stating that the system should not be an instrument to pursue industrial or commercial policy objectives, creating uncertainty over the role that will be played by businesses that manufacture and sell generic drugs. As such, critics fear that this statement is ambiguous and may make developing countries reluctant to use compulsory licensing under the system.[414] One editorial expressed the concern shared by developing countries that, if the statement means 'no for-profit manufacturer or distributor can be involved at any level, the provision is a poison pill and that it is not reasonable to believe that any charitable operation can gear up to make and supply what the global AIDS fight needs'.[415]

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411 Baker (n 229 above).
412 As above.
413 Matthews (n 235 above) 95.
414 See Press Release, MSF, 'Flawed WTO drugs deal will do little to secure future access to medicines in developing countries' (30 August 2003) http://www.msf.org/content/page.cfm?articleid=C1540425-7F56-4D60- A6CB9D7ABA6D627F (accessed 7 September 2011).
415 See 'Putting fighting disease first' *Star Ledger* 10 September 2003.

In addition, the decision leaves uncertainty as to whether or not economic inefficiency is a ground for determining a lack of manufacturing capacity in the importing country. The lack of clarity on this issue has been defended as a matter of 'creative ambiguity' and, at the time the decision came up, some countries, including the US, said that they would oppose 'economic efficiency' as grounds for allowing a country to import generics.[416]

Additionally, the deal gives the WTO itself some kind of new authority to second-guess and interfere in the granting of individual compulsory licences to generic companies. Also, it is submitted here that the administrative burden associated with the procedural arrangements for notifying the WTO of its decision to use the mechanism and undergo TRIPS Council scrutiny may result in lengthy delays and may prove costly for developing country governments.[417]

Moreover, as a measure of trade policy, the August 2003 implementation decision contradicts the basic principles of the WTO and free trade.[418] First, it explicitly accepts a protectionist framework, where rich countries can export to poor countries, but 23 rich countries were allowed to bar imports from developing countries. Second, the long list of new regulatory requirements does not apply to compulsory licences in countries with capacity for domestic manufacturing. One may argue that this could be considered as discriminatory contrary to the spirit and letter of the objectives of the WTO Agreement. Finally, the entire framework of export restrictions is designed to limit rather than promote economic efficiency, which for many countries has been advanced and hailed as one of the rationales for free trade agreements.

Another criticism levied against the August 2003 deal is the requirement of the payment of adequate remuneration. The requirement is somewhat vague as no clear definition has been provided for 'adequate remuneration'. This has led to different interpretations by developed and developing countries.

416 Matthews (n 235 above) 95.
417 As above.
418 As above.

Developed countries maintain that, if developing and least-developed countries are to grant compulsory licences, full compensation to the patent holder is required.[419] At the other end of the spectrum, developing and least-developed countries proposed that the patent holder receive no, or at most minimal, remuneration for the use of the patent.[420] Granting adequate remuneration in the form of full market value, as developing countries urge, would not only be contradictory to the TRIPS Agreement and the Doha Declaration, but would also give patent holders a windfall by enabling them to reap profits in a market where there previously were none.[421]

(c) Putting the August 2003 deal into practice: The case of Rwanda and Canada

The August 2003 deal was hailed as the missing piece in the puzzle in the quest for universal access to medicines. It was hoped that with its entering into force, the problems of access to medicines would be reduced significantly. This has not yet been the case. Only two countries have subsequently used it and, even then, only under very onerous circumstances. In this section, the Canada-Rwandan example is analysed to show the difficulties in using the August 2003 Decision.

No sooner had the August 2003 Decision been passed, when critics started questioning its viability, efficacy and suitability in reducing the persistent problem created by article 31(f). In a joint statement following the announcement of the decision, a group of NGOs referred to it as a 'gift in a red tape'.[422] At the time, many people, especially representatives of pharmaceutical companies who had fought hard for the decision not to be reached, may have argued that it was merely NGO cynicism. However, the NGOs' prediction was borne out by reality when it took four years after the coming into force of the

419 N Ansari 'International patent rights in a post-Doha world' (2002) 11 *International Trade Law Journal* 231.
420 M Lang 'What a long, strange 'TRIPS' it's been: Compulsory licencing from the adoption of TRIPS to the Agreement on Implementation of the Doha Declaration' (2004) 3 *John Marshall Review of Intellectual Property Law* 331-337.
421 As above.
422 n 297 above.

decision for it to be used for the first time. In fact, Rwanda and Canada had to meander and navigate through a complex, complicated and frustrating course and get through protracted negotiations to ensure compliance and subsequent use of the system created by the August 2003 Decision.

It all started in 2004, when Canada became the first developed country to attempt to use the August 2003 Decision in a bid to export medicines to developing countries. The first step Canada took was to enact legislation in May 2004, which was known as 'an Act to amend the Patent Act and the Food and Drugs Act' (the 'Jean Chrétien Pledge to Africa').[423] Prior to that, Canada had indicated in September 2003, a month after the entering into force of the August 2003 Decision, that it intended using the decision. So, the Jean Chrétien Pledge to Africa was a curtain raiser to its pledge of improving access to medicines. However, the Act only came into force on 14 May 2005. The Act constitutes the Canada Access to Medicines Regime (CAMR). Many stakeholders – NGOs, civil society, pharmaceutical companies and policy makers – where consulted before the Act came into force. At the time, Canada put forward the view that the Act 'balances its trade and intellectual property obligations with the humanitarian objectives of the WTO [August 2003] Decision'.[424] For convenience, it would be instructive to have an insight into the salient provisions of the law as well as its eligibility criteria, requirements and application processes. This will provide a clear picture of the platform from which the Canada-Rwanda negotiations and subsequent use of the August 2003 regime took place. It also impacts the recommendation of this thesis about how to adopt August 2003 Decision provisions.

The goal of the CAMR is 'to facilitate timely access to generic versions of patented drugs and medical devices, especially those needed by least-developed or developing countries to fight HIV/AIDS, malaria, tuberculosis and other diseases'.[425] However, as Canada acknowledged, it would require the

423 It has since been renamed the Canada Access to Medicines Regime.
424 Canada Access to Medicines Regime http://www.camr-rcam.gc.ca/intro/context-eng.php (accessed 17 October 2011).
425 As above.

goodwill of pharmaceutical companies to participate in the CAMR to fulfil the humanitarian objective of alleviating public health problems in developing nations.[426]

Some of the important features provided for in the CAMR include the following: Only listed medicines may be exported, although there are procedures for amending the list; all drugs and medical devices exported under the regime must meet the same safety, effectiveness and quality requirements as those produced for the Canadian market; Canada will review products intended for export under the regime, using the same process as products for the Canadian market; once a compulsory licence is issued under the regime, and if a claim for remission is made, Health Canada will remit to the manufacturer the fees normally associated with the regulatory review process; special markings and colouring distinguishable from patented versions in Canada; and drugs to be exported must be those primarily from WHO essential medicines lists.[427]

The importing country and the exporting company (in Canada) must meet certain conditions, as discussed below.

In order to be eligible to benefit from the CAMR, a country must be 'on one of the schedules listing eligible countries and have little or no capacity to

426 As above.

427 As above. The full provisions are: 'Although the WTO decision was an agreement amongst WTO member countries, the regime is available to most non-WTO countries as well; all drugs and medical devices exported under the regime must meet the same safety, effectiveness and quality requirements as those produced for the Canadian market; health Canada will review products intended for export under the regime using the same process as products for the Canadian market; once a compulsory licence is issued under the regime, and if a claim for remission is made, Health Canada will remit to the manufacturer the fees normally associated with the regulatory review process; drugs and medical devices eligible for export under the regime are primarily from the World Health Organisation's Model List of Essential Medicines, but provisions are in place for products to be added to the list; products exported under the regime must have special markings, colouring and labelling, as applicable, to distinguish them from the patented versions sold in Canada. This will assist in preventing the products from being diverted into markets other than those for which they are authorised; to ensure that the regime is used in good faith, patent holders may challenge a compulsory licence in court if the cost of the generic product is more than 25 per cent of the cost of its equivalent patented version in Canada; non-governmental organisations can act as purchasers of licensed pharmaceutical products with the permission of the importing country's government and other measures are in place to ensure that the regime is as transparent as possible.'

manufacture drugs and medical devices'.[428] The eligible countries that are listed in Schedules 2, 3 and 4 to Canada's Patent Act are least-developed countries, recognised by the UN as such, including WTO and non-WTO members; developing countries that are members of the WTO and which had not indicated whether or not they intended to use the August 2003 Decision to 'import patented medicines or import patented medicines only in a public health emergency'; and, lastly, WTO members who had indicated that they would use the August 2003 regime to import patented medicines only in a public emergency and 'developing countries that are not WTO members but are on the Organisation for Economic Co-operation and Development's list of countries eligible for official development assistance'.[429]

The eligible importing country must meet the following requirements:

> [i]dentify a drug or medical device that is on the list of eligible products; if the needed medicines is not on the list, refer to recourse for importing countries and notify the World Trade Organization[430] or the Government of Canada[431] that a particular product

428 As above.

429 Canada Access to Medicines Regime 'Eligible countries' http://www.camr-rcam.gc.ca/countr-pays/elig-admis/countr-pays-eng.php (accessed 12 November 2011).

430 'To notify the World Trade Organization (WTO) of its plans to import a drug or medical device through Canada's Access to Medicines Regime, the government of a WTO member country must 'prepare a letter on official letterhead indicating its plan to import a drug or medical device under the regime. Include in the letter the information required, depending on whether the country is a Schedule 2 of WTO member country that is recognised by the United Nations as a least-developed country; a Schedule 3 of WTO member country that has not indicated whether it intends to take advantage of the WTO decision; or a Schedule 2 of WTO member country that has indicated to the WTO that it will take advantage of the WTO decision in a public health emergency. Mail the letter of notification to the Council for Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization: TRIPS Council, World Trade Organization, Centre William Rappard, Rue de Lausanne 154, CH-1211 Geneva 21, Switzerland' http://www.camr-rcam.gc.ca/countr-pays/proc-formal/notif_wto-avis_omc-eng.php (accessed 17 October 2011).

431 To notify the government of Canada of its plans to import a particular drug or medical device through Canada's Access to Medicines Regime, the government of a country that is not a member of the World Trade Organization (WTO) must (1) prepare a letter on official letterhead indicating its plan to import a drug or medical device under the regime. Include in the letter the information required, depending on whether the country is a Schedule 2-WTO member country that is recognised by the United Nations as a least-developed country; or a Schedule 4-developing country that is on the Organisation for Economic Co-operation and Development list of countries eligible for development assistance; (2) mail the letter of notification to the government of Canada through the Canadian embassy in the country; consult the embassies and consulates section of the Department of Foreign Affairs and International Trade Canada website to find the appropriate embassy.

is needed and find a suitable Canadian pharmaceutical company from which to import the needed product.[432]

The eligible country could request additions to the list of eligible products. However, even then, certain conditions would have to be fulfilled and certain procedures followed.[433]

The above are the requirements and conditions that the eligible importing country has to fulfil. It should be noted that the eligible exporting company has to fulfil certain conditions and follow certain steps. For instance, the eligible company must comply with the regime's anti-diversionary

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[432] Canada Access to Medicines Regime 'Requirements for importing countries' http://www.camr-rcam.gc.ca/countr-pays/import/index-eng.php (accessed 17 October 2011).

[433] 'To request that the government of Canada add a drug or medical device to the list of eligible products the country, company or non-governmental organisation making the request must proceed in the following manner: (1) prepare a letter requesting that the government of Canada add a drug or medical device to Schedule 1 of Canada's Patent Act. If the request is being made by a country, the letter should contain the information that was originally included in the country's notification to either the World Trade Organization (WTO) or the government of Canada, depending on whether the country is a Schedule 2-least developed country as recognised by the United Nations, including those that are not members of the WTO; a Schedule 3-WTO member country that has not indicated whether it intends to take advantage of the WTO decision; or a Schedule 4 WTO member country that has indicated to the WTO that it will take advantage of the WTO decision in a public health emergency; or a Schedule 4 developing country that is not a member of the WTO and is on the Organisation for Economic Co-operation and Development list of countries eligible for development assistance. Note: A country may request an addition to Schedule 1 before it makes its notification to the WTO or the government of Canada. In this case, the letter should, as best as possible, include the information that would be required in its notification. (2) Address the letter to the Minister of Industry and the Minister of Health. The ministers may refer the letter of request to the Advisory Committee established to review additions to Schedule 1.' http://www.camr-rcam.gc.ca/countr-pays/proc-formal/elig_prod-prod_admis-eng.php (accessed 17 October 2011).

measures[434] and determine the royalty payment due the patent holder,[435] and take certain steps and provide certain information[436] to the Canadian

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434 'Canada's Access to Medicines Regime includes a number of measures to prevent diversion of drugs and medical devices to unintended markets. Licensed products must have anti-diversionary features, including specific markings, colouring and labelling, as applicable, to make them distinguishable from the patented versions available on the Canadian market: There must be a permanent display of 'XCL' on labels and all solid dosage form products; for solid dosage forms, the colour must be significantly different from the version sold in Canada; and there must be an export tracking number and the statement 'For export under the General Council Decision. Not for sale in Canada' or 'Pour exportation aux termes de la décision du Conseil général. Vente interdite au Canada' on all labels, samples of which must be provided to the Minister of Health. The distinguishing features are reviewed by Health Canada during the health and safety review of the product. A country that is not a member of the World Trade Organization will be removed from the list of eligible importing countries, if that country fails to adopt anti-diversion measures as specified by art 4 of the August 2003 decision of the WTO. A licence will be terminated if the licensed product is re-exported from the intended importing country with the knowledge of the licence holder and in a manner contrary to the WTO decision of August 2003. The company must also ensure that all conditions of compulsory licences are met' http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/anti-eng.php (accessed 17 October 2011).

435 The formula to determine the royalty rate is 1, plus the number of countries on the UNHDI, minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. Mathematically, the regulatory formula cannot result in a royalty rate in excess of 4 per cent, a ceiling that is consistent with the humanitarian and non-commercial considerations that are the foundation of the Regime.

$$\frac{1 + \#\text{ of countries on UNHDI} - \text{country's rank on UNHDI}}{\#\text{ of countries on UNHDI}} \times 0.04 = \text{royalty rate}$$

For example, if country X is ranked 165 on the UNHDI and there are 177 countries on the UNHDI this year, then the royalty rate for products imported into country X under the Regime would be

$$\frac{1 + 177 - 165}{177} \times 0.04 = 0.0029$$

The patent holder has the right to apply to the Federal Court of Canada for an order setting a higher amount. In considering the merits of such an application, the court must take into account the economic value of the use of the licensed product by the importing country and the humanitarian and non-commercial reasons underlying the issuance of the licence.

436 The company must have a supply agreement with an eligible country for the sale to that country of an eligible product. A copy of this agreement must also be provided to the Commissioner of Patents and the patent holder within 15 days of the day the agreement was signed or the day the compulsory licence is granted, whichever is later; the importing country must notify either the World Trade Organization or the government of Canada and provide the required information, which varies depending on the classification of the country; the company must perform a Canadian patent search and, if a patent exists, identify the patent holder or holders; at least 30 days before submitting the application, the company must try to obtain from the patent holder a voluntary licence to make and export the patented product; before the product is manufactured in quantities for export, the company must have it reviewed by Health Canada. The company does not have to complete the application for a compulsory licence before submitting the product to Health Canada for regulatory review; the company must provide Health Canada with information to establish that the product incorporates anti-

Intellectual Property Office. It must also submit a complete application. The application should be either in English or French and should contain 'an application for authorisation accompanied by a declaration from the applicant stating that it has attempted to negotiate a voluntary licence and a certified copy of the importing country's notification to the World Trade Organization or the government of Canada'.[437] If the application for a compulsory licence is successful, the company still has to fulfil other conditions. These include, among others, complying with the compulsory licence and anti-diversionary measures, provide notice of shipment to the patent owner within a certain period of time and determine the payment of royalty fees.[438]

The above provides an overview of the CAMR. The effectiveness of the August 2003 Decision was tested via the Canadian regime and found wanting – at least with respect to ease of use. In 2007, Rwanda notified the WTO that it was going to grant a compulsory licence to import generic versions of 260 000 packs of TriAvir - a combination of Zidovudine, Lamivudine and Nevirapine used to treat HIV/AIDS over two years - from Apotex Inc, a Canadian pharmaceutical company.[439] GlaxoSmithKline, Shire and Boehringer Ingelheim were the patent holders of the medicines. Under the rules, Apotex Inc. had to attempt to negotiate a voluntary licence with the patentees before producing generic versions of the medicines. Apotex engaged GlaxoSmithKline in negotiations with a view to producing the said medicines. However, the negotiations failed and Apotex was obliged to apply for an export licence under the CAMR.[440]

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diversionary measures This includes a description of the product's distinguishing features (colour, marking and labelling), as required by the Food and Drug Regulations.

437 'Submitting an application' http://www.camr-rcam.gc.ca/compan-entrepris/applic-demande/submit-present-eng.php (accessed 17 October 2011).

438 'Meeting the terms and conditions of compulsory licences' http://www.camr-rcam.gc.ca/compan-entrepris/applic-demande/conditions-eng.php (accessed 20 October 2011).

439 M Royle & T Wessing 'Compulsory licence and access to medicines – Rwandan experience' http://www.currentpartnering.com/2008/02/20/compulsory-licenses-and-access-to-medicines-rwanda-experience/ (accessed 20 October 2011).

440 As above.

The application process, although successful, was cumbersome. In September 2007, the Canadian Patent Authority granted Apotex a compulsory licence to export to Rwanda.[441] Apotex was very critical of the process, stating that it was 'unnecessarily complex' and did not 'adequately represent the interests of those who require treatment'.[442] It even vowed never to use the system again.[443] Some commentators are of the view that the very long drawn-out negotiation process renders the CAMR 'ineffective'.[444]

(d) Some reflections on the Canada-Rwanda case

There have been many arguments as to the utility and suitability of the CAMR, in particular, and the August 2003 Decision, in general, not least because the Canada-Rwanda example provided the first litmus test of the practicability and feasibility of the said decision. On the one hand, Apotex, health campaigners and some scholars hold that the law was too burdensome and to a large extent reflects the unworkablility of the August 2003 Decision. As such, there is thus an urgent need for reform. On the other hand, other scholars find nothing wrong with the CAMR and hold that pricing, and not the law and its procedure, should be blamed for its non-use. They have, however, evaded the broader question on the suitability and utility of the August 2003 Decision, preferring instead to examine CAMR in the light of Apotex's claims. The position of each school of thought is discussed below.

Chief amongst the scholars who are of the view that CAMR should not be criticised as being ineffective and that patent pricing and Canada's uncompetitive nature should be blamed for the fact that the law has been used just once is Attaran. He maintains that the CAMR is comparably among the best pieces of legislation in the world and was a good step towards implementing

441 As above.
442 As above.
443 A Attaran 'Why Canada's access to medicines regime can never succeed' http://findarticles.com/p/articles/mi_7000/is_60/ai_n55386813/pg_2/ (accessed 20 October 2011).
444 M Rimmer 'Race against time: The export of essential medicines to Rwanda' (2008) *Public Health Ethics* 89-103.

the WTO's access to medicines decisions between 2001 and 2003.[445] Even though the Canadian government was more concerned about 'having the bragging rights' to be regarded as the first country willing and able to implement the 2003 decision, the law was largely successful, not least because it is the only law in this area that has been used to date.[446] Thus, the law's failure was more due to economic than legal reasons and, therefore, the Rwandan case is a poor litmus test on which to judge the law.[447] He concludes that efforts to amend it, as evident from discussions of two Bills at the Canadian Parliament, are wasted.[448]

Other scholars have used the Rwanda-Canada example to highlight the cumbersome and bottleneck nature of using the August 2003 Decision. Most scholars believe that the CAMR had a number of shortcomings and that the Rwanda-Canada case was a glaring example of the unworkability of the decision and, as such, reform for a user-friendly system was urgently needed.[449] They hold that the panoply of procedures to be followed and requirements to be met, the lack of capacity and information in potential importing countries and competition from other exporting countries, such as India and China, arms-length negotiations with patent owners and patent authorities and, last but not least, notification to the WTO, are major stumbling blocks in the effective and smooth use of the system.[450]

In addition, countries have adopted different approaches in domesticating the decision, which may lead to inconsistencies in the process of enacting legislation that is compliant to the decision. The CAMR contains provisions that are absent from comparable legislation adopted by other countries, such as Norway, India, Korea and China, to implement the August 2003 Decision.[451] For instance, under the CAMR, the term of compulsory

445 As above.
446 As above
447 As above.
448 As above.
449 Y Gendreau (ed) *An emerging intellectual property paradigm: Perspectives from Canada* (2008) 101.
450 As above.
451 Gendreau (n 336 above).

licences was limited to a two-year period, but with the possibility of renewal, the patent holder could bring a suit for its cancellation. In addition, medicines manufactured for export had to obtain prior approval from the Canadian regulatory authorities.

Elliott is of the view that the CAMR, by providing for a two-year period on compulsory licences, failed to fully incorporate the TRIPS flexibilities and instead could be regarded as TRIPS-plus.[452] Although the CAMR contained some positive elements, such as defining the percentage to be paid as royalty fees to a patent owner, it was far from being the finished product, and therefore was susceptible to future amendment and reform.[453]

As Attaran pointed out, some scholars are of the view that the law, more than anything else, had much to do with political expediency. Its supporters wanted to 'leave a positive legacy and assistance for African countries'.[454] This, combined with pressure from Canadian generic manufacturers and activists, caused the Canadian government to expedite the process by coming up with a draft. It invited a few selected NGOs to comment on it, to ensure that it would be enacted into law before the 2004 Canadian general elections.[455] It appears from the foregoing that effective legal and public scrutiny might not have been used during the legislative process. If this had been employed, it could be that some of the gaps inherent in the law as well as the panoply of regulatory requirements and procedures might have been addressed. As such, Apotex would not have taken a long time to export medicines to Rwanda.

From these criticisms, one can infer that the August 2003 Decision may in theory appear to be a good compromise, but in practice and, as the Canada-Rwanda case has highlighted, it is marred by controversy, which justifies its appellation, 'a gift in a red tape'.

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452 R Elliott 'Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export' (2006) 1 *International Journal of Intellectual Property Management* 109.

453 As above.

454 As above.

455 Gendreau (n 336 above) 109.

Irrespective of the criticism levied and the debates as to whether economics or red tape were to blame for the long drawn-out arms-length negotiations which Apotex had to enter into to ultimately export the drugs to Rwanda, two issues deserve further reflection.

First, one wonders whether sourcing generic medicines from Apotex offered the best internationally-competitive price. This is all the more so because, historically, Canada has not be known for having a robust and competitive market for generic medicines. This begs the question why Indian companies, known as the 'pharmacy of the world', were not considered. Could politics, and not economics, have been at the centre of Rwanda's decision to use a Canadian company? Was Canada looking to strengthen its reputation and to put forward a good image internationally, and was it thus determined to make the August 2003 Decision work? Was Apotex looking for ways to boost its corporate profile and to get a niche of the lucrative markets for generic medicines? These are some of the unanswered questions which may make one think that there were many stakes involved in the Canada-Rwanda case, which go beyond the mere use of the August 2003 Decision.

Second, another point that comes to mind is the question why Rwanda notified the WTO when it appeared that it had no obligation under the August Decision, as it was a least-developed country under the UN classification. At first sight, it appears that such notification was not relevant. This is because, as a least-developed country and as per paragraph 1(b) of the decision, Rwanda is included, as of right, in the least eligible exporting countries. As such, it did not need to make any notification to the WTO, unlike developing and developed countries. However, as posited by Royle and Wessing, an interpretation of article 31*bis* read together with its Annex suggests that such notification might have been necessary.[456] They base their premise on the provision of paragraph 1 of article 31*bis*, read in conjunction with paragraph 2 of the Annex to the

456 Royle & Wessing (n 326 above).

above-mentioned article. The two paragraphs, when combined, are to the following effect:

> The obligations of an exporting member under article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing member(s)

with eligible importing members being

> any least-developed country member, and any other member that has made a notification to the Council for TRIPS of its intention to use the system set out in article 31*bis* and this Annex ('system') as an importer …

Thus, depending on the construction of the sentence, Rwanda might have been required by law to notify the WTO.

Nevertheless, the notification requirement emphasises one of the fears that had been highlighted when the decision was passed – WTO involvement. In the aftermath of the decision, some scholars argued that requiring countries to notify the WTO was adding an extra measure of difficulty to the already bureaucratically-driven WTO.[457] Even though a footnote to paragraph 2 of the Annex states that the 'notification does not need to be approved by a WTO body in order to use the system', it is submitted that by requiring countries, including least-developed countries, to give notification to the WTO, the WTO somehow wanted to be in the scheme of things and wanted some kind of role to play in the process. One wonders why least-developed countries, which had to use the system as of right, would now be required to give notification, it being understood that the notification need not be approved. It could be argued that it is like giving someone a gift with the right hand and taking back the gift with the left hand.

457 Matthews (n 235 above) 95.

As a result of the problems faced in implementing the CAMR, as demonstrated in Apotex's deal with Rwanda, the Canadian Parliament had a first reading of Bill C-393 on 9 March 2011. Bill C-393 was meant to streamline the CAMR and make it more user friendly by providing for a one-licence solution when the CAMR was to be used.[458] This initiative, which was found to be WTO-compliant by certain international trade and intellectual property experts,[459] never saw the light of day because the Canadian Parliament was dissolved without the opportunity to enact Bill C-393 into law.[460]

3.10 Chapter conclusion

This chapter has examined the flexibilities contained in the TRIPS Agreement and its aftermath, more especially the Doha Declaration and the paragraph 6 decision. It commences with an examination of the meaning of public health flexibilities and why and how they are crafted. It discusses the public health flexibilities found in the Agreement, reflecting an attempt to strike a balance between the interests of patent owners in the north and users of patented products – in this case medicines – in the south. Despite the potential availability of these flexibilities, access to medicine problems continued to affect countries in the south, especially those with chronic health problems. One of the problems was that the TRIPS flexibilities were found to be inadequate and, at worst, wanting when tested, especially the controversial article 31(f). This is followed by an examination of cases in certain developing countries that uncover the problems of utilising TRIPS flexibilities in the face of developed country pressures, especially from the US. The three cases discussed showed that the TRIPS Agreement was, at best, not working, or, at worst, not in the interests of developing countries with dire health and access to medicine problems. The TRIPS interpretation and potential application caused problems. For instance, Brazil, the Philippines and South Africa, relying on some of the TRIPS flexibilities to enact access to medicine-friendly laws, found that the

458 'Children can't wait! Dying for drugs in developing countries, http://www.aidslaw.ca/EN/camr/index.htm (accessed 24 January 2012).
459 Eg, Frederick Abbot twice testified before the Canadian Parliament that Bill C-393 was WTO-compliant.
460 Elliot (n 339 above).

legislation they enacted was the subject of considerable criticism, especially by the US, who alleged that the challenged legislation violated TRIPS.

In addition, the 20 years of patent exclusivity adopted with regard to patent protection could stifle developing countries' access to generic medicines. The cases above show the extent to which developed countries and big pharmaceutical companies can go in order to further private interests and, in certain cases, doing everything to earn 'super profits' at the detriment of developing countries' health and access to medicine plights. After the discussion of these emblematic cases, many questions were raised about the utility and suitability of TRIPS relative to public health. These questions sparked a new TRIPS and public health debate, culminating in a series of reforms within the WTO. First, there was the Doha Declaration of November 2001 in Qatar on TRIPS and Public Health, followed by the 30 August 2003 Decision on article 31(f) of TRIPS and the Hong Kong Ministerial, by which TRIPS was to be revised, especially the controversial article 31(f). However, the successor to article 31(f) – the 30 August Decision and the pending article 31*bis* – has proven to be too complicated and difficult to use. The Canada Access to Medicines Regime (among the first regime to put the 30 August Decision in practice) and the subsequent Canada-Rwanda case are eloquent testimony to the difficulties in using the so-called reformed or new provisions of TRIPS.

The above notwithstanding, the post-TRIPS developments can be hailed as progressive in terms of facilitating access to medicines. Although these developments are not successful in totally addressing the problem of inadequate access to medicines in resource-poor countries, especially African countries, TRIPS public health flexibilities provide a platform for certain best practices for certain sub-Saharan African countries, such as OAPI countries. While African countries, in general, and OAPI members, in particular, should seriously consider TRIPS flexibilities when drafting new legislation or amending their existing IP legislation, they should also consider practical ways outside the TRIPS Agreement of promoting and protecting access to medicines in their respective territories.

CHAPTER 4: AN ANALYSIS OF THE OAPI PATENT REGIME RELATIVE TO ACCESS TO MEDICINES

The general aim of this chapter is to critically examine the OAPI patent regime relative to access to medicines. The chapter investigates the reasons behind the incorporation of patent provisions in the OAPI regime and critically examines the extent to which the OAPI regime facilitates, or does not facilitate, access to medicines.

Chapters 2 and 3 discussed the TRIPS Agreement and its flexibilities relating to access to medicines. These two chapters set the background to the discussion and analysis in this chapter, which analyses the successive OAPI agreements relative to access to medicines. To start with, by drawing largely from World Health Organization (WHO) country studies on access to essential medicines, the chapter (in section 4.1) looks at the access to medicines problems faced by African Intellectual Property Organisation (OAPI) member states. It then (in section 4.2) discusses the evolution of the current OAPI patent regime by looking at the origins of the intellectual property regimes in the region; the motivations behind such laws; how the relevant provisions, especially those on patents, were negotiated and drafted; how they have been implemented; and the amendments of the relevant law up to the Revised Bangui Agreement of 1999. Focusing on the current OAPI regime (in section 4.3), the chapter discusses the main objectives and structure of the current regime. The next part of the chapter (section 4.4) enquires as to whether and to what extent the current regime (i) hinders or (ii) promotes access to medicines, and considers to what extent the OAPI regime effectively incorporates TRIPS flexibilities and post-TRIPS development flexibilities. The final part (section 4.5) looks at the reasons for this state of affairs. Answers to the above questions pave the way for chapter 5, which examines how the OAPI patent regime should be reformed to promote and facilitate improved access to medicines.

4.1 Access to medicine problems faced by OAPI member states

4.1.1 HIV/AIDS

Sub-Saharan Africa is the region of the world most stricken by global pandemics, especially HIV/AIDS.[1] According to the UNAIDS report on the global AIDS epidemic, of the 35.3 million people living with HIV, about 25 million people in Africa are living with the disease.[2] Like most developing and least-developed African countries, OAPI member states are battling to curb, prevent or cure many tropical diseases and, most recently, life style diseases. HIV/AIDS and malaria are amongst the diseases with the most considerable impact, be it social, political or economic.[3] Although not as high as in other parts of Africa, the prevalence rate of HIV in OAPI member states is a cause for concern. The Central African Republic,[4] Gabon,[5] Cameroon[6] and Côte d'Ivoire[7] have some of the highest HIV prevalent rates among OAPI members. Some 2.1 million people live with HIV/AIDS in these countries, which is about 10 per cent of the total number of people in Africa living with the disease.[8] Below is a table of prevalence rates of HIV in some OAPI member countries.

Table 1: HIV/AIDS in OAPI member states[9]

Countries	HIV Prevalent Rates (age 15-49)
Benin	1.2%
Burkina Faso	1.2%
Cameroon	5.3%
Central African Republic	4.7%
Chad	3.4%
Congo	3.4%

1 UNAIDS Report on the global HIV/AIDS epidemic http://www.unaids.org/en/resources/campaigns/globalreport2013/factsheet/ (accessed 10 July 2014).
2 As above.
3 As above.
4 4.7% http://www.unaids.org/en/regionscountries/countries (accessed 10 July 2014).
5 5.2% prevalent rate (n 4 above).
6 5.3% prevalent rate (n 4 above).
7 3.4% prevalent rate (n 4 above).
8 http://www.unaids.org/en/regionscountries/countries (accessed 10 July 2014).
9 As above.

Côte d'Ivoire	3.4%
Gabon	5.2%
Guinea	1.3%
Guinea Bissau	2.5%
Mali	1.0%
Mauritania	0.7%
Niger	0.8%
Senegal	0.9%
Togo	3.2%

4.1.2 Malaria and other diseases

Aside from HIV/AIDS, there are other diseases that cause havoc in OAPI member states. Chief amongst them is malaria. In 2013, malaria caused an estimated 627 000 deaths in Africa, including OAPI member countries.[10] In Africa, a child dies every minute from malaria, which also accounts for approximately 22 per cent of all children's deaths on the continent.[11] In fact, 90 per cent of all deaths from malaria occur in sub-Saharan Africa.[12] As Table 2 below shows, the population of more than three-quarters of OAPI member countries are 50 per cent at risk of contracting malaria, while in little fewer than half of the countries, there are 100 confirmed cases of malaria per 1 000 people. The table below shows the percentage of the population at risk of malaria and the distribution of confirmed cases per one thousand.

Table 2: Population at risk of malaria and distribution of confirmed cases per 100[13]

Countries	Percentage of population at risk	Distribution of confirmed cases per 1000

[10] http://www.who.int/malaria/media/world_malaria_report_2013/en/ (accessed 10 July 2014).
[11] As above.
[12] As above.
[13] Country profiles 2014 http://www.who.int/malaria/publications/country-profiles/en/index.html (accessed 10 July 2014).

Benin	50%	>100
Burkina Faso	50%	>100 (North) 50 – 100 (South)
Cameroon	25-50%	10 – 50 (South) 50 – 100 (rest of the country)
Central Africa Republic	Ineffective data	Ineffective data
Chad	Ineffective data	Ineffective data
Congo	Ineffective data	Ineffective data
Côte d'Ivoire		10 – 50 (most parts of the country) and 50 – 100 (South east of the country)
Gabon	50%	>100 (most parts of the country) 10 – 50 and 50 – 100 (rest of the country)
Guinea		50 – 100 (most parts of the country) 10 -50 (South east of the country)
Guinea Bissau		10 – 50 and 50 – 100 (most parts of the country) and >100 (coastal parts of the country)
Mali	Ineffective data	Ineffective data
Mauritania	<1%	
Niger	50%	>100
Senegal	50%	Unevenly spread as various parts of the

		countries have different number of cases
Togo	50%	>100

Besides HIV/AIDS and malaria, there are many other diseases that affect the citizens of OAPI member states. Some of the more serious disease include tuberculosis, hepatitis B, pertussis, meningitis, leprosy, cholera and measles.[14] Some of these diseases disproportionately affect people living with HIV/AIDS and account for a significant portion of the deaths of people living with HIV/AIDS.[15] Table 3 below shows the incidence rate of tuberculosis per 100 000 people in the OAPI member states.

Table 3: Incidence rate of tuberculosis per 100 000 people in OAPI member states

Countries	**Incidence of tuberculosis per 100 000 people[16]**
Benin	93
Burkina Faso	215
Cameroon	182
Central African Republic	327
Chad	283
Congo	382
Côte d'Ivoire	399
Gabon	501
Guinea	318
Guinea Bissau	229
Mali	324
Mauritania	330
Niger	181

14 http://data.worldbank.org/sites/default/adi_2011-web.pdf (accessed 15 June 2012).
15 HIV and TB factsheets, Centre for Disease Control and Prevention (CDC) http://www.cdc.gov/hiv/resources/factsheets/hivtb.htm (accessed 1 August 2012).
16 As above.

Senegal	282
Togo	446

4.1.3 General perspectives on access to medicines in the OAPI region

The state of the HIV/AIDS pandemic, malaria and other diseases requires access to medicines for their treatment as well as to curb their spread. To ensure access to medicines, states pass legislation, rules and regulations, create government departments, collaborate with local regional and international organisations and take an active role in monitoring the activities of agencies that in one way or another deal with health service delivery.

Chief among the mechanisms for promoting access to medicines is the national budgetary allocation to health care, of which medicine is a sub-set. A large budgetary allocation for health care services could lead to increased spending by the government for medicines, including essential medicines. This is because once the health budget is large enough and properly managed, used and allocated, there might be sufficient funds for the purchase of necessary medicines. However, it should be pointed out that the existence of a significant health budget may not necessarily translate into increased expenditure on medicines, partially because a large proportion of health budgets may actually go to salaries and facilities, while commodities are neglected.[17] Moreover, governments do not always offer medicines for free. Patients often pay user fees or buy outright from their own pockets.

Irrespective of the above, citizens of resource-poor countries, like the majority of the OAPI member states,[18] are caught in a dilemma of not having the resources to buy medicines and not having governments coming to their aid with necessary medicines. Even in African countries where governments purport to provide for certain medicines, in instances where the budgetary

[17] See Amnesty International 'Corruption by topic – health' http://www.transparency.org/topic/detail/health (accessed 4 November 2014).
[18] Twelve of the 16 OAPI member states are least-developed countries.

allocation for health care is too small, difficulties in accessing medicines - be it essential or otherwise - become the norm. This is because without the government subsidising or paying for medicines, the prices of these medicines would be unaffordable, especially by most sections of the population that live on less than US $2 a day.[19]

Although its effectiveness might be found wanting, recourse to the private health sector is one potential remedy. However, the private health sector usually sells at high prices or buys the medicines abroad, which can prove to be expensive because of transportation costs, import duties and falling exchange rates. According to the WHO, generic medicines in the public sector outlets are cheaper than those in private sector outlets.[20] However, these medicines are generally unavailable in public sector outlets because of being out of stock and other reasons. This forces many people to turn to the private sector. The WHO states that generic medicines at private sector outlets costs an average of 610 per cent more compared to the internationally referenced price.[21] A 610 per cent difference in price is stratospheric anywhere in the world - and all the more so in certain developing and least-developed countries where, as mentioned above, the average incomes of people are meagre. These charges to up to 610 per cent are known as mark-ups. According to the WHO, mark-ups are 'a charge added to the purchasing price to cover the costs and margins of the wholesaler or retailer'.[22] In some countries, the governments fix the percentage of the mark-up. However, in other countries, where prices are unregulated and where the government does not charge a fixed percentage as mark-up, middle-men and retailers may charge what they wish,[23] thereby causing an increase in price.

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19 'People living on less than US $2 a day in selected African countries' http://www.africapedia.com/PEOPLE-LIVING-ON-LESS-THAN-US$2-A-DOLLAR-PER-DAY-IN-SELECTED-AFRICAN-COUNTRIES (accessed 9 June 2012).

20 WHO: 'Access to essential affordable medicines' http://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf (accessed 4 November 2014).

21 'Millennium Development Goals: Progress towards the health-related Millennium Development Goals' WHO Fact Sheet 290, May 2011.

22 http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf (accessed 25 July 2013).

23 As above.

As stated, a large enough budgetary allocation for health services, properly managed, used and allocated, could lead to the availability of a large variety of medicines for different illnesses and diseases that may be prevalent in a particular country. Table 4 below shows the general expenditure on health by OAPI member states as a percentage of total government expenditure between 2000 and 2008. It also shows the median availability of selected generics, both in the public and private sectors, as well as the median consumer price ratio of selected generics in the public and private sectors.

Table 4: OAPI member states' general expenditure on health as percentage of government expenditure between 2001 and 2011[24]

Countries	**General government expenditure on health as % of government expenditure**		**Median availability of selected generics[25]**		**Median consumer price ratio of selected generic medicines[26]**	
	2001	2011	Public	Private	Public	Private
Benin	13%	13%	87.1%	72.1%	2.2%	2.9%
Burkina Faso	10%	13%				
Cameroon	6.6%	7.5%	58.3%	52.5%	2.2%	13.6%
Chad	14%	5.%	31.3%	13.6%	3.9%	15.1%
Central Africa Republic	14.%	13.2%				
Congo	4.8%	5.3%	21.2%	31.3%	6.5%	11.5%
Côte d'Ivoire	6.6%	6.6%				

[24] UNAIDS Abuja +12: Shaping the future of health in Africa.

[25] This shows the percentage of listed generics in stock at public sector and private sector outlets; http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf 115 (accessed 14 February 2012).

[26] According to the WHO, this is an expression on how much greater or less the local medicine price is than the international reference price; http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf 115 (accessed 14 February 2012).

Gabon	4.8%	6.6%				
Guinea	5.2.0%	6.6.%				
Guinea Bissau	2.3%	8.0%				
Mali	9.6%	11.1%	80.1%	70.0%	1.8%	5.4%
Mauritania	N/A	N/A				
Senegal	8.5%	12.5%				
Togo	8.0%	15.0%				

Table 5 shows the defence budgets of OAPI member states in 2000 and 2010.

Table 5: Military expenditure as percentage of GDP[27]

Countries	**Military expenditure as percentage of GDP**	
	2000	Most recent data
Benin	0.6%	1% (2008)
Burkina Faso	1.2%	1.2% (2009)
Cameroon	1.3%	1.6% (2010)
Chad	1.9%	6.2%
Congo	1.4%	1.1%
Côte d'Ivoire	1.5% (2003)	1.5% (2008)
Gabon	1.8%	1% (2007)
Guinea	1.5%	2.2% (2004)
Guinea Bissau	4.4%	2.1% (2005)
Mali	2.2%	1.9% (2009)
Mauritania	3.5%	3.8% (2009)
Senegal	1.3%	1.6% (2009)
Togo	1.6% (2003)	1.7% (2008)

[27] Stockholm International Peace Research Institute (SIPRI) Yearbook: Armaments, disarmament and international security (2011).

In recent years, countries in the OAPI region have embarked on improving their military at a time when health, education and the building of infrastructure are pressing priorities. Military expenditure is chosen as a comparator because this data is available and, to some extent, shows where the priorities of many OAPI member countries lie.

It should, however, be pointed out that accessibility of medicines is also determined by affordability/pricing of medicines in the region, decisions of pharmaceutical companies whether to register medicines in particular countries or not, the coverage of medicine provision (that is, who goes without medicines), the degree of out-of-pocket expenditure on medicines, and the existence or non-existence of essential medicine lists.

Although Africa is home to about 11 per cent of the world's population, it consumes less than 1 per cent of the world's health expenditure and carries about 25 per cent of the world's burden of diseases.[28] Although this applies to Africa in general, it is also a true reflection of the state of health in the OAPI region. One of the reasons for the low consumption of medicines relates to affordability, which is impacted by the prices of these medicines. Between 2002 and 2008, the median consumer price of selected generics in OAPI member states was on average about 3 per cent higher than the international prices of the same generic medicines. Although the 3 per cent rate appears not to be too high, however, with most Africans, including those from the OAPI region, living on less than US $1 a day, a 3 per cent[29] rate higher than the international average may make such medicines unaffordable.

This is further compounded by the fact that out-of-pocket expenditure on medicines in the OAPI region averages about 90 per cent[30] of private

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[28] Strengthening Pharmaceutical Innovation in Africa: Designing strategies for national pharmaceutical innovation: choices for decision makers and countries. Council for Health Research and Development (COHRD), 2012 2.

[29] See Table 4, OAPI member states' general expenditure on health as percentage of government expenditure between 2001 and 2011.

[30] WHO Global Health Observatory Data Repository; http://apps.who.int/gho/data/node.country.country-GHA?lang=en (accessed 11 November 2013).

expenditure on health. With such an exorbitant amount, at least by African standards, coming out of the family budget, the family thus would have to prioritise. The impact of this is that certain medicines will not be purchased as there may be other pressing family priorities to cater for, such as education, accommodation, feeding and transportation.

Another factor that may affect accessibility of medicines is the presence or absence of essential medicine lists. Essential medicines are defined as 'those that satisfy the priority health care needs of the population'.[31] Essential medicines are intended 'to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage, with assured quality, and at a price that individuals and the community can afford'.[32] The presence of the essential medicine list, therefore, is important in facilitating access to medicines as it contains the medicines that are intended to be (i) available at all times; (ii) available in adequate amounts and in appropriate dosages; and (iii) affordable. The WHO Model Essential Medicines List is 'a guide for the development of national and institutional essential medicine lists'.[33]

Table 4 raises a number of observations. The majority of OAPI member states increased their health budgets in the periods between 2000 and 2008; nine did so; one stood still; and three decreased the percentage spent on health. At first sight, at least for the countries that increased their percentage, this is a welcoming development as it indicates some sort of progressive realisation towards improving health care. However, on a closer look, certain issues come to the fore. To begin with, evidence seems to show that expenditure of governments from the OAPI region tends to grow in percentage as the GDP per person increases.[34] Most often, such expenditure tends to grow where there is economic growth, higher taxes, better tax collection and budget

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31 http://www.who.int/medicines/services/essmedicines_def/en/ (accessed 11 November 2013).

32 http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_section4_web.pdf (accessed 11 April 2015).

33 As above.

34 Health expenditure *per capita* http://data.worldbank.org/indicator/SH.XPD.PCAP (accessed 25 July 2013).

support from donors. Irrespective of the above, the tricky issue is whether the increase in expenditure is really commensurate with the increase in population size, especially in Africa, where there is an annual average population growth of 4 per cent.[35] However, as mentioned above, in the absence of economic growth, an increase in tax revenue and donor funding, this may not be the case. In addition, given resource constrains in many African countries as well as prioritisation of other needs, there is hardly any matching of the expenditure to reflect increases in population size.

In Table 5, seven OAPI member states increased their defence budgets between 2000 and 2010. For instance, Chad spent 1.9 per cent of its GDP on defence in 2000, but spent about three times this percentage in 2008. By way of comparison, in 2000, it spent 13.1 per cent of total government expenditure on health and only increased this by 0.7 per cent in 2008. Cameroon, on the other hand, spent 6.6 per cent of its total expenditure on health in 2000. However, by 2008, this figure had dropped to 6.1 per cent. While the health expenditure was decreased, the defence budget saw an increase. In fact, in 2000, it stood at 1.3 per cent of the total budget, but by 2010, the figure had increased to 1.6 per cent. This begs the following question: If there is an increase in defence spending, why this instead of an increase in the health budget? In answering this question, one may be tempted to consider many other variables, such as the threat of civil wars, a desire to maintain peace and perhaps a desire to prevent foreign attacks. Whatever the reason advanced, most African countries, especially the OAPI member states, had committed to spending 15 per cent of their budgets on health,[36] targeting reduced child mortality, improving maternal health and combating HIV/AIDS, malaria and other diseases under goals 4, 5 and 6 of the Millennium Development Goals (MDGs).[37]

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35 Population growth (annual percentage http://data.worldbank.org/indicator/SP.POP.GROW (accessed 14 July 2014).

36 Abuja Declaration on HIV/AIDS, Tuberculosis and Other Infectious Diseases, OAU/SPS/ABUJA/3 24-27 April 2001.

37 These are eight goals adopted by heads of state as part of the Millennium Declaration in September 2000 to be achieved by 2015.

In addition, some of the OAPI member countries did not witness any form of civil war or external attack during the relevant period and, therefore, may not advance a legitimate and, in my opinion reasonable, explanation to justify any sudden increase in military expenditure to the detriment of the health sector. Whether or not the defence budget is increased, OAPI member states, especially those[38] that have signed the Abuja Declaration, have an obligation to respect the 15 per cent they have committed to allocate on their health budgets.[39] The relevant provision, paragraph 26 of the Abuja Declaration, calls on all signatory states to commit to allocating at least 15 per cent of their annual budgets on health. In addition, signatory states are to take all necessary steps to ensure the effective use of material and financial resources to improve health, especially supporting people with HIV and tuberculosis.[40]

Notwithstanding the above, it should be pointed out that government expenditure on health in some developing countries are a product of (i) increased resources from GDP growth, high taxes, better tax collection and/or donor budget support; (ii) government prioritisation of health as opposed to military, educational or infrastructural priorities; and (iii) macro-economic policies, usually mediated by the International Monetary Fund (IMF), which mandates low rates of inflation, small fiscal deficits, increased foreign currency reserves and debt repayment, frequently resulting in sub-additionality[41] or substitution for donor aid and government spending.

According to a 2013 UNAIDS report, only six African countries, Liberia, Madagascar, Malawi, Rwanda, Togo and Zambia, had met the 15 per cent

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38 Benin, Burkina Faso, Gabon, Central African Republic, Cameroon, Chad, Niger, Guinea, Congo, Mauritania, Côte d'Ivoire, Togo and Mali.

39 Abuja Declaration (n 36 above).

40 The full provision of this section states: 'We commit ourselves to take all necessary measures to ensure that the needed resources are made available from all sources, and that they are efficiently and effectively utilised. We pledge to set a target of allocating at least 15 per cent of our annual budget to the improvement of the health sector. We undertake to mobilise all the human, material and financial resources required to provide care and support and quality treatment to our populations infected with HIV/AIDS, tuberculosis and other related infections.'

41 A Makulec '"If you give a country a dollar …" Sub-additionality in global health financing' http://communicatingdata.com/2012/01/25/if-you-give-a-country-a-dollar-subadditionality-in-global-health-financing/ (accessed 14 July 2014).

commitment.[42] A number of other countries, Djibouti, Ethiopia, Lesotho and Swaziland,[43] came close to it. None of the OAPI countries achieved the 15 per cent target. Therefore, there is a need for the effective implementation of laws and policies.

4.2 History of the OAPI patent regime

4.2.1 Origins

Prior to independence, most African states' intellectual property laws were governed by the laws in force in the territory of the colonial master. This was the case of the Francophone African countries whose patent rights were governed by French laws and administered by the French National Institute of Industrial Property. When the majority of member countries of the French Union gained independence in 1960, it became necessary to create a specific structure in each of the new independent states, in accordance with international conventions on industrial property.[44] In September 1962, 12 former French colonies[45] gathered under the auspices of the *Union Africaine et Malgache* (UAM), which later became *Organisation Commun Africain et Malgache* (OCAM),[46] and signed the Libreville Agreement leading to the creation of the African and Malagasy Patent Rights Authority (OAMPI). The creation of this body found its legal justification in article 19 of the Paris Convention for the Protection of Industrial Property.[47] This article states that countries which are signatories to the Paris Convention serve the right to

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42 UNAIDS 'Abuja+12: Shaping the future of health in Africa' (2013) 5 http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2524_Abuja_report_en.pdf (accessed 15 July 2014).

43 As above.

44 F Orsi et al 'AIDS, TRIPS and "TRIPS plus": The case for developing and less developing countries' in B Andersen (ed) *Intellectual property rights, innovation, governance and the institutional environment* (2003) 79.

45 These countries included Cameroon, Central African Republic, Republic of Congo, Republic of Chad, Republic of Côte d'Ivoire, Republic of Dahomey (Benin), Republic of Upper Volta (Burkina Faso), Republic of Gabon, Republic of Mauritania, Republic of Senegal, Malagasy Republic and Republic of Niger.

46 C Deere 'TRIPS implementation in Francophone Africa' in C Deere *The implementation game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries* (2009) 250.

47 'History of OAPI' http://www.oapi.wipo.net/en/oapi/historique.htm. (accessed 25October 2015).

undertake separately among themselves specific agreements for the protection of patent rights, so long as these agreements are not conflicting with the provisions of the Paris Convention.

4.2.2 The Libreville Agreement of 1962

The Libreville Agreement dealt with issues relating to patents, trademarks or trade names and industrial drawing or models. It was applicable to the 12 African countries of French expression and culture that were signatory to it. The Agreement was based on three fundamental principles. The first was the adoption of a uniform patent legislation and the putting in place of common administrative procedures leading to a uniform system of patent rights protection application.[48] The second was the creation of a common authority, as the organisation serves as a national patent rights protection department for each member state and, lastly, the centralisation of procedures such that a single title issued in one state was deemed to have been issued in all the member states.[49] Lastly, the centralisation of procedures made it necessary by the introduction of uniform legislation and a joint office so that any property rights granted could be split into independent national rights in every member country. The reason for such centralisation and the role France and other countries and organisations played in ensuring that this happened is discussed later in this chapter.

4.2.3 The Bangui Agreement of 1977 and the birth of OAPI

Barely 15 years after its entering into force, the Libreville Agreement was replaced by the Bangui Agreement of 1977. Many reasons for this change have been advanced by observers.[50] First, it appeared that some members did not feel comfortable having to cede their sovereignty to a supranational body. This may have been the case of the Malagasy Republic, which withdrew a few years

48 As above.
49 As above.
50 Orsi et al (n 44 above).

after the coming into force of the Libreville Agreement.[51] Second, it was felt, and rightly so, that the Libreville Agreement did not cover all rights, notably, models, trade names, products and service trademarks.[52] Third, there was a need to better involve patent rights in development and the desire that the organisation leads to greater economic integration.[53] These reasons led to the creation of a new body, called the African Intellectual Property Organisation (OAPI), following the adoption of a new convention signed in Bangui on 2 March 1977. As will be seen later, France and the WIPO played an important role in this process.

The Bangui Agreement of 1977 introduced for the first time the patentability of pharmaceutical products - a provision that was absent in the Libreville Agreement. It is not clear why the Bangui Agreement of 1977 included pharmaceutical patents. However, given the legacy of French influence on the structure of IP laws in its African colonies, as well as the technical support provided by France and the WIPO in the drafting of the Agreement, one might be tempted to conclude that the inclusion of pharmaceutical patents would have been influenced by these.[54] In addition, since the impact of stringent IP protection on access to medicines was not a priority for international and local NGOs at the time, there was little opposition to the inclusion of pharmaceutical patents. Nonetheless, the 1977 Agreement also tried to balance public interests with the rights of patent holders.[55] For example, the duration and continuous existence of patents depended on the ways in which they were exploited locally and the resulting advantages for the local population.[56]

The 1977 Bangui Agreement adopted the elements of novelty, inventive steps and industrial application as conditions *sine qua non* for the granting of patents. This was provided for in article 1(1). According to this article, patents

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51 As above.
52 As above.
53 As above.
54 Deere (n 46 above).
55 R Jourdain 'Les droits de propriété intellectuelle et la santé publique dans l'Accord de Bangui révisé : Défis majeurs en santé publique pour les pays africains (2002) *Commerce, Propriété Intellectuelle et Développement Durable Vus de l'Afrique* ICTSD, Enda, Solagral 106.
56 As above.

could be granted to products and processes. As per article 2, the criterion to be considered in determining the novelty of a product or process is that the state of such a product or process should not have been known technically prior to the application of the patent.

The patent owner had certain rights and obligations under the 1977 Agreement. With regard to the rights of the patent owner, for instance, he or she had the right to prevent others from producing, importing, offering for sale, selling or using the patented product or a product resulting from a patented process.[57] Any of these acts constituted a violation of the rights of the patent owner. As for the obligations, article 58(2) provided that the patent owner had to use or exploit the patent. If the patent holder failed to do so, no action would be entertained against someone who used the said unexploited patent.

The duration of the protection accorded to a patent under article 6 was ten years following the date of filing the patent application. The duration could be extended twice for a period of five years each. However, before this could be done, the patent owner had to fulfil certain conditions. He or she had to show proof to OAPI that the invention was being used or exploited locally in one of the member states of OAPI unless there are sufficient reasons to justify the non-local exploitation of the invention, and importation was not a legitimate reason. Jourdain is of the view that the reason for this provision was to ensure that patents effectively contributed to the industrial development of countries in the OAPI region and not only to grant monopoly rights to patent owners.[58] It is questionable whether the objective of having a general working requirement so as to build an industrial base was really achievable. This is because there was no obligation to produce the products locally, thereby leading to the building of local capacity, infrastructure, and so forth.

Exceptions to the patent owner's rights were provided in the form of compulsory licences and *ex officio* licences. Any person residing in one of the

57 Art 1(2) 1977 Bangui Agreement.
58 Jourdain (n 55 above).

OAPI member states could apply to court for the issuance of a compulsory licence. However, such a person had to satisfy certain conditions. To begin with, pursuant to the Paris Treaty on Industrial Property, article 44 requires that such application could only be made four years after the date of filing or three years after the date of issuing of the patent. In addition, the patented invention must have not been 'worked' in the territory of one of the OAPI member states at all, or must not have met the demand for the product on reasonable terms, for instance, must have been insufficiently worked.[59] These conditions were meant to ensure that a patent granted by OAPI did not only confer rights on the patent owner, but there were also certain obligations *vis-à-vis* the local population, such as that there was no obstacle to accessing patented products.[60] Article 44(1)(iii) also clarified that a compulsory licence could be granted when local working of the patent was being prevented or hindered by the importation of the patented product. Lastly, pursuant to article 44(1)(iv), a compulsory licence could be granted where the refusal of the patent owner to grant voluntary licences would be prejudicial to the establishment and development of commercial and industrial activities in the country where the patent was granted. Although a failure to work could be justified by legitimate reasons, importation would not constitute a legitimate reason. In addition to satisfying the grounds for a licence under article 44, pursuant to article 46, the applicant must present an application with the required information, including evidence of having tried without success to enter into a contractual licence with the patent owner.

Pursuant to article 55, *ex officio* licences were given to governments for them to exploit and use a patented invention, which was of vital importance to national defence, public health or the national economy. Unlike with compulsory licences issued pursuant to article 44, which requires local working (see article 46(1)(iv)), an *ex officio* government-use licence issued on the grounds of national defence or public health could be granted to an importer (see article 55(2)). In terms of procedure, pursuant to article 57, following a request from a

59 Art 44(1)(i) 1977 Bangui Agreement.
60 Jourdain (n 55 above).

competent minister, the minister in charge of intellectual property must contact the patent owner for the use or exploitation of the latter's invention in a manner aimed at satisfying public health or the needs of the national economy. If such was not possible within 12 months after the request or if the existing use or exploitation of the patented product prejudiced public health, the government has the right to use or exploit the patented invention. In the absence of agreement on terms, the terms are to be set by the court. These provisions could have served as legal bases to improve access to essential medicines when a patent was the major obstacle.[61]

A number of observations can be gleaned from the 1977 Agreement in the context of access to medicines. Of particular note is the period of patent term protection and the conditions attached to its extension. The patent term was to be for a period of ten years, twice renewable. The renewal was dependent on whether or not the patent was being worked in the OAPI region. It is not clear what the drafters had in mind by providing a ten-year period and by attaching conditions on the renewal of the patent. It is questionable whether the drafters may have had access to medicines concerns in mind. This is because patent protection and access to medicines were not a major issue during the 1970s - at least from an OAPI perspective. Arguably, the drafters might have focused on the issue of medicines in order to extend patents to pharmaceutical products. This is because, as mentioned above, metropolitan France, which favoured stringent patent protection, was at the forefront of the development and entry into force of a regional IP law in its former West and Central African colonies.[62]

Notwithstanding the above, the ten-year period provided is a relatively limited period for the patent owner to exercise his exclusive rights before generic versions of the medicines could come onto the market, unless an extension was granted. This was a positive step in the context of access to medicines when contrasted with the current 20-year TRIPS term. The

61 As above.
62 Deere (n 46 above).

consequence was the shortening of the time for the introduction of generic products to the market.

Furthermore, although the patent term could be extended twice for five-year periods, such renewal was not automatic. The patent owner had to show proof of working the patent in the region. This appears to make it easier for generic competition to carve out a position for itself. However, there is no evidence that generic companies in the OAPI region have used this provision to effect any reduction on the price of medicines.

In addition, the 1977 Agreement provided for 'licences of right' and *ex officio* licences. Under article 54, a patentee who had not previously been barred from issuing a voluntary licence could apply to OAPI to enter a licence of right under its patent in OAPI's Patent Register.[63] Once this was done, it became possible for any person to obtain a licence to exploit the said patent upon such terms as shall, in the absence of an agreement between the interested parties, be fixed by a civil court.[64] It should be pointed out that the patent may at any time apply to OAPI to cancel the 'licence of right'.[65] However, such cancellation could only be done if there was no licence of right in force or if all the licencees agreed thereto following the payment of fees which would have been payable had the entry not been made in the register.[66]

Article 55 of the Bangui Agreement of 1977 provided for *ex officio* licences. It stated:

> (1) An *ex officio* licence may be obtained at any time for the exploitation of a patented invention of vital importance to:
>
> (a) national security;
>
> (b) public health;
>
> (c) the national economy
>
> …

63 Art 54(1) Bangui Agreement of 1977.
64 Art 54(2) Bangui Agreement.
65 Art 54(3) Bangui Agreement.
66 As above.

(2) In the cases provided for in paragraphs 1(a) and (b), an *ex officio* licence may even be obtained for importation.

Article 57 of the Bangui Agreement of 1977 gave a government the right to issue a compulsory licence in instances where it is of vital importance to public health where the patent owner had refused to negotiate with the government within a period of 12 months.[67] If the patent owner refused to negotiate with the government within the 12-month period, the government had the right to grant a compulsory licence by way of a text issued by the competent ministry within the said government, which text would determine the conditions with regard to the scope and duration of the compulsory licence.[68] The compulsory licence shall enter into full force once the text granting it had been published.[69] If no agreement was reached as to the payment of the use of the licence, the court would be called upon to determine the payments.[70] However, it should be pointed out that the government could prolong the 12-month period if the patent owner in question had a legitimate reason for not negotiating with the government within the 12-month period.[71]

The provision of a compulsory licence was a welcome development as it gave the government the right to protect its people where the patent owner became intransigent. By so providing, the 1977 Agreement was re-emphasising the cardinal importance of states to take action for the benefit of the health of its citizens.

4.2.4 Revision of the Bangui Agreement in 1999

The year 1999 was a turning point in the history of OAPI. This is because of the revision of the Bangui Agreement. Developments at the international stage could have triggered this revision. By the mid-1990s, a multi-lateral trading system had been created, known as the World Trade Organization (WTO),

67 Arts 55(1c) & 57(2) Bangui Agreement.
68 Art 57(2) Bangui Agreement.
69 Art 57(4) Bangui Agreement.
70 Art 57(5) Bangui Agreement.
71 Art 57(3) Bangui Agreement.

whose objectives, among others, included the promotion and liberalisation of international trade. The coming into force of the WTO and its TRIPS Agreement had as consequence the reformation of the OAPI system. All OAPI member states who had signed the WTO Agreement had to adhere to its provisions and related agreements, including TRIPS. Developing countries were to conform to TRIPS before 1 January 2000, while least-developed countries were to conform to the TRIPS Agreement by 2006.[72] (As previously discussed, this transition period for least-developed countries was extended to 2013 and then to 2021 for TRIPS, generally, and until 2016 for pharmaceuticals.[73]) On the face of it, the reform was brought about to allow OAPI member states to become fully compliant with TRIPS. However, this could not have been the sole reason. This is because TRIPS, which applied to OAPI member states, had an on-going active transition period for least-developed countries. However, the revised Bangui Agreement, as will be seen in subsequent discussions, neither created a separate section for least-developed countries, nor gave them the opportunity to benefit from the transition period provided for by the TRIPS Agreement. The current regime is discussed fully in the next section.

4.3 The current OAPI regime

The Revised Bangui Agreement was signed in 1999, but entered into force in February 2002.[74] As mentioned above, OAPI is made up of 17 member states. Its headquarters are in Yaoundé, the political capital of Cameroon. All member states who were members of the Bangui Agreement of 1977 have automatic membership of the Revised Bangui Agreement of 1999.[75] The Revised Bangui Agreement also provides for associated membership.[76] Any African country

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72 These transition periods were subsequently changed: Developing countries were to comply with TRIPS by 1 January 2005 while LDCs are to comply on or before 2016.

73 See para 7 of the Doha Declaration which provides that least-developed countries 'will not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 and 7 Part II of the TRIPS Agreement or to enforce rights provided under these sections until 1 January 2016, without prejudice to the rights of least-developed country members to seek other extensions of the transition periods as provided for in a rticle 66.1 of the TRIPS Agreement'.

74 'Objectives et missions de l'OAPI' http://www.oapi.int/index.php/en/aipo/objectifs-et-missions (accessed 1 August 2012).

75 Art 22 Revised Bangui Agreement.

76 Art 21 Revised Bangui Agreement.

that is not a member of the Bangui Agreement of 1977 can apply for associate membership with the board of directors of OAPI.[77] An associate member is admitted by a majority vote of the board of directors.[78]

4.3.1 Mandate and functioning of OAPI

OAPI's mission includes the implementation and enforcement of administrative procedures under the uniform system of protection of intellectual property as well as international conventions on IP that OAPI member states have signed and ratified. In addition, OAPI has to render IP services to its member states.[79]

The aims and objectives of OAPI are spelt out in article 2 of the Revised Bangui Agreement. These aims include the putting in place of a uniform regime for the protection of intellectual property rights within OAPI member states with a view to promoting economic development; training nationals from member states on intellectual property rights; and co-ordinating the distribution of IP information among member states.

From the above, it is noted that one of the objectives of OAPI is engaging in IP rights training and an awareness campaign. However, despite this objective, OAPI has been more in breach than in observance thereof. This is because for more than the 20 years of its existence, OAPI as an organisation did not actively engage with local universities, nor create a centre for IP rights training. It was not until 2004 that a fully-fledged postgraduate programme on IP rights commenced in an OAPI member state, and then only with partial support from OAPI. In addition, OAPI only started its own training centre, the Denis Ekani Training Centre, in 2005. It is submitted that this is one of the areas where OAPI has failed in terms of creating awareness and providing a platform for meaningful discussion.

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77 Art 22 Revised Bangui Agreement.
78 As above.
79 *Objectives et missions de l'OAPI* http://www.oapi.int/index.php/en/aipo/objectifs-et-missions (accessed 1 August 2012).

Ten of the undergraduate students I spoke with at the Universities of Buea and Yaoundé II in Cameroon[80] did not know the basics of IP rights and what OAPI stands for and what it was doing. This is regrettable, especially in this age of globalisation and information technology where, with the click of a mouse, one has access to a myriad of information. It is recommended that OAPI step up its education and awareness campaigns to sensitise citizens and to create IP expertise in its member states. Absence of education and training leads to absence of critical information as well as a lack of interest in the impact of IP rights on access to medicines. Perhaps there was not much opposition to the Revised Bangui Agreement because most of the NGOs and citizens of OAPI member states and even organisations that have expertise were not given an adequate opportunity to participate in the revision process.[81] The revision process, including people who were involved, who led the drafting and who promoted it, is analysed later in the chapter.

4.3.2 Structure of OAPI

OAPI is made up of three main organs, namely, the board of directors, the superior appeals commission and the directorate-general. The board of directors, the highest-ranking body in OAPI,[82] is made up of representatives from all member states.[83] Each member state has one representative.[84] A member state may request a representative from another country to represent it.[85] However, a member of the board of directors will not be allowed to represent more than two countries.[86] The board of directors, among other things, establishes the necessary regulations for the implementation of the Revised Bangui Agreement, verifies and approves the accounts of OAPI, approves OAPI annual reports, reviews applications for accession into the Revised Bangui Agreement, lays down the amount to be paid by each member

80 Discussions with 10 law students from the Universities of Buea and Yaoundé II (Cameroon), June 2012, following questions listed on the questionnaire which is annexed to this thesis as Annex 1.
81 Deere (n 46 above) 275.
82 Art 29 Revised Bangui Agreement.
83 Art 28 Revised Bangui Agreement.
84 As above.
85 As above.
86 As above.

state and associated member state as contributions to OAPI, and decides on the need to create special commissions to tackle specific issues.[87] The board of directors meets once a year for an ordinary session, but can hold an extraordinary session convened by the President if the need arises.[88] Decision making in the board of directors' meetings is via majority through a one-member, one-vote system.[89] In case of a draw, the President's vote becomes final.[90]

The unanswered questions about the board are the following: (i) who nominates them; (ii) what the process involved in their selection is; and, most importantly, what level of scrutiny they have over regulations to implement the Revised Bangui Agreement. It should be pointed out that the OAPI Secretariat took the lead in driving the implementation of TRIPS during the negotiations of the Revised Bangui Agreement.[91] There is little or no evidence of the Board's vetting or scrutinising of the negotiations and the ultimate text that led to the revised Bangui Agreement. In fact, during the negotiation process, the OAPI Director-General held the view that the inefficiency of member countries and the complexities of IP meant that the Secretariat had to drive the entire process. With the Secretariat driving the process, one may conclude that there was very little, if any, input from member states and the board members who represented them in OAPI.

The superior appeals commission is made up of three members, selected through a lottery system from a list of members selected by member states.[92] The appeals commission reviews appeals on the rejection, application for the protection, extension and/or restoration of intellectual property rights.[93]

The directorate is managed by the director-general who is the highest-ranking official in OAPI. The director-general manages and represents OAPI in

87 Art 29 Revised Bangui Agreement.
88 Art 31 Revised Bangui Agreement.
89 As above.
90 As above.
91 Deere (n 46 above) 265.
92 Art 33.
93 As above.

all civil activities. The director-general attends all board meetings and performs the functions of a secretary in all board meetings.[94] The director–general, in conformity with the staff guidelines recruits, names and dismisses the staff of OAPI, except high-ranking personnel.[95] The current director-general is Paulin Edou from Gabon.

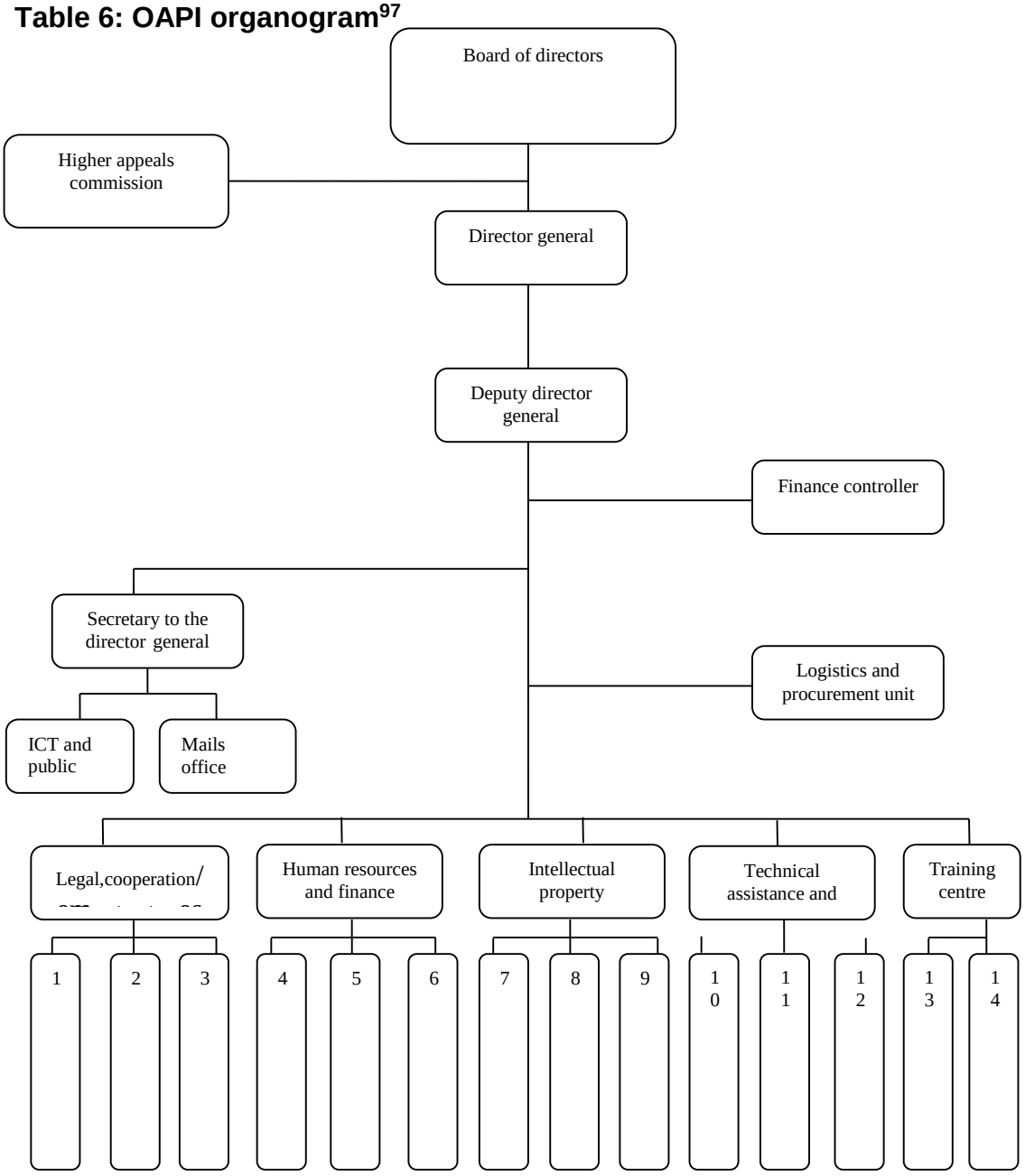
It should be noted that patent applications from OAPI member states can either be filed directly or indirectly. Indirect filings are made directly through local national IP offices which transmit the applications to Yaoundé or directly through OAPI headquarters in Yaoundé. In addition, the Bangui Agreement incorporates the WIPO Patent Co-operation Treaty (PCT) by reference. This implies that OAPI member states will respect the priority filing date of a patent in any of the PCT member countries.

Table 6 below shows OAPI's organogram. As mentioned above, at the top of the organogram is the board of directors, which is made up of representatives of OAPI member states. These representatives are usually ministers in charge of commerce and industry and industrial property in OAPI member states.[96] Directly below is the higher appeals committee which, although not an executive body, hears cases and issues decisions on disputes regarding IP registrations and filings. The board of directors and the higher appeals committee only meet from time to time and are not directly concerned with the direct administration and management of OAPI affairs. The director-general is the person in charge of the day-to-day running of the organisation and is assisted in his duties by a deputy director-general. There are seven departments immediately following the deputy director-general down the pecking order. These departments, among others, include finance control, legal, training, human resources and intellectual property protection departments. Within these departments are sub-departments or units. There are 14 sub-departments or units in total.

94 Art 35.
95 As above.
96 Eg, in Cameroon, the Minister of Commerce has for more than five decades been Cameroon's representative at OAPI's board of directors.

A closer look at the units shows that there is some duplication. For instance, under the human resources and finance department, there is a unit for training. Similarly, under the training centre department, there is a training and programme unit. Furthermore, under the department of technical assistance and development, there is a documentation, publication and dissemination of technical information unit and a small and medium-sized enterprise support and technical and scientific research unit. Similarly, there is a research, publication and documentation unit under the training centre department. From the foregoing, one is tempted to conclude that OAPI has a structural problem in terms of duplication of services. Cognisant of the financial constraints of most OAPI member states, it is recommended that some of the units, especially those mentioned above, be merged.

Table 6: OAPI organogram[97]



List of the names of all 14 units

1 Legal affairs unit

2 International negotiations and co-operation unit

3 Copyrights and emerging issues unit

4 Human resources and training department

5 Accounts and budget unit

6 Finance unit

97 Organogram sourced from http://www.oapi.int/index.php/en/aipo/cadre-institutionnel/organigramme (accessed 21 August 2012).

7 Patents unit

8 Trademarks and other distinctive signs unit

9 Examination unit

10 Strategic use of IP and statistic unit

11 Documentation, publication and dissemination of technical information unit

12 Small and medium-sized enterprise support and technical and scientific research unit

13 Training and programme unit

14 Research, publication and documentation units

4.3.3 Relationship between the WTO TRIPS Agreement and the Revised Bangui Agreement of 1999

Chapters 2 and 3 discussed the TRIPS Agreement as well as its flexibilities in some detail. The requirements of the TRIPS Agreement have a direct bearing on OAPI member states because they are all members of the WTO Agreement and thus of the TRIPS Agreement. It should be pointed out that the WTO Agreement provides for a 'single undertaking', meaning that once a state signs the Agreement, that state is bound by all its constituent agreements except the Plurilateral Agreement.[98] 'Single undertaking' also means that 'the provisions of the [WTO] agreement are subject to the integrated WTO dispute settlement mechanism which is contained in the Dispute Settlement Understanding'.[99] It should be recalled that article 1 of the TRIPS Agreement provides for a minimum standard of obligations and, because of this minimum approach, it has been described as a 'floor and not a ceiling'.[100] This means that Members

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98 This agreement that has a narrower group of signatories covers (i) trade in civil aircraft; (ii) government procurement; (iii) dairy products; and (iv) bovine meat (this was terminated in 1997); hHttp://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm10_e.htm (accessed 10 June 2012).

99 'Frequently asked questions about TRIPS in the WTO' hHttp://www.wto.org/english/tratop_e/tripsfq_e.htm#SingleUndertaking (accessed 10 June 2012).

100 Art 1 states that [m]embers shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.' See

, when enacting regional or national laws, cannot set standards below those provided for in the TRIPS Agreement, but could go beyond their obligations under TRIPS. This is why the Bangui Agreement, for instance, reflects the main patent provisions provided for in the TRIPS Agreement and even contains certain TRPS-plus provisions. In fact, the TRIPS Agreement is mentioned in the Preamble to the Bangui Agreement.[101]

Furthermore, TRIPS neither precludes Members from forming regional bodies regulating intellectual property rights, nor does it preclude members from having a supranational law dealing with IP. Article 1 of the TRIPS Agreement gives member states the liberty to determine the appropriate legal regime to implement the TRIPS Agreement. Therefore, OAPI member states were at liberty to enact a regional law dealing with intellectual property rights, which regional law implements the TRIPS Agreement.

Furthermore, , regional IP laws and IP bodies are allowed to operate in tandem with the TRIPS Agreement so long as articles 3 and 4 of the TRIPS Agreement, dealing respectively with the principles of national treatment and most-favoured national treatment, are not violated. According to the principle of national treatment, TRIPS member states are obliged to treat nationals of other member states no less favourably than they would treat their own nationals. Most-favoured national treatment means that if TRIPS Members were to accord special treatment to other members, they are obliged to accord such treatment immediately and unconditionally to other members. Thus, OAPI member states could have a regional IP law and a regional IP body, as long as the provisions of the regional IP law do not discriminate against nationals from non-OAPI member states as well as non-member states. It is important to note here that the WTO Agreement even recognises the important contribution to

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also C Correa *Intellectual property rights, the WTO and developing countries: The TRIPS Agreement and policy options* (2000) 8.

101 The Preamble to the Revised Bangui Agreement expressly mentions arts 8 and 69 of the TRIPS Agreement.

the expansion of world trade by closer regional integration of countries through regional bodies, customs unions, free trade agreements, and so forth.[102]

As discussed at length previously, the TRIPS Agreement as well as subsequent developments, such as the Doha Declaration and the August 2003 Decision, contain certain flexibilities that member states are free to include within their local laws. Some of these flexibilities are only for least-developed countries, but others are available for any WTO Member. Of the 17 OAPI member states, only four are non-least-developed countries. These countries are Cameroon, Gabon, Côte d'Ivoire and the Republic of Congo. This means that any regional IP law could have and should have taken into account the different stages of development of the respective member states. As will be seen in the subsequent subsections, although some of the TRIPS flexibilities have been incorporated in the Revised Bangui Agreement of 1999, in most instances, the Revised Bangui Agreement has either failed to incorporate key flexibilities or, even worse, incorporated TRIPS-plus provisions.

4.4 Patent regime of the Revised Bangui Agreement relating to access to medicines: Lack of the inclusion of all TRIPS public health flexibilities

4.4.1 Limited incorporation of TRIPS flexibilities in the Revised Bangui Agreement of 1999

As mentioned earlier, the coming into force of TRIPS paved the way for the revision of the Bangui Agreement. Article 43 of this Agreement provides that it will enter into force two months after the deposit of instruments of ratification of at least two-thirds of state parties to the Bangui Agreement of 1977. In compliance with this provision, Annex 1 of the Revised Bangui Agreement dealing with patents entered into force on 28 February 2002.[103] The granting of

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102 See para 2 Understanding on the Interpretation of Article XXIV of the General Agreement on Tariffs and Trade 1994, Annex 1 A, Multilateral Agreements on Trade in Goods.

103 A Tankoano 'Les importations parallèles et les licences non volontaires dans le nouveau droit des brevets des Etats membres de l'OAP' (2002) *Commerce, Propriété Intellectuelle et Développement Durable Vus de l'Afrique* ICTSD, Enda, Solagral 118.

patents in any of the 17 OAPI member states is regulated by the Revised Bangui Agreement. Once a patent is granted in a particular member state, it is deemed to have been automatically granted to all OAPI member states.

The Revised Bangui Agreement of 1999 incorporates, at least to some extent, some but not all of the TRIPS flexibilities. As discussed previously, TRIPS flexibilities include (i) parallel importation; (ii) compulsory licences; (iii) defining high standards of patentability and disclosure; (iv) establishing pre- and post-grant opposition; (v) adopting all permitted exclusions from patentability, including articles 27(2) and (3) exemptions from patentability; (vi) the adoption of a wide variety of limited exceptions, including research, education, prior use, early working/Bolar, etc and paragraph 6 system; (vii) data protection rather than exclusivity; and (viii) extended transition periods. The extent to which these flexibilities have been effectively incorporated in the Revised Bangui Agreement of 1999 is discussed below.

However, before getting to the flexibilities as spelt out in the Revised Bangui Agreement, it is necessary to mention the patent term as provided for in the Agreement. Article 9 of the Revised Bangui Agreement deals with the duration of patent term protection. It states that the term of a patent shall expire at the end of the 20th calendar year following the filing date of the application. This is, however, subject to the patentee paying his annual fees on the anniversary date of the filing of its/his/her patent application.[104] For the continued validity of patents granted or recognised under the Bangui Agreement of 1977, article 68 of the Revised Bangui Agreement provides that the above-mentioned patents shall remain in force for a period of 20 years from its filing date.

4.5 Critical analysis of the limited incorporation of TRIPS public health flexibilities and post-Doha developments in the Revised Bangui Agreement of 1999

104 Art 40 of Annex 1 of the Revised Bangui Agreement, 1999.

A careful examination of the OAPI regime shows that, although it contains certain provisions to limit some of the patent exclusivity of a patent owner, it departs significantly from the provisions of the earlier Bangui Agreement of 1977. More significantly, an examination of the Revised Bangui Agreement shows that it does not fully incorporate the public health flexibilities provided for by the TRIPS Agreement and post-TRIPS developments.

4.5.1 Transitional provisions on the application of the TRIPS Agreement

The Revised Bangui Agreement fails to incorporate the transition rules for LDCs. Paragraph 7 of the Doha Declaration and resulting extension agreement allows LDCs to not issue patents for pharmaceutical products until 2016.[105] However, this is not the case with OAPI. All the countries that are members are required to give 20 years for patent protection, including for pharmaceuticals.[106] Of the 17 OAPI member states, only four are developing countries. The remaining 13 are LDCs. Thus, LDCs that are members of the OAPI regime do not enjoy the policy space provided for by the extended LDC transition period.

It could be argued that the Revised Bangui Agreement was negotiated before the Doha Declaration that extended patents for pharmaceutical products to 2016 for LDCs.[107] However, this argument is not very tenable, when discussed in conjunction with other events. After the Revised Bangui Agreement was concluded in 1999 and before it entry into force in 2002, the Africa Group, motivated by the case in South Africa pitting pharmaceutical companies against the South African government, was active in calling for the revision of TRIPS.[108] In fact, it was the Africa Group that put forth the idea of a TRIPS and public health declaration at the WTO Ministerial Meeting in Doha.[109] It is most unlikely that OAPI member states were not aware of the process, given the fact that they are all members of the WTO and members of the Africa

105 Extension of the transition period under art 66.1 for least-developed country members Decision of the Council for TRIPS of 29 November 2005.
106 Art 19 of Annex 1.
107 Phone conversation with Dr Tshimanga Kongolo of the World Intellectual Property Organisation (WIPO), 10 March 2012.
108 See the discussion and analysis of *PMA v The President of South Africa* in ch 3.
109 As above.

Group of countries within the WTO. Moreover, during the original TRIPS Article 66(1) extension until 2006, OAPI members must have been aware that LDCs were free to withdraw all existing IP legislation.

Even before the Doha Declaration, the problem with making use of any flexibility by OAPI member states could be traced back as far as the entry into force of the 1977 Bangui Agreement. This Agreement dealt with patents in general and made no distinction between ordinary patents and patents for pharmaceutical products, even though there had been a distinction in the original Libreville Agreement. One may be tempted to think that this explains why the developing and least-developed countries of OAPI may not make use of the extension given by articles 65[110] and 66[111] of the TRIPS Agreement for countries that had not included patents for pharmaceutical products under their national law. However, this view might not be tenable. This is because, at any point in time prior to the end of the original transition period, these LDCs could have lawfully amended their laws to reject all of TRIPS. Although the 2005 extension in paragraph 5 tied their hands with respect to retracting existing IP protections from 2006 through to 2013, the 2016 pharmaceutical extension is an exception to this bar. This is because the 2016 extension allows LDCs to roll back existing levels of protection.

However, if the transitional periods provided for by the TRIPS Agreement were not utilised because of the 1977 Bangui Agreement, there was no excuse why the transition periods, especially the ones applicable to OAPI LDC member states, were not reflected in the Revised Bangui Agreement of 1999. By the time the Revised Bangui Agreement was signed in 1999, OAPI member states,

110 Art 65.4 provides: 'To the extent that a developing country member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that member, as defined in paragraph 2, it may delay the application of the provisions on product patents … to such areas of technology for an additional period of five years.'

111 Art 66.1 states: 'In view of the special needs and requirements of least-developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this Agreement … for a period of 10 years from the date of application as defined under paragraph 1 of article 65. The Council for TRIPS shall, upon duly motivated requests by least-developed country members, accord extensions of this period.'

which were LDCs, still had six years to deny patent protection to pharmaceutical companies.

One of the reasons advanced why the transition period was not adopted by OAPI member states that were LDCs was because of the principle of 'common procedure' upon which OAPI was founded.[112] The aim of this principle was to strengthen regional co-operation and harmonisation initiatives to make the region globally competitive.[113] In the context of OAPI, the 'common procedure' upon which it was founded became some 'sort of a Trojan horse, by means of which measures highly prejudicial [to OAPI member states that were LDCs] were introduced'.[114] It would have been easy to adopt a provision that granted patents in general, but excluded patents on pharmaceutical products in LDCs, as long as an applicable WTO TRIPS transition provision was in force.

4.5.2 Extension of patent terms on new and existing patents from 10 to 20 years and its implications

Closely linked to the above, article 9 of the Revised Bangui Agreement extended the term of patent protection from 10 years, as was provided for in the 1977 Agreement, to 20 years in compliance with article 33 of the TRIPS Agreement. However, at the time the Agreement entered into force, not only were new inventions granted a 20-year patent term, but all unexpired patents were extended to a 20-year term pursuant to article 68. This meant that all patents previously granted that had not expired as of the effective date were extended for what was in effect an extra 10 years. Thus, generic companies that had anticipated entering the market at the expiry of the protection granted to a certain patent were forced to reconsider their position. Patent owners therefore had a windfall in terms of having ten extra years of protection, as they were allowed to continue with their monopoly and high prices as their patent terms were extended to take full advantage of the new regime. The TRIPS Agreement did not require retroactive extension of patents that had been

112 Orsi et al (n 44 above).
113 As above.
114 As above.

granted under the previous regime, making this retroactive patent term extension TRIPS-plus.

4.5.3 Compulsory licences

Article 46 of Annex 1 of the Revised Bangui Agreement allows the granting of a compulsory licence on three of the old grounds, but drops the local working grounds. The TRIPS Agreement clearly provides for non-working licences as it incorporates by reference the Paris Convention, which has a provision on non-working patents. However, articles 8(1) and 8(2) have been cited as justifying the granting of a compulsory licence on the grounds of failing to work the patent locally as well.[115] This is because article 8(1) allows countries to adopt measures to promote and protect their socio-economic and technological development. In addition, member states may also invoke article 8(2) to grant a compulsory licence when the patent is protected, but worked in a way which fails to result in the international transfer of technology.[116] By discontinuing compulsory licences on the grounds of failure to work locally, the Revised Bangui Agreement has seriously undermined industrial policies in the region.

As before, under Article 46 of Annex 1 of the Revised Bangui Agreement, a compulsory licence may be granted to any person, but only if that person makes his or her request after the expiry of four years from the filing date of the patent application or three years from the date of grant of the patent.[117] Moreover, such a person must fulfil one or more of the following conditions: First, the person must show that the patent is not being worked on the territory of a member state at the time the request is made; second, that the working of

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115 Third World Network Manual on good practices in public health-sensitive policy measures and patent laws (2002) 78. Art 8 titled Principles states: '1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices with unreasonably restraint trade or adversely affect the international transfer of technology.'

116 C Correa *Intellectual property rights, the WTO and developing countries* (2000) 7-8.

117 Art 46 Revised Bangui Agreement, 1999.

the patent invention on such territory does not meet the demand for the protected product on reasonable terms; or, third, on account of the refusal of the patent holder to grant licences on reasonable commercial and industrial terms and procedures, the person must show that the establishment or development of commercial activities on such territory is unfairly and substantially prejudiced. Notwithstanding the above, a compulsory licence may not be granted if the owner of the patent provides legitimate reasons for the non-working of the invention.[118] However, importation is no longer an illegitimate reason. Rather than expanding the grounds for compulsory licences as allowed by the TRIPS Agreement and as clarified by the Doha Declaration to whenever public health or other public interest needs arise, or where anti-competitive practices are found, the Revised Bangui Agreement of 1999 in fact reduced the grounds for compulsory licences.

Placing limitations on the time period for negotiations with the patent owner is also permissible but has not been adopted. Countries can set a maximum period of negotiations with the patent owner before a compulsory licence is issued and can also waive prior negotiations with the patent owner in cases of emergency, public-non-commercial use or competition violations.[119] However, the Revised Bangui Agreement does not waive prior negotiations with the patentee.

In addition, the Revised Bangui Agreement unreasonably restricts the time period during which a compulsory licence cannot be considered. Article 46(1) provides:

> At the request of any person made after the expiry of a period of four years from the filing date of the patent application or three years from the date of grant of the patent, whichever period expires last, a non-voluntary licence may be granted.

118 Art 46(2) Revised Bangui Agreement.

119 East African Community *Regional intellectual property policy on the utilisation of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation* (2013) 19.

It is submitted that the above provision is unduly onerous. The time limitation in article 5A of the Paris Treaty only applies to licences for failure to work or insufficient working, not licences granted on other grounds. However, article 46 of the Revised Bangui Agreement applies this long waiting period to all grounds. In addition, even though the TRIPS Agreement allows compulsory licences to be satisfied by importation, the Revised Bangui Agreement continues to require local production.

Another permissible provision governing the issuance of compulsory licences is creating an easy-to-use administrative and appeal process. In such a scenario, the authority to grant a compulsory licence could be conferred to an administrative unit or institution. This would require creating such units and train the staff on compulsory licences and issues related to patents. However, this is not the position in the OAPI region. Under the Revised Bangui Agreement, a compulsory licence is instead granted by a civil court where the patentee has designated his or her agent and upon the request of third parties that provide evidence on their capacity to use the patent and the existence of the grounds for compulsory licences.[120] This could take a long time and be unduly expensive, compared to a situation where an administrative unit was created and provided with trained staff to assist with the administrative process inherent in the granting of a compulsory licence.

Determining the remuneration guidelines as to what should be paid to the patentee is another compulsory licence flexibility. Under the TRIPS Agreement, the granting of the compulsory licence is subject to the payment of adequate remuneration to the patent holder. However, TRIPS does not set any threshold with regard to adequate remuneration. UNDP has recommended a figure of 4 per cent.[121] The Revised Bangui Agreement has given the courts the power to determine the remuneration. Under the Revised Bangui Agreement, the court shall determine the amount of the remuneration to be paid by the licencee to the owner of the patent, in the case of disagreement between the

120 Art 48 of Annex 1 of the Revised Bangui Agreement.
121 WHO *Remuneration guidelines for non-voluntary use of patent on medical technologies* (2005).

parties. The remuneration shall be equitable, due regard being had to all the circumstances of the case.[122] Given the courts' authority to determine the remuneration of patent holders without any guidance could be problematic. First, courts in the OAPI region are not specialised in patent matters. There are generalist courts. They may base their thinking on the general award of damages and could order a large amount to be paid as remuneration to the patent owner.

The WTO's August 2003 Decision on paragraph 6 of the Doha Declaration created permissible grounds for countries with manufacturing capacity to export pharmaceuticals to countries lacking such capacity. This has been encapsulated in TRIPS as the proposed article 31*bis*. Article 31*bis* provides:

> The obligations of an exporting member under article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

However, a number of notifications have to be made to the WTO before such exportation, as provided for by Annex 2 to article 31*bis*. According to paragraph 2 of the Annex, the terms for granting a compulsory licence for exports are the following:

(i) The eligible importing member should notify the TRIPS Council of the names and expected quantities of the product needed.

(ii) A non-least-developed country member should confirm that it has insufficient or no manufacturing capacity for the pharmaceutical product in question in one of the ways set out in the Appendix to the Annex, and that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence.

122 Art 49(4)(b) of Annex 1 of the Revised Bangui Agreement.

Furthermore, the compulsory licence issued by the exporting member should state -

(i) that only the amount necessary to meet the needs of the eligible importing member may be manufactured, and the entire production must be exported to the latter;
(ii) that the manufactured products must be clearly identified as being produced under the system through special labelling or marking, special packaging and/or special colouring/shaping of the products (provided that such distinction is feasible and does not have a significant impact on price); and
(iii) that before shipping the products, the licensee should post on a website the quantities being supplied to each destination

In addition, the exporting member must notify the TRIPS Council of the grant of the licence, including the conditions attached to it. The notification provided must include

(i) the name and address of the licencee;
(ii) the product(s) for which the licence has been granted;
(iii) the quantity(ies) for which it has been granted;
(iv) the country(ies) to which the product(s) is (are) to be supplied; and
(v) the duration of the licence.

Under article 31*bis*3, however, exports or re-exports of pharmaceutical products within trade agreements mostly made up of LDCs are not subject to the notifications and requirements listed above. Article 31*bis* provides:

> With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO member is a party to a regional trade agreement within the meaning of article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that member under article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that

> share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

Irrespective of the above, OAPI member countries are still free to use the 30 August licences, but only if the Revised Bangui Agreement is amended to allow such licences and only if appropriate procedures are specified both in the Agreement and in any relevant national legislation of OAPI members. In fact, with only four of the OAPI countries being developing countries with the other 13 being least developed, they have not taken advantage of the exemption of complying with the conditions and notification requirements discussed above. A majority of OAPI member states are least-developed countries.

Irrespective of the permissible grounds for the issuance of compulsory licences discussed above, none of the OAPI member states has thus far issued a compulsory licence. In 2005, Cameroon declared its intention of issuing compulsory licences. However, that was as far as it went.[123]

(a) Government-use and compulsory licences

In addition to allowing compulsory licences that can serve both private and public sector use, article 31 of the TRIPS Agreement provides for public, non-commercial use of patents (government use) as another flexibility. One of the most important features of public non-commercial use is that it does not require prior negotiation of a voluntary licence on commercially-reasonable terms. Instead, it requires notice when the government knows of the blocking patent and it also requires adequate remuneration. It should be pointed out that TRIPS does not provide a definition of 'public, commercial' or 'government' use. The key issue for government use appears in the nature and purpose for which the patent is used – that it be for governmental, non-commercial purposes rather than for pure profit making. This means that government use could also include use by and for the government and, thus, government-use licences could be

123 Deere (n 46 above) 284.

granted to commercial, for-profit entities that are producing products for public, non-commercial purposes by government.[124]

Under the 1977 Agreement, *ex officio* licences were only given to governments for them to exploit and use a patented invention that was of vital importance to national defence, public health or the national economy. Using the *ex officio* licence mechanism, the appropriate ministry of a member state could contact the patent owner for the use of its invention so as to meet public health or other needs. If this was not possible within 12 months after the request or if the existing use/exploitation of the patent product prejudiced public health, the government had the right to use the patented invention. In addition, the government could use *ex officio* licences to import patented products.

The Revised Bangui Agreement in article 56 also provides for *ex officio* licences, which shall be subject to the same conditions as compulsory licences granted under article 46 of the Revised Bangui Agreement. It is granted in situations where patents are of vital importance to the economy of the country, to the public health and national defence of the country, or where non-working or insufficient use of such patents seriously compromises the satisfaction of the country's needs. Where any of these situations exists, *ex officio* licences may be granted by an administrative enactment by the competent minister of the member state concerned. This enactment shall specify the beneficiary administration, the conditions, the terms and the scope of the *ex officio* licence. Should there be any disagreement between the owner of the patent and the administration concerned on the said conditions, then the competent local court shall have jurisdiction to entertain the dispute.[125]

In addition, under the Revised 1999 Agreement, *ex officio* licences could only be invoked when the patent in question is of vital relevance to the economy, public health or national defence, and even then the licence is subject

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124 M Sisule & C Oh 'The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' Paper commissioned by the Commission on Intellectual Rights, Innovation and Public Health (CIPIH) (2005) 20.

125 Art 56(2) Revised Bangui Agreement.

to the same conditions as the non-voluntary licence, including waiting periods and grounds for the licence.[126] Thus, unlike under the 1977 Agreement, where the government could issue an *ex officio* licence to protect public health, the economy and national defence, now before issuing an *ex officio* licence it will first have to satisfy additional conditions proving that the patent is not being worked at all, that the working of the patent does not meet the demand for the protected product on reasonable terms, or that the establishment or development of an industrial or commercial activity is being unfairly or substantially limited. In fact, these additional conditions are highly undesirable, and constitute a TRIPS-plus limitation on the use of *ex officio* licences.

Article 46 of Annex 1 of the Revised Bangui Agreement provides for non-voluntary licences for non-working patents. Article 46(1)(c) provides:

> At the request of any person made after the expiry of a period of four years from the filing date of the patent application or three years from the date of grant of the patent, whichever period expires last, a non-voluntary licence may be granted where one or more of the following conditions are fulfilled:
> …
> On account of the refusal of the owner of the patent to grant licences on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced.

Where the above situation exists, the applicant will have to make a request for a non-voluntary licence to a civil court of the domicile of the patentee or, if the patentee is domiciled abroad, to the civil court of either his elected domicile or the place in which the patentee has named an agent for purposes of filing. The request shall contain a list of requirements and shall be accompanied by proof that the requester has previously approached the patentee by registered letter, requesting a contractual licence, but has been unable to obtain such a licence from him subject to reasonable commercial terms and procedures and within a reasonable time. Once the application is filed, the civil court shall make a decision either granting or refusing the non-voluntary licence. If the application

126 Art 56(3) Revised Bangui Agreement.

is granted, the court shall specify the scope of the licence and the amount of remuneration to be paid by the licensee.

Anyone applying for a patent in a particular jurisdiction should be willing to work out the patent immediately after filing in that jurisdiction, although this may be constrained for medicines that have to go through a separate clinical trial and drug regulatory approval process. This requirement of having the patentee work the patent would stop frivolous applications and filings and would ensure that patent owners do not indirectly block the use of generics in places where they are not interested in carrying out operations, but where the need for generics could be crucial. Historically and before the coming into force of TRIPS, some developed countries did not put a time frame after which a compulsory licence may be issued for non-working patents.[127] Although they were enacted prior to the entry into force of TRIPS, OAPI should have used these examples for guidance when the Bangui Agreement was revised.

From the above, any person may make an application against the IP holder in instances of non-working of patents. In enacting the above clauses, OAPI was in the process of discouraging non-working patents. This, on the face of it, is a welcome development in the context of access to medicines and public health. However, deep down the line, it is evident that the articles have many shortcomings. Firstly, it qualifies the damages resulting from non-working patents to be substantial. This could be a rather strong requirement as, if the

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127 See Patents Act 1977, ch 37 (as amended by Copyright, Designs and Patents Act 1988) of the United Kingdom. Sec 48(3) provides: 'The grounds (for the grant of a compulsory licence) are (a) where the patented invention is capable of being commercially worked in the United Kingdom, that is not being so worked to the fullest extent that is reasonably practicable; (b) where the patented invention is a product, that a demand for the product of the United Kingdom (i) is not being met on reasonable terms, or (ii) is being met to a substantial extent by importation; (c) where the patented invention is capable of being commercially worked in the United Kingdom, but it is being prevented or hindered from being so worked – (i) where the invention is a product, by the importation of the product; (ii) the invention is a process, by the importation of the product obtained directly by means of the process or to which the process is being applied.'
See also sec 36(2) of the Patent Law (Federal Law of 1970, as last amended by the Law of 23 May 1984 amending the Patent Law and the Law Introducing Patent Treaties) of Australia. Sec 36(2) provides: 'Where a patented invention is not worked sufficiently in Australia and where the patentee has not taken all steps required for such working, any person may apply for a licence to work the patent for the purposes of his business, unless the patentee shows that the invention could not reasonably have been worked, or could not reasonably have been worked to a great extent, in Australia owing to difficulties of exploitation.'

consequences are not substantial, then the non-working practice may continue. Secondly, the request has a long list of requirements to be fulfilled, failing which the application cannot be brought.

It should be pointed out that, under the Revised Bangui Agreement of 1999, the conditions for the issuance of *ex officio* licences are the same as for non-voluntary licences.[128] The conditions for the granting of a compulsory licence is encapsulated in article 48 of the Revised Bangui Agreement. The article provides:

> (1) The request for the grant of a non-voluntary licence shall be made to the civil court of the domicile of the patentee or, if the latter is domiciled abroad, to the civil court of either his elected domicile or the place in which he has named an agent for the purposes of filing. Only requests made by persons domiciled on the territory of a member state shall be considered. The owner of the patent or his agent shall be informed thereof without delay.
>
> (2) The request shall contain -
>
> (a) the name and address of the requester;
>
> (b) the title of the patented invention and the number of the patent in respect of which a non-voluntary licence is requested;
>
> (c) evidence that the working of the patented invention on the above mentioned territory does not meet demand for the protected product on reasonable terms;
>
> (d) in the case of a non-voluntary licence requested under article 45 above, a statement by the requester in which he undertakes to work the patented invention on the territory of one of the member states in such a way as to meet the needs of the market.
>
> (3) The request shall be accompanied -
>
> (a) by proof that the requester has previously approached the owner of the patent, by registered letter, requesting a contractual licence, but has been unable to obtain such a licence from him subject to reasonable commercial terms and procedures and within a reasonable time;
>
> (b) in the case of a non-voluntary licence requested under article 46 or 47, by proof that the requester is capable of working the patented invention.

128 Art 56(3) Revised Bangui Agreement.

From the provisions of article 48 above, a number of observations may be made. First, the applicant for a compulsory licence must be domiciled in a member state. The concept of domicile has different meanings in different contexts. For purposes of jurisdiction, domicile means 'a legal residence which is the place where a person has a fixed dwelling with an intention of making it his/her permanent home'.[129] From this definition of the concept of domicile, the implication of the requirement of domicile is that the person must have had the intention to reside in one of the OAPI countries on a permanent basis, failing which the person's application for a compulsory licence will not be received.

Second, article 48 requires that the applicant for a compulsory licence undertakes to work the patented invention in the territory of one of the OAPI member states. This means that the compulsory licence cannot be extended to the act of importation. This provision is neither justifiable nor sustainable. It is not justifiable because, at the moment, OAPI member states do not have the manufacturing capacity to produce most drugs. If there was to be an epidemic, it would be difficult to see how an OAPI member state, even though armed with an *ex officio* licence, would produce the required medicines. The provision is also not sustainable, even assuming that OAPI member states have the capacity to produce locally in the event that they issue an *ex officio* licence, because the price of the drug they eventually produce might be more expensive[130] compared to generics from, for example, Brazil or India. It was this problem of local manufacturing capacity which paved the way for the Doha Declaration, the 30 August 2003 Decision and the subsequent inclusion of article 31*bis* of the TRIPS Agreement.

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129 *Snyder v McLeod* 971 So 2d 166 (Fla Dist Ct App 5th Dist. 2007.

130 It might be more expensive because of a constellation of factors, including human resource constrains, inadequate infrastructure, high operating cost, weak links between local and international supplies, high cost of local commercial capital, poor price control, industry fragmentation and low production quality standards. See 'Local production and access to medicines in low and middle-income countries: A literature review and critical analysis' (2011) http://apps.who.int/medicinedocs/documents/s19061en/s19061en.pdf 14-15 (accessed 10 August 2013).

A number of recommendations have been advanced for developing and least-developed countries to make proper and better use of government-use provisions.[131] Any government-use system should be simple and straightforward, not overly legalistic; second, government-use provisions should be strong by giving government broad powers to issue government-use licences; and, lastly, the system of compensation should be straightforward and easy to administer.

(b) Parallel importation

Regional parallel importation is expressly addressed in the Revised Bangui Agreement, unlike the 1977 Bangui Agreement, where exhaustion was not mentioned. One can deduce the concept of regional parallel importation from article 8, which deals with the limitation of rights conferred to the patent. Sub-paragraph (1)(a) provides that the rights deriving from a patent shall not extend to acts in relation to subject matter brought onto the market on the territory of a member state by the owner of the patent or with his consent. This spells out the regional exhaustion of rights, as parallel importation only from any member state of OAPI is authorised, albeit with the consent of the patent holder.[132] However, OAPI has not adopted the maximum flexibility it is permitted under article 6 of TRIPS, as it failed to adopt international adoption, and it further limits even regional parallel importation to cases of consensual market entry rather than any lawful entry (as in Kenya).

As discussed above, the Revised Bangui Agreement provides for regional exhaustion. The effect of this provision on regional exhaustion is that it renders OAPI member states unable to source medicines internationally once the patent owner puts them on the market outside the OAPI region. While article 6 of TRIPS makes it possible for WTO member countries to adopt an international exhaustion regime, the Bangui Agreement limits its members' ability to benefit from an international exhaustion regime, an important TRIPS

131 Sisule & Oh (n 124 above) 25.
132 Art 8(a) Revised Bangui Agreement.

flexibility. The full extent of the negative implication of OAPI's regional exhaustion regime on access to medicines was highlighted by Catherine Gavin in a conference on the implementation of TRIPS in Geneva. At the conference, Gavin provided evidence showing that in 2002, the lowest cost of the anti-retrovirals AZT and 3TC in the OAPI region was US $1.96 and US $0.94 in Togo and Senegal respectively, whereas it was only US $0.65 in India.[133] She concluded that, had OAPI member states adopted an international exhaustion regime, Togolese nationals would have had the option of buying the medicines in India, rather than in Senegal (that afforded the lowest price in the OAPI region), which was 45 per cent higher than the price in India.[134] However, since that was not the case because OAPI had a regional exhaustion regime, they had to source the medicines from Senegal, which was not the most competitive price on the international market.

OAPI's regional exhaustion regime is a major stumbling block in any meaningful access to medicines initiative. This is because most of the citizens of OAPI member states do not have the luxury of spending their meagre income on medicines, which are expensive because of the regional exhaustion regime. It should be noted that it was not clear whether the medicines mentioned by Gavin were all original products.

4.5.4 Adoption of TRIPS articles 27(2) and 27(3) exceptions from patentability

As discussed above, article 27(2) of TRIPS provides for exemptions from patentability. The relevant part of the article provides that

> [m]embers may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious

133 S Moon 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical assistance – how to get it right' Conference Report, 28 March 2002, International Conference Centre of Geneva 3.
134 As above.

> prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Article 6 of Annex 1 of the Revised Bangui Accord captures part of the provisions of article 27(2) of TRIPS. Article 6(a) provides that patents shall not be granted for 'inventions the exploitation of which is contrary to public policy or morality, provided that the exploitation of the invention shall not be considered contrary to public policy or morality merely because it is prohibited by law or regulation'.

Articles 6(c) and (e) of Annex 1 of the Revised Bangui Accord contain additional exclusions from patentability, as couched in article 27(3) of the TRIPS Agreement. It should be recalled that the exclusions provided in article 27(3) include the following: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Under article 6(c) of Annex 1 of the Revised Bangui Agreement, patents shall not be granted on 'inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes'. On its part, article 6(e) captures subsection (a) of article 27(3) by providing that patents shall not be granted for 'methods for the treatment of the human or animal body by surgery or therapy including diagnostic methods'.

However, although not expressly provided for by TRIPS, there is also other excludable subject matter, exercised differently by different countries, including, for example, discoveries, computer programmes, business methods, abstract ideas and theories, isolated genes and other products isolated from nature, and plant and animal varieties. These exclusions have been used in many countries.[135] The purpose of these exclusions, for example, abstract

135 Eg, US and India.

ideas, among other things, is to prevent patenting 'basic tools of scientific and technological work' because patenting such discoveries 'might tend to impede innovation more than it would tend to promote it'.[136] It should also be pointed out that the Indian Patent Act (as amended)[137] contains a long list of some of the exclusions to patentability mentioned above. Under section 3 of the Indian Patent Act,[138] the following are excluded from patentability: 'the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature';[139] plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals';[140] 'a mathematical or business method or a computer programme *per se* or algorithms'.[141]

In line with other countries, article 6 of Annex 1 of the Revised Bangui Agreement provides for the 'non-patentability' of discoveries, scientific theories and mathematical methods;[142] schemes, rules or methods of doing business;[143] computer programmes;[144] mere presentations of information;[145] works of an exclusive ornamental nature;[146] and literary, architectural and artistic works or any other aesthetic creation.[147] In addition, it can be argued that abstract theories could be brought under the exclusion of scientific theories, if it relates to scientific issues or under the exclusion of literary, architectural and artistic works if the abstract idea relates to arts. Accordingly, the Revised Bangui Agreement does appear to have used many of the TRIPS-compliant exclusions from patentability.

4.5.5 Limitation of rights conferred on the patentee

136 *CLS Bank Int'l v Alice Corp (Pty) Ltd* 768 F Supp 2d 221, 242-255 (DDC 2011).
137 Indian Patents Act, 1970 (as amended in 2005).
138 As above.
139 Sec 3(C) Indian Patents Act, 1970 (as amended in 2005).
140 Sec 3(J) Indian Patents Act.
141 Sec 3(K) Indian Patents Act.
142 Art 6(b) Revised Bangui Agreement.
143 Art 6(d) Revised Bangui Agreement.
144 Art 6(g) Revised Bangui Agreement.
145 Art 6(f) Revised Bangui Agreement.
146 Art 6(h) Revised Bangui Agreement.
147 Art 6(i) Revised Bangui Agreement.

Limitations to the patentee's rights are provided for in article 8 of Annex 1 of the Revised Bangui Agreement. Unlike article 30 of the TRIPS Agreement, which provides for limited exceptions without listing them, article 8(1) of Annex 1 of the Revised Bangui Agreement lists what exceptions are to be recognised. It provides that the patentee's rights shall not extend to

(a) acts in relation to subject matter brought onto to the market on the territory of a member state by the owner of the patent or with his consent;
(b) the use of objects on board foreign aircraft, land vehicles or ships that temporarily or accidentally enter the airspace, territory or waters of a member state;
(c) acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific or technical research;
(d) acts performed by any person who in good faith on the filing date, or where priority is claimed, on the priority date of the application on the basis of which the patent is granted on the territory of a member state, was using the invention or making effective and genuine preparations for such use, in so far as those acts are not different in nature or purpose from the actual or planned earlier use.

In the context of this research, the most relevant provision is subsection (c), which provides for research and experimentation exceptions. In the context of access to medicines and public health, article 8 leaves little room for manoeuver as it lists specific exceptions, unlike article 30 of TRIPS which lists conditions under which an exception falling under it can be construed. At first sight, it would seem that the language of article 30 leaves greater room to manoeuvre as it does not list specific exceptions, rather the conditions under which any exception falling under it should be construed. However, it appears to be better to lose some common exceptions, while leaving the door open to others. Thus, unlike article 30 of TRIPS, through which the following exceptions can be used (and have in fact been used), research and experimentation on an invention; educational use; acts done privately for non-commercial purposes; preparation of medicines under individual prescription; and Bolar or early working exceptions, only the research and experimentation exceptions can be used under article 8(c) of Annex 1 of the Bangui Agreement.

It is submitted that the research and experimentation exceptions can be used under article 8 of the Bangui Agreement when broadly interpreted. Although not specifically spelt out in article 8, Bolar can be argued to be early working carried out for experimental purposes. Like the US, OAPI or its member state courts could read the Bolar exception into article 8 and interpret it to include obtaining approval domestically or from a foreign government before importation, carrying out consumer studies, and explaining clinical trials and technics to the public. This notwithstanding, it is submitted that it is better to expressly adopt early working exceptions rather than to rely on research exceptions and to try and interpret it as covering the early working exception. This could be relevant in instances where commercial-related use is not directly allowed.

Research exceptions are clearly spelt out in article 8 of Annex 1 of the Revised Bangui Agreement. Thus, there will be no problem in its application and use. As stated above, the important question which has arisen regarding the research exceptions is whether the research is for commercial or non-commercial use. Under the Revised Bangui Agreement, research can be interpreted broadly and a distinction is not made as to commercial/non-commercial use, as article 8(1)(c) makes it clear that the rights deriving from the patent shall not extend to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research. However, the problem that could arise is the possibility that scientific and technical research is not considered to cover commercial research. Therefore, the best option would be for OAPI to expressly adopt an early working provision. OAPI members could seek guidance from the Indian Patent Act, which provides:

> [A]ny act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that

> regulates the manufacture, construction, use, sale or import of any product … shall not be considered as an infringement of patent rights.[148]

In sum, under the Revised Bangui Agreement, the exceptions to patents (limitations of the rights conferred to the patentee) enacted are parallel importation on foreign vessels, research and prior use. Widely-recognised exceptions which have been omitted include education, private non-commercial use and individual preparation and inclusion of language, similar to article 30 of TRIPS, which allows the recognition of other non-conventional limited exceptions. These additions will be discussed in chapter 5 as recommendable exceptions to be adopted by under the Bangui Agreement.

4.5.6 Competition-based flexibilities

The Revised Bangui Agreement does not provide for competition-based flexibilities. This is strange, considering its importance in facilitating access to medicines, as well as the fact that it is provided for in the TRIPS Agreement. It is recommended that OAPI adopts the TRIPS provision by having an addendum that incorporates by reference the competition-based flexibilities as provided for in articles 8(1), 31(k) and 40 of the TRIPS Agreement. However, providing for competition-based flexibilities is not enough. There should be resources dedicated to implementing competition-based flexibilities. This is because, despite having legislation containing competition-based flexibilities, most developing and least-developed countries have failed when it comes to implementation.[149] Many reasons have been advanced for the non-implementation of competition laws and policies in many developing and least-developed countries. These reasons, among others, include financial and budgetary resource constraints, weaknesses in drafting the law, political and economic constraints and the lack of a culture of competition.[150]

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148 Sec 107A(a) Indian Patent Act (as amended).

149 UNDP paper on using competition law and policy to promote access to medicines: http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf (accessed 7 July 2014).

150 As above.

4.5.7 Additional flexibilities: Standard of patentability

Adopting a stringent standard of patentability is an additional TRIPS public health flexibility. Article 2 of Annex 1 of the Bangui Agreement lays down the minimum standards of patentability. It defines a patentable invention as one that is 'new, involves an inventive step and is industrially applicable'. This tracks the TRIPS language of article 27(1).

The Revised Bangui Agreement defines novelty, inventive step and industrial application. With regard to novelty, an invention shall be new if it has not been anticipated by prior art. Article 3(2) provides that prior art shall consist of everything made available to the public in any place and by any means or method, before the filing date either of the patent application or of a patent application filed abroad the priority of which has been validly claimed.

Article 4 of Annex 1 of the Bangui Agreement defines inventive step. It provides that

> an invention shall be regarded as resulting from an inventive step if, having regard to the prior art, it would not have been obvious to a person having ordinary knowledge and skill in the art on the filing date of the patent application or, if priority has been claimed, on the priority date validly claimed from it.

The provision highlights the requirements of non-obviousness based on prior art. Article 4, although it is a welcome development compared to some other jurisdictions and international instruments that only list the standards of patentability but fail to define them, does not go far enough as the standard that assesses inventiveness is not strict enough. This is because it limits inventiveness to 'persons having ordinary knowledge and skill in the art' rather than to 'persons highly skilled in the art'. This is because the more expertise is considered when evaluating the non-obviousness of an invention, the higher

the possibility of that invention to be deemed obvious.[151] The definition also does not address the standard to use with respect to 'indirect' teaching and combining prior teaching.

Article 5 of Annex 1 of the Bangui Agreement provides for industrial application. It provides that

> '[a]n invention shall be considered industrially applicable if it can be made or used in any kind of industry. The term "industry" shall be understood in its broadest sense; in particular it shall cover handicraft, agriculture, fishery and services.'

As it stands, the industrial application could be broadly interpreted to include, for instance, experimental research without providing for its specific uses. This may create monopoly rights and may exclude innovation, as prospective researchers would not be able to use the existing patented experimental research in their research activities.[152]

Disclosure requirements are provided for by article 14 of Annex 1 of the Bangui Agreement. Article 14(1)(d)(iii) of Annex I of the Agreement requires for the claim defining the scope of the protection sought not to go beyond the contents of the specification of the invention for which the application has been made. The disclosure requirement under article 14 is welcome, especially given its importance to manufacturers of generic medicines, as the patentee is required to provide sufficient, complete, thorough and precise information about the patent. However, it is limited in scope compared to the disclosure requirements under TRIPS. As discussed above, under article 29 of TRIPS, TRIPS members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. In addition, TRIPS members may require the applicant to indicate the best mode for carrying out the invention

151 East African Community Regional Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013) East African Community, Arusha, Tanzania.

152 UNDP Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law, 2013, 36.

known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. Also, members have the right to require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Disclosure under the Bangui Agreement is only limited to the requirement for the patent application to define the scope of the protection sought, which shall not to go beyond the specification of the invention for which the application was made. As discussed in the recommendations below, OAPI should adopt stringent disclosure standards which are important to provide the basis for copying and continuing innovation. Such disclosure standards should include the obligation that the patent applicant indicates the best mode for carrying out the invention known to the patentee, as well as the obligation for the patent applicant to provide information relating to any of his or her corresponding foreign applications.

The Revised Bangui Agreement does not expressly provide for pre-grant opposition procedures. Article 24 provides that any invention that is not patentable under article 6 shall be rejected. In addition, any patent application that does not contain a specification of the invention for which the application has been made, the drawing necessary or useful for the understanding of the invention, the claim defining the scope of the protection sought and a descriptive abstract summarising the contents of the claim, as spelt out in article 14(d), shall be rejected.[153] Furthermore, a patent application shall be considered as defective where the patent application contains restrictions, reservations and conditions and does not describe in a precise and succinct manner the purpose of the invention.[154] The applicant shall be notified of the defect, who shall be asked to correct the defects within a period of three months from the date of notification, with the three-month period being extended by 30 days in case of a justifiable need at the request of the applicant or his or her agent.[155] In the event that the defects are not remedied within three months or

153 Art 24(2) of Annex 1 of the Revised Bangui Agreement.
154 Art 24(4) of Annex 1 of the Revised Bangui Agreement.
155 As above.

within four months, in case there was an extension, the patent application shall be rejected.[156]

Article 39 provides three instances where a patent can be invalidated after it has been granted. The first instance is where the patent is granted, but it is later realised that the patent was not new, had no inventive step and was not capable of industrial application. The second instance is where the patent was not supposed to be granted because it constituted a non-patentable subject matter, as provided for in article 6.[157] The last instance is where the patent application contained restrictions, reservations and conditions and did not describe in a precise and succinct manner the purpose of the invention.

A patentee who has not paid his or her annual fees on the anniversary of the filing of his or her patent shall forfeit all his or her rights, although he or she would be granted a six-month grace period within which he or she would be allowed to pay the fees.[158]

The procedures for bringing an action for invalidity or forfeiture of the patent are spelt out in articles 43 and 44 of Annex 1 of the Bangui Agreement. Actions seeking invalidity or forfeiture of a patent may be brought by anyone having an interest therein.[159] The office of the public prosecutor may be an intervening party and may make submissions seeking a declaration of absolute invalidity or forfeiture of a patent.[160] The appropriate court to hear a matter of invalidity or forfeiture shall be a civil court. Once an action for invalidity or forfeiture is brought, the civil court shall examine and adjudicate in the manner prescribed for summary proceedings and shall proceed to pronounce the decision in favour or against invalidity or forfeiture.[161] If the court's decision is

156 Art 24(5) of Annex 1 of the Revised Bangui Agreement.
157 The non-patentable subject matter provided under art 6 includes: invention that is contrary to public policy or morality; discoveries, scientific theories and mathematical methods; inventions having essentially biological processes other than microbiological processes; surgical and therapeutical diagnostics methods, computer programmes and literary, architectural and artistic works.
158 Arts 40(1) & (2) of Annex 1 of the Revised Bangui Agreement.
159 Art 43(1) of Annex 1 of the Revised Bangui Agreement.
160 Art 43(2) of Annex 1 of the Revised Bangui Agreement.
161 Art 44 of Annex 1 of the Revised Bangui Agreement.

based on invalidity or forfeiture, it shall inform OAPI who, in turn, shall enter the forfeiture or invalidity in the special register of patents.[162]

The persistent question, however, is whether a decision of the court based on invalidity or forfeiture is binding on all other OAPI members. Article 45 of the Revised Bangui Agreement is not particularly clear on this issue. Article 45 provides:

> Where the absolute invalidity or forfeiture of a patent has been pronounced by a court decision that has become *res judicata*, the competent court shall inform the Organization thereof, and the invalidity or forfeiture pronounced on the territory of a member state shall be entered in the Special Register of Patents and published in the form specified in article 32 above for granted patents.

Article 45 does not expressly state the effect from a member state on other members of a court decision. However, one notes two important provisions with article 45. First, the article provides that OAPI shall only be informed when the decision has become *res judicata*. This implies that OAPI only receives the decision when it has become final and there are no appeals pending. Second, the article states that, once the condition above is satisfied, OAPI will in turn have it published. Article 25 of the Revised Bangui Agreement provides for recording acts by OAPI in the Special Register of Patents. Article 25 is to the effect that the OAPI Administrative Council shall draw up regulations concerning the acts to be recorded in the Special Register of Patents, on pain of their not being enforceable against third parties. Therefore, publication in the Special Register implies that the forfeiture or invalidity is recognised by OAPI and is enforceable against third parties. However, there is nothing in the provisions of article 45 that would appear to make invalidation entered in respect of one member state to be binding on other members. Nevertheless, since OAPI plays a mainly administrative as opposed to a judicial function, there is therefore a basis for it not to preclude new actions on the invalidity or forfeiture of the patent in local courts.

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162 Art 45 of Annex 1 of the Revised Bangui Agreement.

4.5.8 Enforcement mechanisms

With regard to the enforcement of patent rights, the Revised Bangui Agreement of 1999 sets out the procedural and the substantive aspects of both civil and criminal remedies. It also provides for a quasi-civil/criminal action for the seizure of offending goods.[163]

Article 7(5) provides for civil remedies to the patent owner. It provides:

> The owner of the patent has the right to institute legal proceedings before the court of the place of the infringement against any person who commits an infringement of the patent by performing without his consent one of the acts mentioned in paragraph (3), or who performs acts that make it probable than an infringement will be committed.

The acts mentioned in article 5(3) constituting an infringement when a patent has been granted for a product include manufacturing; importing; offering for sale; selling and using the product; holding the product for the purpose of offering it for sale; selling it; or using it. When the patent has been granted for a process, the acts constituting an infringement will include using the process and engaging in acts mentioned above in relation to a product resulting directly from the use of the process. The remedies provided for in article 7(5) can most commonly be used as they can be brought as a matter of right by the patent holder.

Regarding civil procedures, Article 66 of Annex I of the Bangui Agreement puts the burden of proof in the case of process patents on the defendant. It gives the courts the authority to order the defendant to prove that that process used in making an identical product is different from the patented process in one of the following situations: (i) when the product made by the process is new; and (ii) when there is a strong probability that the identical product had been made by means of the process and the owner of the patent having been unable, in spite of reasonable effort, to establish what process had actually been used.

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163 Art 64 of the Revised Bangui Agreement of 1999.

The major shortcoming of article 66 is that it is somewhat ambiguous and needs some explanation. The first sentence refers to civil actions under article 1, but article 1 does not refer to civil actions. This seems to be a remnant from the original Bangui Agreement, which in article 1 did make reference to the right to exclude others. This shows that proper work was not done during the drafting and editing of the Revised Bangui Agreement.

Title V of the Revised Bangui Agreement, entitled infringement, legal proceedings and penalties, primarily addresses criminal actions which must be prosecuted by the Office of the Public Prosecutor.

With regard to criminal procedures and remedies, article 58 provides for a fine of from 1 000 000 FCFA to 3 000 000 FCFA in case of violations of the patentee's rights. In addition, where the violator is a recidivist,[164] a term of imprisonment of from one to six months may be added to the fine mentioned above.[165] In case of a criminal case against a violator of the patentee's rights, the Agreement provides that only a public prosecutor can commence an action, based on the complaints of the patentee, in the criminal court.[166] The criminal court also has jurisdiction to rule on the arguments advanced by the accused in a criminal action, even if the arguments relate to alleged invalidity or forfeiture of the patent.[167]

It is submitted that such a criminal enforcement of a patent violation is TRIPS-plus, because article 61 of TRIPS provides criminal sanctions only for wilful trademark counterfeiting and copyright pirating on a commercial scale. OAPI's criminal enforcement provision is overly stringent and may be used to frighten generic companies or producers.

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164 The Revised Bangui Agreement defines a recidivist as someone who had been fined for violating a patentee's rights within the past five years.
165 Art 58 of the Revised Bangui Agreement, 1999.
166 Arts 61 & 62 of the Revised Bangui Agreement, 1999.
167 Art 62 of the Revised Bangui Agreement.

In case the patentee has evidence of the existence of counterfeit versions of its invention, it can obtain an order from the president of the civil court.[168] The order is granted against the payment of a caution. Once the order is granted and the goods are seized, the patentee has 10 days in which to bring a civil or criminal action against the counterfeiter, failing which the seizure is null and the patentee may be subject to the payment of damages to the alleged counterfeiter.[169]

One important observation emerges from the above. The Revised Bangui Agreement provides for both procedural and substantive law with regard to patent enforcement in its member countries. This may mean additional cost and the allocation of resources by member countries to effect enforcement. This may be burdensome and may give rise to the possibility of the patent holder bringing all sorts of claims, especially frivolous ones.

It should be noted that patent owners may, acting in pursuance of an order, engage bailiffs or public or ministerial officials, including customs officers, if necessary with the aid of an expert, to make a detailed inventory with or without seizure of the allegedly infringing goods.[170] In effecting the seizure, as mentioned above, the complainant may furnish security, which shall be sufficient, but not such as to discourage the seizure process.[171]

The complainant is required to provide security, but the law provides that the security should be such that it does not discourage enforcement procedures. This is vague. The law should have at least provided that the security should be equal to or greater than the value of the goods seized. This would discourage frivolous claims. In addition, the provision of security is discretional as the law states that the order may require the complainant to furnish security. The implication of using ‘may’, not ‘shall’, means that there

168 Arts 63 to 65 of the Revised Bangui Agreement, 1999.
169 As above.
170 Art 58 of the Revised Bangui Agreement.
171 As above.

could be instances where enforcement can be effected with no security. This may open the flood gates for frivolous claims.

Finally, article 67 requires the confiscation or destruction of infringing objects. It provides that confiscation or destruction of recognised infringing objects shall be ordered against the infringer, the receiver, the introducer or the retailer. In addition, the objects confiscated may be handed over to the owner of the patent, without prejudice to the right to further damages and publication of the judgment, where appropriate.

4.6 Reasons for the non-incorporation of certain TRIPS flexibilities within the Revised Bangui Agreement of 1999

It should be noted that the Revised Bangui Agreement came into force in 2002. It was expected that since it finally came into force after the TRIPS Agreement, it would contain TRIPS flexibilities relative to access to medicines. However, this was not the case, as was discussed above. A number of reasons have been advanced as to why the Bangui Agreement did not provide for TRIPS flexibilities. From the outset, it should be pointed out that there are very few studies[172] that have attempted to paint a complete picture as to why the Revised Bangui Agreement of 1999 did not provide for the flexibilities that are contained within TRIPS and those that came after TRIPS. After open-ended interviews with stakeholders,[173] an analysis of existing literature[174] and personal observations,[175] it was discovered that the reasons for the non-incorporation of all the TRIPS public health flexibilities by the Revised Bangui Agreement are many and varied. For convenience, they are grouped into internal and external

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172 Some of these studies include Deere (n 46 above); Jourdain (n 55 above).

173 The interviews were conducted throughout the period under which the thesis was written. The interviewees were OAPI officials, government officials, law students, law professors, law practitioners and members of civil society and NGOs. An annex of the questions asked and the number of interviewees is attached to the thesis.

174 The Bangui Agreement of 1977, the Revised Bangui Agreement of 1999, NGO reports and analyses, minutes of meetings held by the Africa group in Geneva.

175 Personal impressions deduced from (i) my more than 20 years of living in Cameroon, and OAPI member states; (ii) my years of teaching intellectual property and access to medicines; (iii) my internship at OAPI; and (iv) discussions and interactions with experts and representatives from NGOs and civil society organisations.

reasons. The internal reasons include inadequate capacity; the domineering nature of OAPI; little interest in intellectual property rights; and the absence of very strong and vocal civil society organisations. The external factors include the French influence over most Francophone African countries; the role of international organisations, especially the WIPO; the role of other foreign powers; and the fact that the Revised Bangui Agreement was negotiated before the Doha Declaration.

4.6.1 Internal factors

(a) Inadequate capacity

Inadequate capacity has always been pinpointed as one of the reasons why African countries have not taken a leading role in international trade negotiations, especially negotiations at the level of the WTO.[176] OAPI countries are not exceptions when considering the problem of inadequate capacity. During the negotiations of the Revised Bangui Agreement, there was not much capacity relating to IP in OAPI member states.[177] This weak IP capacity would have made it difficult for national IP officials to formulate, conceptualise, articulate and implement trade and intellectual property rights and policies friendly to health or, better still, that would promote access to medicines.[178] The weak IP capacity could be explained in a number of ways. There was no specialised programme on IP rights that would have trained and prepared citizens or experts from these countries to appreciate and understand IP-related issues.[179] In addition, most of the laws were those that were applicable in France and had been transplanted to these countries as a result of colonialism.[180] Even if they were localised, IP rights issues, as will be seen below, were mostly handled by experts with support from France, international

176 V Mosoti 'Africa in the first decade of WTO dispute settlement' (2006) 7 *Journal of International Economic Law* 427-453.
177 Deere (n 46 above) 262.
178 As above.
179 The first fully-fledged postgraduate programme in intellectual property rights in the region only commenced in Cameroon in 2004.
180 Deere (n 46 above) 282.

organisations and other pro-strong intellectual property rights groups.[181] Everything was left in the hands of OAPI that had the mandate to regulate intellectual property rights issues in its member states. The consequence of this was that there was little or no national interest from OAPI member states to commit money for analysis on the subject of IP. OAPI, with the support of international organisations, did almost everything, with little or no national level consultations.[182] Therefore, there was a huge vacuum in terms of interest in and enthusiasm for IP rights, making it difficult to have any kind of academic, social or intellectual movement to raise health and other human rights concerns when the Bangui Agreement was negotiated and drafted.

Besides, historically, very few African countries have been active in trade negotiations, in general, and IP and access to medicines negotiations, in particular, at the level of the WTO in Geneva. Unfortunately, OAPI member states are not among the few active African countries.[183] Even when the Africa Group was pushing for reforms of the TRIPS patent regime relating to access to medicines that culminated in the adoption of the Doha Declaration of 2001, there is no evidence that OAPI member states were particularly active.[184] Moreover, at the time the Bangui Agreement was signed, there was little or no opposition from civil society organisations and local legislators, since not many of them could fully assess the access to medicine implications of the many stringent IP provisions in the Agreement. In fact, the only meaningful press releases opposing the negotiations of the revised Bangui Agreement came from a Canadian NGO, International Rural Advancement Foundation, and a Spanish NGO, GRAIn, which raised concerns about the implications of the Revised Bangui Agreement of 1999, stating that

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181 As above.

182 As above.

183 Eg, Kenya and Zimbabwe played an important role in mobilising African countries during the periods leading to the Doha Conference in 2001.

184 See TRIPS and Public Health, submission of the Africa Group and other developing countries to the Special TRIPS Council Meeting of June 2001, 5 http://www.twnside.org.sg/title/twr131d.htm (accessed 12 June 2012). See also J Gathii 'The legal status of the Doha Declaration on TRIPS and public health under the Vienna Convention on the law of treaties' (2002) 1 *Harvard Journal of Law and Technology* 296.

> [n]ot only is it [revised Bangui Agreement] out of step with other developments in Africa, it would lock [OAPI] governments into legislation that no other developing country has adopted, and which is far more restrictive than is necessary to meet their international obligations[185]

and that the influence from foreign countries was such that 'African [OAPI] patent offices are being asked to climb a wagon other countries in other regions may never accept'.[186]

(b) Domineering nature of OAPI

From its inception in the 1960s, OAPI has literally had the upper hand with regard to anything related to IP rights in its member countries. By signing the various regional IP agreements, OAPI member states ceded most of their sovereignty on IP issues to OAPI. OAPI benefited from this policy space and singlehandedly drafted the laws and policies with support from international organisations, leaving its member countries with the unenviable option to sign whatever was presented to them.[187] The Revised Bangui Agreement of 1999 provides for national intellectual property co-ordinating bodies. However, the influence of these bodies appears peripheral, if anything.[188] In Cameroon, for instance, the co-ordinating body is made up of a small group of people housed in the Ministry of Commerce and Industry.[189] Given the fact that IP rights were barely taught at universities in member states, it could not have been expected that the national bodies would have experts on IP, who could have provided guidance to their national governments on the implications of the Revised Bangui Agreement or, better still, could have brought this to the attention of OAPI. One argument is that Cameroonians could have studied IP at other universities abroad. However, there is no evidence that studying IP was considered seriously and rewarding by prospective students.

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185 Deere (n 46 above) 265.
186 As above.
187 As above.
188 Personal observations at the Ministry of Commerce and Industry in Cameroon, 8 May 2012.
189 As above.

In addition, the relationship between national IP co-ordinating bodies and OAPI was akin to seller and buyer. For the most part, their role was administrative and they had to rely on OAPI for research and policy guidance, if any.[190] In addition, it appears that national governments did not wish to be seen as opposed to the mainstream policies of most powerful governments, such as the US and those EU member states who had instated IP protection as part of domestic and international policy by enacting pieces of domestic law on IP and by aggressively pursuing the inclusion of stringent IP provisions in international agreements.[191] Thus, OAPI could do whatever they wanted, without any credible check, assessment or opposition from its member states.

(c) Absence of strong and vocal civil society organisations

Most OAPI member states did not have strong and vibrant civil society organisations that could provide a viable challenge to OAPI's laws and policies. This problem was further compounded by the fact that, even for those that existed, it would have been more difficult for them to have any regional influence, since they were mostly local and national, and not regional. However, there are a few reasons to explain the inertia by civil societies in the OAPI region.

First, there was a huge vacuum in terms of knowledge of IP rights and its implications on access to medicines, either because IP was not a popular field or may have been considered technical.

Secondly, almost everything was done at the OAPI headquarters in Yaoundé. Thus, CSOs interested in the issues were hampered by the distance to Yaoundé. To make matters worse, the Bangui Agreement came into force at a time where there were many barriers to effective and smooth communication. E-mail and the internet were not as popular in 1999 as they are today.

190 Deere (n 46 above) 282.

191 Deere (n 46 above) 231. In fact, three OAPI member countries were suspended from benefiting from AGOA (Central African Republic in 2003, Côte d'Ivoire in 2004 and Mauritania in 2006 because of violating eligibility criteria, signifying that the US would take the range of conditions (including IP protection) seriously.

Telephone and fax costs were exorbitant, not to mention the cost of a return flight ticket to the OAPI headquarters in Cameroon.

Thirdly, even among interested NGOs, there was no evidence of joint co-ordination of their activities.[192] *Medicins Sans Frontières* (MSF) was one of the few NGOs active in drawing the attention to the consequences of the TRIPS-plus provisions in the Bangui Agreement.[193] In fact, not until the middle of the negotiating process did NGOs start voicing concerns about the potential impact of the Revised Bangui Agreement.[194] This neglect, no doubt, created favourable ground for OAPI to flourish in their quest to ensure that the Bangui Agreement came into force. This is in stark contrast to the activities of NGOs in South Africa, such as the Treatment Action Campaign. The negotiations relating to the Bangui Agreement were done against the backdrop of important processes, such as the widespread condemnation of the pharmaceutical companies' lawsuit against the South African government,[195] and came into force in 2002 after the WTO backlash in 1999 following the Seattle Debacle.[196] One would have imagined the momentum generated by these events to generate interest in pro-access to medicine movements in OAPI member countries. Sadly, this was not the case.

Fourthly, even organisations that had the technical means were not given the opportunity to participate and give comments at the time the agreement was being negotiated.[197]

4.6.2 External factors

(a) French influence over most Francophone African countries

192 Deere (n 46 above) 274.
193 Deere 273.
194 Deere 265.
195 Although the South African government did not undertake to revise its patent law and is only considering doing so now as a result of the the TAC/MSF Fix Patent Law Campaign, the case involving the pharmaceutical companies created a lot of momentum and was an eye-opener at the time.
196 'The Seattle debacle: What happened and what next?' http://www.twnside.org.sg/title/focus13.htm (accessed 28 February 2013).
197 Deere (n 46 above) 275.

The French influence on the socio-political and economic affairs of their former colonies, even after independence, has been well documented.[198] These influences were maintained through the myriad of co-operation agreements, ranging from security to political, economic and cultural. In fact, even before this panoply of co-operative agreements, which gave France a strong foothold in its former colonies, French colonial policies themselves had been crafted in such a way as to leave behind a perpetual French legacy. For instance, unlike the British that had indirect rule where they ruled their colonies through locals or nationals of the said territories, the French instituted direct rule. The direct rule was predicated on the policy of assimilation where nationals from French colonies were expected to think, behave and live like French people.[199] This policy was fostered by Charles de Gaulle through his *Communauté Franco Africaine*, which was aimed at maintaining colonial legacies and which frowned at any attempt by former French colonies to sever close ties with France.[200]

The impact of these policies was that French colonies saw themselves as part of France and invariably adopted French culture, including French laws. In fact, after independence and, until recently, French civil and contract laws were adopted *mutatis mutandis* by most of France's former colonies.[201] Thus, when its former colonies were thinking of enacting a law on intellectual property, France took a keen interest and played an important role.

For example, most OAPI countries modelled their copyright laws after the French model. France persuaded 11 of its former colonies to join the Berne Convention and, lastly, encouraged the creation of regional IP bodies, such as the *Union Africaine et Malgache* (UAM) and *Organisation Commun Africain et Malgache*).[202] In addition, during the negotiations of the Bangui Agreement, the

198 J Benneyworth 'Ongoing relationships between France and its former African colonies' http://www.e-ir.info/2011/06/11/the-ongoing-relationship-between-france-and-its-former-african-colonies/ (accessed 28 February 2012).
199 As above.
200 As above.
201 Most West and Central African countries that are former French colonies incorporated most aspects of the laws prevailing in France at the time of independence.
202 Deere (n 46 above) 250.

Institute Nationale pour la Proprieté Intellectuelle (INPI), which is the national IP institute of France, gave technical and financial support to OAPI before and during the negotiations and even had a co-operative agreement with OAPI dating as far back as 1982.[203] Therefore, with France's stringent pro-IP stands and enormous influence on its former African colonies and OAPI structures, there was every reason to believe that OAPI would not have produced a document that would be against the wishes and goals of France.

(b) Role of other foreign powers

Like France, other foreign powers took interest in the Bangui Agreement. The only difference between their involvement is that it was not as direct and overt as that of France. For instance, during the negotiations of the Revised Bangui Agreements, African countries, including former French-African colonies, were involved in the negotiations of the Cotonou Agreement with the EU and the US was working on the final drafts of the African Growth and Opportunity Act (AGOA). These two agreements had an indirect influence on the outcome of stringent IP provisions in the Bangui Agreement. This is because both the US and EU pushed for stringent IP protection.[204] For instance, one of the eligibility criteria to receive preferential market access to the US under AGOA was the need to have domestic IP protection.[205] OAPI members may therefore have gone with providing for a strong IP regime not to offend either the EU or the US, which had called for strong IP protection through international fora like the WTO. Thus, the stakes could have been too high for OAPI member states, as they risked missing out on the lucrative US markets via AGOA by including anything that could have been interpreted as weak IP laws.[206]

(c) Role of international organisations

203 As above.
204 Art 46 Cotonou Agreement.
205 Sec Africa Growth and Opportunity Act, 2000.
206 Art 46 Cotonou Agreement.

International organisations such as the WIPO, EPO and WTO at various points played an active role before and during the negotiations of the Revised Bangui Agreement and some believe that they had a significant role in the outcome of final agreement.[207] These organisations provided technical, material and financial support to OAPI. For instance, the WIPO had a co-operative agreement with OAPI and held consultative meetings with OAPI and other national IP organisations once every year.[208] In addition, the WIPO also commented on the draft versions of the Revised Bangui Agreement and hired a consultant to do the drafting.[209] The WIPO provided free patent searches to OAPI members and at one point hosted its website.[210] The WIPO may be seen as being on the side of pharmaceutical companies as it has often been seen to be in favour of strong IP laws.[211] Given the relationship between the WIPO and OAPI and the WIPO's perceived stance for strong IP laws, it was no surprise that the Revised Bangui Accord did not make full use of flexibilities. One would not expect the WIPO to invest money, time and effort in something that would have an outcome diametrically different from what its interests are.

(d) Negotiations of the Revised Bangui Agreement preceding the Doha Declaration of 2001

The Revised Bangui Agreement entered into force in 2002, which is a year after the Doha Declaration. On the face of it, one would have expected the Revised Bangui Agreement to incorporate the flexibilities that were outlined in the Doha Declaration, *a fortiori*, as it came after the Doha Declaration. However, it should be noted that the negotiations of the Bangui Agreement commenced in the 1990s and was actually signed in 1999. It needed the ratification by a number of states before coming into force. Thus, it only came into force when the ratification quota was met. Even though it came into force when the ratification quota was met in 2002, it had been finalised some time before. It was difficult

207 MSF alleged that: the revised Bangui Agreement was 'inspired by WIPO whose budget is partially funded by industrialists' and was 'revised under pressure exerted by pharmaceutical industries of the North'. See Deere (n 46 above) 241.
208 http://www.wipo.int/sme/en/documents/oapi.htm (accessed 31 October 2014).
209 E-mail exchanged with Dr Maurice Batanga, Legal advisor, OAPI, 20 March 2012.
210 As above.
211 Deere (n 46 above) 277.

then to go back to the negotiation table and discuss the incorporation of the flexibilities inherent in the Doha Declaration into the Revised Bangui Agreement. This might have taken much time, effort and commitment, and it would have been exceedingly difficult to restart treaty negotiations. In this respect, when the Revised Bangui Agreement came into force in 2002, it did not contain any of the flexibilities contained in the Doha Declaration. In fairness, then, one cannot directly blame OAPI member countries for not incorporating the flexibilities provided for in the Doha Declaration into the final text of the Revised Bangui Agreement.

Irrespective of the above, during the time the Revised Bangui Agreement of 1999 was negotiated, pro-access to medicine ideas, initiatives and stances were gathering momentum. For instance, there were the activities of anti-globalisation movements that were against the WTO and its polities, including its intellectual property rights agreement - TRIPS.[212] This reached a crescendo during the WTO meeting in Seattle in 1999 where there were demonstrations against the WTO and globalisation.[213] In addition, during the late 1990s, when the Revised Bangui Agreement was negotiated, there were many pro-access to medicine campaigns against pharmaceutical companies following their lawsuit against the government of South Africa.[214] TRIPS had entered into force four years earlier, so it would have been expected that the Bangui Agreement would have incorporated all its flexibilities. Furthermore, there were numerous pro-access demonstrations, especially at the Durban AIDS Conference of 2000[215] and internationally, during Al Gore's US 2000 presidential election campaign,[216] which would have provoked amendments to the Bangui Agreement. At the level of the WTO TRIPS Council, the Africa Group was at the forefront of calling for reforms of the WTO patent regime relating to access

212 P Siplon *AIDS and the policy struggle in the United States Georgetown* (2002) 123 124.
213 As above. See also 'The Seattle debacle: What happened and what next?' http://www.twnside.org.sg/title/focus13.htm (accessed 28 February 2013).
214 The legal suit was *Pharmaceutical Manufacturers Association & Others v President of the Republic of South Africa & Others* (Transvaal Provincial Division case 4183/98).
215 E Cameron 'Patents and public health: Principle, politics and paradox' inaugural British Academy law lecture held at the University of Edinburgh, 19 October 2004, 536.
216 P Siplon (n 212 above) 121.

to medicines.[217] Thus, the negotiators and drafters of the Revised Bangui Agreement should have benefited from the wealth of information propounded by pro-access to medicines activist groups and should have made them reflect in the ensuing Revised Bangui Agreement. Therefore, although the Doha Declaration preceded the negotiations and drafting of the Revised Bangui Agreement, it can be argued that the drafters and negotiators should have at least kept abreast with the pro-access to medicine views at the time and should have somehow incorporated them into the Revised Bangui Agreement.

Moreover, during the negotiation of the Revised Bangui Agreement, the WTO transitional periods for implementing TRIPS were still in force. These three-fold transitional periods were applicable to both developing and least-developed countries. The first period was from 1995 to 2000,[218] at the end of which developing countries were obliged to implement TRIPS. The second period, from 2000 to 2005,[219] gave an additional five-year period for countries that did not have product patent protection for pharmaceuticals or agro-chemicals at the time the TRIPS Agreement came into force, to do so by 2005.[220] The third period that applied to least-developed countries was from 1995 to 2006.[221] The Revised Bangui Agreement would have incorporated these transitional periods by reference and only left the signatory states to apply them when the transition periods came to an end as prescribed by TRIPS.

4.7 Chapter conclusion

This chapter has discussed at length the failed incorporation of TRIPS flexibilities into the Revised Bangui Agreement of 1999. The main points raised are that the Revised Bangui Agreement of 1999 failed to fully incorporate all permissible TRIPS flexibilities. It has been shown that a constellation of factors militated against the inclusion of TRIPS flexibilities in the Revised Bangui

217 T Kongolo 'WTO Doha Declaration and intellectual property: African perspectives' (2002) *African Yearbook of International Law* 185-201.
218 Art 65(2) TRIPS Agreement.
219 Art 65(4) TRIPS Agreement.
220 S Musungu & C Oh *The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines? (*2005) 22.
221 Art 66.1 TRIPS Agreement.

Agreement of 1999. These factors are based on intensive desk-top research, open-ended interviews[222] and personal observations, and are grouped into two broad categories, namely, internal and external factors. The chapter has also demonstrated that, irrespective of the internal and external factors, there was an enabling environment and a golden opportunity for OAPI member states and drafters of the Revised Bangui Agreement of 1999 to fully incorporate TRIPS flexibilities originally or to have amended it since. For instance, the momentum generated by access to medicine campaigns in the late 1990s and the compromise most pro-strong-IP countries were willing to make in negotiations relating to IP and public health were great opportunities that OAPI member states could have used to provide for access to medicine-friendly legislation. The overwhelming impact of this has been the inability of OAPI member states to provide and facilitate access to medicines to its citizens and the conspicuous failure to utilise advantages that many developing and least-developed countries fought hard to achieve internationally. In the next chapter, recommendations on how OAPI member states can change the *status quo* to take full advantage of local and international developments on how to incorporate and make use of flexibilities to promote access to medicines will be discussed.

222 See bibliography for the list of interviewees.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion (or findings)

This chapter will summarise chapters 1 to 5, highlighting the key points of each chapter. Thereafter, it will proffer recommendations for reforms. Lastly, it will demonstrate how these recommendations could be taken forward at the national, regional, continental and international levels.

This thesis has examined the OAPI patent regime and the problems OAPI member countries faced and are facing in facilitating access to medicines for their citizens. The thesis has discussed the TRIPS patent regime, access to medicines, and the flexibilities provided for by TRIPS and the extent to which they have been adopted in the Revised Bangui Agreement. In the process, it has highlighted the problems developing countries and LDCs face in using TRIPS to promote and protect access to medicines. All these approaches were adopted to investigate what is happening internationally and regionally, to provide useful lessons to OAPI countries and, more importantly, to measure the progress of the OAPI regime *vis-à-vis*, first, what is provided for in the TRIPS Agreement and, second, whether OAPI has kept pace with developments in other regions of Africa and the world.

The goal of this thesis is to analyse the reasons why OAPI member countries have not taken full advantage of TRIPS flexibilities so as to facilitate access to medicines in their respective countries. In order to achieve the above objective, the thesis is broken down into five chapters, dealing with a range of issues comprising an analytical and logical discussion of the provisions and interpretation of the TRIPS patent regime relative to access to medicines and TRIPS flexibilities, the problems affecting access to medicines in the OAPI region, and the TRIPS patent regime.

Chapter 1 provides the background to the thesis. It sets out the objectives, research methodology, hypothesis and literary review. The overriding contention of chapter 1 is that, unlike some other African countries, OAPI member states have not fully utilised the flexibilities provided for in the TRIPS Agreement. To explore this hypothesis, the chapter outlines a number of research methods and approaches that would be used to undertake the research. These methods range from descriptive, narrative and analytical tracks, to discussions and interviews with selected groups of lecturers, students and NGO representatives. Chapter 1 also underscores the limited research, articles and books on access to medicines in the OAPI region. In fact, one of the principal reasons for undertaking the research was to fill this void and to deduce recommendations for reforms.

In chapter 2, the salient TRIPS patent provisions relative to access to medicines are analysed. The aim is to set the background for the ensuing discussions in the subsequent chapters. In the course of the chapter, the evolution of the interpretation and implementation of these patent provisions, be they at the level of the WTO or the national level, are examined. In the course of interpretation and implementation, some of the patent provisions were found wanting and restrictive, especially with regard to access to medicines. These deficiencies paved the way for subsequent negotiations and amendments to parts of TRIPS articulated and further encoded in the Doha Declaration and the August 2003 Decision and the permanent amendments to TRIPS of December 2005.

TRIPS flexibilities are discussed in chapter 3. The focus is on their meaning, scope of application and the degree and extent of their implementation. As in chapter 2, chapter 3 looks at the evolution and interpretative history of the flexibilities. Important national and international cases are also discussed. The conclusion in this chapter is that some TRIPS provisions contain flexibilities which, if implemented, would go a long way towards assuaging the problems most developing countries and LDCs face in protecting, promoting and facilitating access to medicines.

Chapter 4 provides a detailed discussion of the OAPI patent regime. It is the central part of the thesis as it relates to the main issue under study, namely, the OAPI patent regime in respect of access to medicines. The chapter traces the evolution of OAPI from when it was first created in 1962 to 1999, when it enacted its last comprehensive patent law, which is part of the Revised Bangui Agreement. It discusses the institutional framework of OAPI. More importantly, it substantiates that OAPI member countries have not made full use of the available TRIPS flexibilities. It investigates and discusses some of the reasons that could be advanced for the non-use of the flexibilities. It concludes that the reasons, though many and varied, can conveniently be divided into two main categories: those informed by internal and those by external factors. As discussed in chapter 4, the internal factors include the following: inadequate capacity; the domineering nature of OAPI; and the absence of a strong and vocal civil society. The external factors include the French influence over most Francophone African countries; the role of other foreign powers; and the role of international organisations.

The final chapter offers recommendations for reform. These recommendations are discussed below.

5.2 Recommendations

The preceding discussions have given a breakdown of the main issues considered in the substantive chapters of the thesis. One of the recurring findings is that the OAPI patent regime has certain problems, as discussed in chapter 4, and, as such, is in need of reform. This section will make some recommendations for the reform of the OAPI patent system.

5.2.1 OAPI countries should make increased use of TRIPS public health flexibilities

The major recommendation of this thesis is that OAPI revises the Bangui Agreement to include all the flexibilities provided for by the TRIPS Agreement, the Doha Declaration, and the 30 August Decision. Better still, since revising the entire OAPI Agreement may be a long and cumbersome process, taking into account the problems of obtaining consensus from all the member states, it is recommended that an amendment be made, taking the form of a one-page document stating that OAPI LDC members need not implement all the patent provisions, to be appended to the OAPI Agreement. Detailed changes that must be made are contained in the subsequent paragraphs.

To fully take advantage of the TRIPS flexibilities and to promote access to medicines in its respective territories, OAPI should do the following:

(a) OAPI should use the transitional provisions of the TRIPS Agreement delaying its implementation in LDCs

The Revised Bangui Agreement should incorporate the transition rules for LDCs. The resulting extension agreement allows LDCs to not implement TRIPS provisions until 2021 or when they cease to be a least-developed country.[1] Of the 17 OAPI member states, only four are developing countries. The remaining 13 are LDCs. Thus, LDCs that are members of the OAPI regime do not enjoy the policy space provided for by the extended LDC transition period - 2021. OAPI member states should revise the Bangui Agreement so as to take into consideration the transition period for LDCs as adopted by the TRIPS Council. A clause stating that such extension should stay in place until 2021 and should continue as may be agreed upon and provided for by the TRIPS Council should be inserted. In this

[1] Extension of the transition period under art 66(1) for least-developed country members, decision of the Council for TRIPS of 11 June 2013 IP/C/64.

way, the transition period is tied up with that agreed by the TRIPS Council after 2021.

(b) OAPI should exclude materials excluded from patentability

Articles 27(2) and 27(3) of TRIPS provide for exemptions from patentability. However, although not expressly provided for by TRIPS, other excludable subject matter also exists, exercised differently by different countries, including discoveries, computer programmes, business methods, abstract ideas and theories, isolated genes and other products isolated from nature, and plant and animal varieties. The Bangui Agreement does not expressly provide for the exclusion of abstract ideas, like some jurisdictions, for instance, India.[2] However, it can be argued that abstract theories could be brought under the exclusion of scientific theories, if they relate to scientific issues, or under the exclusion of literary, architectural and artistic works. If the abstract idea relates to arts, it is recommended that OAPI broadens the list of excludable patentable subject matter to include what has been provided and used by other countries. Such a list could include abstract ideas and would therefore not leave it to interpretation.

(c) OAPI should make use of the permissible grounds for the issuance of compulsory licences

(i) Incorporating broad grounds for the issuance of compulsory licences

OAPI should revise the Bangui Agreement to include all the broad grounds for the issuance of compulsory licences as adopted by different countries and different jurisdictions. OAPI can do this by modifying all the provisions of the current article 46 of the Revised Bangui Agreement. Section 8 of the East African Community Health Protocol on Public Health-Related WTO-TRIPS Flexibilities may be used to

[2] Sec 3 Indian Patents Act 1970 (as amended in 2005).

provide guidance. This is because section 8 comprehensively lists most of the grounds that could be used to issue compulsory licences. Using section 8 of the EAC Protocol as guidance, OAPI can modify its article 46 as follows:

> All member states shall be free to determine and stipulate in their national laws the grounds upon which the competent authorities may issue non-voluntary licences, including government-use licences. These grounds shall include:
> (a) where there is national emergency or other situations of extreme urgency;
> (b) where the patented invention is used for non-commercial purposes;
> (c) to remedy anti-competitive behaviour or the abuse of patent rights, including cases in which the patented invention is made available at excessive prices only or in cases in which refusals to licence constitute an abuse of a dominant position;
> (d) where the local demand is not satisfied because the patented invention is made available to the public in insufficient quantity or quality, or at unreasonably high prices;
> (e) where the public interest, in particular public health so requires;
> (f) where a patented invention claimed in a subsequent patent cannot be used without infringing a previous patent;
> (g) for the purposes of giving effect to the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO's General Council on August 30, 2003 (Paragraph 6 Decision), to make use, offer for sale for export to an eligible importing country a patented health product, including a patented process regarding that health product;
> (h) for the importation of a patented health product for the purposes of giving effect to the Paragraph 6 Decision;
> (i) all member states shall draft guidelines and regulations on the implementation of the Paragraph 6 Decision both as eligible importing countries and as exporting countries, including the conditions and notification requirements established by this Decision.

OAPI could go further by broadly defining the public interest ground stated in paragraph (e) of the clause above. OAPI can use section 84 of the Indian Patent Act (as amended) as guidance. As such, the public interest ground could be worded as follows:

> (d) In the case of public interest, a non-voluntary licence will be issued if the issuing authority is satisfied that the reasonable requirements of the public interest with

respect to the patented invention have not been satisfied the reasonable requirements of the public shall be deemed not to have been satisfied -

(1) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,
   (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in a member state or the trade or industry of any person or class of persons trading or manufacturing in a member state is prejudiced; or
   (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
   (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(2) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, a state, is prejudiced; or

(3) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or

(4) if the working of the patented invention in the territory of a member state is being prevented or hindered by the importation from abroad of the patented article by
   (i) the patentee or persons claiming under him; or
   (ii) persons directly or indirectly purchasing from him; or
   (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

(ii) Limiting the period for negotiations with the patent owner

OAPI could limit the time period for negotiations with the patent owner for the use of the latter's patent. Article 48(3)(a), dealing with the period for negotiations with the patent owner, provides that the request for the grant of a non-voluntary licence shall be accompanied by '(a) proof that the requester has previously approached the owner of the patent, by registered letter, requesting a contractual licence, but

has been unable to obtain such a licence from him subject to reasonable commercial terms and procedures and within a reasonable time …'

'Reasonable time', as provided for in the clause above, is not defined. The danger is that the patent owner may protract the negotiations and claim that the said negotiation period falls within a reasonable time. It is recommended that the Revised Bangui Agreement be modified to set a maximum period of negotiations with the patent owner before a compulsory licence is granted.[3] OAPI could draw inspiration from the East African Community[4] by modifying article 48(3)(a) to the effect that the grant of a non-voluntary licence shall be accompanied by '(a) proof that the requester has previously approached the owner of the patent, by registered letter, requesting a contractual licence, but has been unable to obtain such a licence from *him within a period of 90 days* …'

(iii) Waiving the period of negotiations with the patent owner

OAPI countries can modify article 46 of Annex 1 of the Revised Bangui Agreement to give its member countries the opportunity to waive the negotiation period with the patent owner in certain circumstances in cases of emergency or public non-commercial use and competition violations. In such instances, negotiation with the patent owner is not required. OAPI can do this by amending article 46 of the Revised Bangui Agreement by adding a new article 46(3), which should state:

> Notwithstanding the above, member states shall waive the prior negotiation requirements referred to in article 48(3)(a) in cases of national emergency, other situations of extreme urgency, public non-commercial use and where compulsory licences are to be issued to remedy anti-competitive behaviour of the patent right holder.[5]

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3 East African Community *Regional intellectual property policy on the utilisation of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation* (2013) 19.

4 Sec 8(2)(1) East African Community Health Protocol on Public Health Related WTO-TRIPS Flexibilities.

5 This is the same provision under sec 8(2)(2) of the East African Community Health Protocol on Public Health Related WTO-TRIPS Flexibilities.

Such an amendment will give OAPI countries the benefit of addressing health emergencies in a short time, rather than engaging in lengthy negotiations which may affect health care responses to emergency situations.

(iv) Creation of an easy-to-use administrative and appeal process

OAPI should encourage all its member countries to provide for easy-to-use administrative processes by interested parties for the issuance of a compulsory licence, as opposed to the current system where only civil courts are given the jurisdiction to issue compulsory licences. An easy-to-use administrative process will reduce the time necessary for the issue of compulsory licences, unlike the current system which requires filing a submission to court. OAPI member countries would need to create and equip these national administrative centres and train its personnel. In such a scenario, the authority to grant a compulsory licence could be conferred to a national administrative unit or institution. Once the compulsory licence is issued, OAPI publishes it in its Special Register. OAPI would have to ensure that such publication gives legitimacy to the decision of the administrative unit to apply across all OAPI member countries. This could be achieved by modifying the Revised Bangui Agreement, replacing courts with administrative centres as the entities charged with granting compulsory licences and the courts only featuring in cases of appeal by the patent holder. In addition, article 49 of the Revised Bangui Agreement should be modified to include the extraterritorial effect of a decision to grant a compulsory licence by one of the national administrative centres in a member country. Such modification could take the form of a new article 49(6), which will provide:

> Once the decision of the administrative unit granting a non-voluntary licence has been published by OAPI, it becomes applicable to all OAPI member states.

To ensure that the administrative centres are functional, efficient, effective and accessible, many of these units should be created in member states and staffed by persons well-trained on the subject of compulsory licences and issues related to patents.

(v) Determining the remuneration paid to patent owners

OAPI should provide a threshold not to be surpassed when issues relating to the remuneration of the patent holder come to the fore. Currently, issues relating to remuneration are left to the courts to decide. In fact, article 49(4)(b) of the Revised Bangui Agreement, which deals with remuneration, simply empowers courts to determine remuneration by considering what is equitable and taking into consideration the circumstances surrounding the case - the request for a compulsory licence. It is submitted that this provision does not take into consideration current best practices regarding the determination of remuneration in cases of the granting of compulsory licences. It is recommended that OAPI should set a threshold by providing for the figure recommended by the UNDP of 4 per cent of the value of the medicines.[6] OAPI can settle the question of adequate remuneration by taking inspiration from section 8(3) of the East African Community Health Protocol on Public Health-Related WTO-TRIPS Flexibilities. OAPI can do so by modifying article 49(4)(b) of the Revised Bangui Agreement with the following new clause:

1 Member states shall provide that remuneration to the patent right holder in the case of a non-voluntary licence shall not exceed 4 per cent.

2 All member states shall require the competent authorities, in determining the amount of adequate remuneration to the patent right holder in the case of a compulsory licence, to take into account the need to correct anti-competitive practice and to reduce the amount of remuneration accordingly.

3 In determining remuneration to the patent right holder with respect to any licence granted for the export under the Paragraph 6 Decision, the competent authorities

[6] UNDP -WHO; Technical Co-operation for Essential Drugs and Traditional Medicine - Remuneration Guidelines for Non-Voluntary Use of a Patent (2005).

> shall take into account the economic value of the authorisation to the eligible importing country.
>
> 4 All member states shall waive the payment of adequate remuneration to the patent right holder for a licence granted under the Paragraph 6 Decision for the importation of a patented health product that is also under patent in the prospective exporting country in respect of that health product for which remuneration is paid in the exporting country.

Such a stipulation will create certainty and clarity and will exclude the long court process and the 'equitable and all circumstances' tests the court would have employed to determine the remuneration to be paid to the patent owner.

(vi) Utilising the August 2003 licence

It is recommended that the Revised Bangui Agreement be amended so that OAPI member states make full use of the August 2003 licences. As discussed above, the WTO's August 2003 Decision on paragraph 6 of the Doha Declaration created permissible grounds for countries with manufacturing capacity to export pharmaceuticals to countries lacking such capacity. This has been encapsulated in TRIPS as the proposed article 31*bis*. Article 31*bis* of TRIPS provides:

> The obligations of an exporting member under article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

However, to benefit from the above, a number of notifications, conditions and requirements have to be satisfied.[7]

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[7] According to para 2 of the Annex, the terms for granting a compulsory licence for exports are that (i) the eligible importing member should notify the TRIPS Council of the names and expected quantities of the product needed; (ii) non-least-developed country member should confirm that it has insufficient or no manufacturing capacity for the pharmaceutical product in question in one of the ways set out in the Appendix to the Annex, and that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence. Furthermore, the compulsory licence issued by the exporting member should state (i) that only the amount necessary to meet the needs of the eligible importing member may be manufactured, and the entire

Under article 31*bis*3, however, exports or re-exports of pharmaceutical products within trade agreements mostly made up of LDCs are not subject to the notifications and requirements mentioned above. Since more than half the members OAPI are LDCs, OAPI as a regional group is free to use the 30 August licences. In order to use the 30 August licences, the Revised Bangui Agreement will need to be amended to allow such licences and appropriate procedures will have to be specified both in the modified Revised Bangui Agreement and in any relevant national legislation of OAPI members. The Revised Bangui Agreement would have to provide for importation as well as exportation.

(d) OAPI should modify the provisions on government-use licences

The Revised 1999 Agreement provides for *ex officio* licences (likened to government-use licences). *Ex officio* licences can only be used when the patent in question is (i) not being worked on the territory of a member state at the time the request is made; (ii) the working of the patented invention on such territory does not meet the demand for the protected product on reasonable terms; and (iii) on account of the refusal of the owner of the patent to grant licences on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced.[8] These conditions are undesirable, and constitute a TRIPS-plus limitation on the use of *ex officio* licences. It is recommended that article 46 of the Revised Bangui Agreement be modified to remove the above stringent conditions attached to the

production must be exported to the latter; (ii) that the manufactured products must be clearly identified as being produced under the system through special labelling or marking, special packaging and/or special colouring/shaping of the products (provided that such distinction is feasible and does not have a significant impact on price); and (iii) that before shipping the products, the licencee should post on a website the quantities being supplied to each destination In addition, the exporting member must notify the TRIPS Council of the grant of the licence, including the conditions attached to it. The notification provided shall include (i) the name and address of the licencee; (ii) the product(s) for which the licence has been granted; (iii) the quantity(ies) for which it has been granted; (iv) the country(ies) to which the product(s) is (are) to be supplied; and (v) the duration of the licence.

8 Art 46 Revised Bangui Agreement.

issuance of government-use licences. The new recommendation should, in the first place, be simple and straightforward, and not overly legalistic. Second, government-use provisions should be strong by giving governments broad powers to issue government-use licences. Lastly, the system of compensation should be straightforward and easy to administer.

Furthermore, under the Revised Bangui Agreement of 1999, *ex officio* licences cannot be extended to the act of importation.[9] This provision is not justifiable because, at the moment, OAPI member states do not have the manufacturing capacity to produce most drugs. If there were to be an epidemic, it would be difficult to see how an OAPI member state, even though armed with an *ex officio* licence, could produce the required medicines. Therefore, it is further recommended that the article be modified to include imports, not only domestic products. This is because some countries' domestic markets may not be able to provide for certain medications as the countries may not have manufacturing capacity.

(e) OAPI should adopt an international exhaustion regime

As discussed in chapter 4, the Bangui Agreement currently provides for a regional exhaustion regime. This has a number of shortcomings, including limiting the ability of OAPI member states to source medicines internationally once the patent owner puts them on the market outside the OAPI region. Accordingly, OAPI should modify the Bangui Agreement and replace the regional exhaustion regime with an international exhaustion regime. With regards to access to medicines, under international exhaustion, for instance, once the medicines are sold, the rights of the patent owner are deemed to have been 'exhausted', meaning that the patent holder cannot control the resale and further distribution of the medicines within, for instance, the OAPI region.

9 Art 46 Revised Bangui Agreement.

(f) OAPI should adopt exceptions that have been used under article 30 of TRIPS

Limitations to the patentee's rights are provided for in article 8 of Annex 1 of the Revised Bangui Agreement. Unlike article 30 of the TRIPS Agreement, which provides for limited exceptions without listing them, article 8(1) of Annex 1 of the Bangui Agreement lists which exceptions are to be recognised. The current OAPI dispensation does not leave much room for manoeuvre as it lists specific exceptions, unlike article 30 of TRIPS, which lists conditions under which an exception falling under it can be construed. From the foregoing, OAPI should broaden the exceptions under article 8 to include the following exceptions that have been used under article 30 of the TRIPS Agreement: research and experimentation on an invention; educational use; acts done privately for non-commercial purposes; preparation of medicines under individual prescription; and Bolar or early working exceptions. With these inclusions, OAPI countries will have many options other than the current provisions under article 8 of Annex 1 of the Revised Bangui Agreement.

To effectively use the Bolar exception, OAPI would have to amend its article 8. Such amendment will have a new article 8(1)(e) which shall contain a specific Bolar provision. OAPI could borrow from section 107(a) of the Indian Patent Act (as amended), which provides:

> Certain acts not to be considered as [patent] infringements:
> For the purposes of this Act -
> (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product ...

(g) OAPI should provide competition-based flexibilities

The Bangui Agreement does not provide for competition-based flexibilities. This omission is strange, considering their importance in facilitating access to medicines as well as the fact that such flexibilities are provided for in the TRIPS Agreement. It is recommended that OAPI adopts the TRIPS provision by having an addendum that incorporates by reference competition-based flexibilities as provided for in articles 8(1), 31(k) and 40 of the TRIPS Agreement. However, providing for competition-based flexibilities is not enough. There should be resources dedicated to implementing the competition-based flexibilities. This is because, despite having pieces of legislation containing competition-based flexibilities, most developing and least-developed countries have fallen short when it comes to implementation.[10] Many reasons have been advanced for the non-implementation of competition laws and policies in many developing and least-developed countries. These reasons include financial and budgetary resource constraints, weaknesses in legal drafting, politico-economic constraints and the lack of a culture of competition.[11]

[10] UNDP paper on using competition law and policy to promote access to medicines http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf accessed 7 July 2014).

[11] As above.

(h) OAPI should make use of additional flexibilities

(i) Standard of patentability

OAPI should adopt a stringent standard of patentability as an additional TRIPS public health flexibility. This implies the strict application of the three patentability criteria: novelty, inventive step and industrial application, as well as the standard of patentability which will exclude the patenting of new forms of existing medicines, combinations, and new uses. In particular, the following modification should be effected to the Bangui Agreement:

The definition of 'inventive step' in article 4 is the following:

> An invention shall be regarded as resulting from an inventive step if, having regard to the prior art, it would not have been obvious to a person having ordinary knowledge and skill in the art on the filing date of the patent application or, if priority has been claimed, on the priority date validly claimed from it.

This definition is overly constraining as it limits inventiveness to 'persons having ordinary knowledge and skill in the art'. The phrase 'persons having ordinary knowledge and skill in the art' should therefore be changed to 'persons highly skilled in the art'. As discussed in chapter 4, this phrase captures a better standard because the more expertise is considered when evaluating the non-obviousness of an invention, the higher the possibility of that invention being deemed obvious.[12]

The definition of 'industrial application' in article 5 of Annex 1, namely,

> an invention shall be considered industrially applicable if it can be made or used in any kind of industry (the term 'industry' shall be understood in its broadest sense; in particular it shall cover handicraft, agriculture, fishery and services)

[12] East African Community Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (2013) East African Community, Arusha, Tanzania.

is too broad. This is because, as the provisions stands, the patentability of research tools, for instance, could be allowed whether or not their uses have been specified. This may create monopoly rights and may exclude innovation, as prospective researchers would not be able to use the existing patented experimental research in their research activities. In such a situation, 'patent protection could serve as a deterrent to innovation, by allowing the patent holder to exclude others from conducting potentially-useful scientific investigations'.[13] OAPI should modify this definition and adopt a new one that insists on the 'strict application of industrial application and limit the patentability of research tools to only those for which a specific use has been identified'.[14] The Revised Bangui Agreement can also define the requirement of 'industrial applicability' by 'expressly stating that compounds of experimental or speculative use shall not be capable of industrial application'.[15] The modification will discourage the application for patents for research tools for general uses, without proven specific uses for the research tools, and will prevent such patents from being granted.

OAPI members should amend their requirement for the standard of patentability by excluding the patenting of a mere discovery of new uses for medicines. This will prevent patentees from claiming patents for new uses for their patented products. OAPI can use section 3(d) of the Indian Patent Act (as amended) as guidance. Section 3(d) of the Indian Patent Act (as amended) provides:

> The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable.

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13 UNDP *Using law to accelerate treatment access in South Africa: An analysis of patent, competition and medicines law* (2013) 36.
14 As above.
15 n 12 above.

The implication of the above provision would be to prevent pharmaceutical companies from 'obtaining patents on old medicines which are just a mere increment or trivial improvement of the known substances and also a refusal to the patent on discovery of a new form or new use of old drugs'.[16]

(ii) Modification of the post-grant opposition procedures

Under the Bangui Agreement, invalidation and forfeiture proceedings can only be brought in a civil court and the office of the prosecutor could be an intervening party. This situation could waste time as the office of the prosecutor is involved. It is recommended that OAPI modify its articles 43 and 44 to include (i) national patent offices to act as first instance in post-grant opposition cases; and (ii) the provision of a limited period within which the prosecutor may intervene. These amendments will ensure the avoidance of long and costly litigation and will make the procedure clear and unambiguous.

(iii) Adoption of pre-grant opposition procedures

As discussed above, pre-grant opposition, when included under local IP laws, could be a useful procedure to promote access to medicines. In fact, the TRIPS Agreement provides for pre-grant opposition. Article 62(4) of TRIPS allows members under their local laws to provide for procedures such as opposition, revocation and cancellation of patents. Opposition could be lodged both during the period when a patent application is being reviewed (pre-grant opposition), and after the patent has been granted (post-grant opposition).

16 A Sharma 'India: Section 3(D) of Indian Patents Act 1970: Significance and interpretation' http://www.mondaq.com/india/x/295378/Patent/SECTION+3D+OF+INDIAN+PATENTS+ACT+1970+SIGNIFICANCE (accessed 9 August 2015).

Opposition, especially against questionable patent monopoly, if successful, can lead to a decrease in price since the patent will be rejected, thereby allowing the production of low-priced generics. This will in turn facilitate access to medicines. Unfortunately, the Revised Bangui Agreement does not provide for pre-grant opposition. Section II, titled Grants of Patents, which lays down the procedures for the granting of patents, does not provide for any pre-grant opposition. It is highly recommended that the Revised Bangui Agreement be amended so that it adopts pre-grant opposition procedures. In order to fully benefit from pre-grant opposition to patent applications, OAPI should ensure that the procedures for submitting and deciding pre-grant opposition applications are easy to use. This will ensure that all stakeholders concerned, including patients' groups, take advantage of the procedures. OAPI can use section 25 of the Indian Patent Act (as amended)[17] as a guideline. Section 25(1) deals with the procedure for pre-

[17] Sec 25(1) provides: 'Opposition to the patent. (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground (a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims; (b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim (i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or (ii) in India or elsewhere, in any other document: Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or subsection (3) of section 29; (c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim; (d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim. Explanation: For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only; (e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim; (f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act; (g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed; (h) that the applicant has failed to disclose to the controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge; (i) that in the case of a convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title; (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological

grant opposition to patents. Under this provision, any person or any third party or government may challenge the application for the granting of a patent and in writing inform the controller of patents of its opposition against the granting of a patent after the application for a patent has been published, but before the granting of the patent. Under section 25, pre-grant opposition can be made on the following grounds:

(i) wrongfully obtaining the invention;
(ii) anticipation by prior publication;
(iii) anticipation by prior date, prior claiming in India;
(iv) prior public knowledge or public use in India;
(v) obviousness and lack of inventive step;
(vi) non-patentable subject matter;
(vii) insufficiency of description of the invention;
(viii) non-disclosure of information as per the requirement or providing materially false information by an applicant;
(ix) patent application not filed within 12 months of filing the first application in a convention country;
(x) non-disclosure/wrong mention of source of biological material; and
(xi) invention anticipated with regard to traditional knowledge of any community, anywhere in the world.

(iv) Modification of enforcement mechanisms

It is recommended that OAPI modify its article 66. The first sentence refers to civil actions under article 1, but article 1 does not refer to civil actions. Article 1 should therefore be modified so that the first sentence of article 66, which cross-references civil actions under article 1, is removed. The opening phrase of article 66 will now be as follows:

material used for the invention; (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, but on no other ground, and the controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed.'

> For the purpose of civil procedure for a violation of the owner's rights if the subject matter of the patent is a process for making a product …

In addition, OAPI should remove criminal prosecutions for alleged patent violations. It should modify the fines (between 1 000 000 and 3 000 000) and the terms of imprisonment (one to six months) provided for in article 58, and should limit these to cases of wilful trademark counterfeiting and copyright pirating on a commercial scale rather than to only violations of patent rights. This is because the current criminal enforcement provision is stringent and may be used to limit businesses, generic companies or producers, especially in OAPI countries, that may enter into free trade agreements (FTAs) with the US or EU that contain strong patent enforcement mechanisms.

The complainant is required to provide security, but the law provides that the security should be such that it does not discourage enforcement procedures.[18] This position is vague. The law should have at least provided that the security should be equal or greater than the value of the goods seized. This would discourage frivolous claims. In addition, the provision of security is discretionary as the law states that the order may require the complainant to furnish security. The implication of using 'may' (and not 'shall') is that there could be instances where enforcement can be effected without security. This may open the floodgates to frivolous claims.

(v) Modification of disclosure requirements

It is recommended that OAPI should modify its disclosure requirements. Article 14 of the Revised Bangui Agreement provides:

18 Art 67 of the Annex 1 of the Revised Bangui Agreement.

> Any person wishing to obtain a patent for an invention shall file with the Organization or with the Ministry responsible for industrial property, or send to it by registered mail with a request for acknowledgment of receipt,
>
> (a) his application to the Director-General of the Organization in a sufficient number of copies;
>
> (i) a specification of the invention for which the application has been made, set out clearly and completely so that a person having ordinary knowledge and skill in the art could carry it out …

From the foregoing, disclosure under the Revised Bangui Agreement is limited to the requirement for the patent application to define the scope of the protection sought which shall not to go beyond the specification of the invention for which the application was made.

However, it is limited in scope compared to the disclosure requirements under TRIPS. As discussed above, under article 29 of TRIPS, TRIPS members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. In addition, TRIPS members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. Also, members have the right to require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

As discussed in the recommendations below, OAPI should adopt stringent disclosure standards which are important in providing the basis for copying and continuing innovation. Such disclosure standard should include (i) the obligation that the patent applicant indicates the best mode for carrying out the invention known to the patentee; and (ii) the obligation for the patent applicant to provide information relating to any of his or her corresponding foreign application.

Regarding item (i) above, OAPI could draw inspiration from article 29(1) of TRIPS, which requires the disclosure of best mode by the patent applicant.[19] The implementation of a best mode requirement could be a 'key source of technological knowledge transfer, which could ensure long-term security in the supply of essential medicines'.[20]

Regarding item (ii), OAPI could follow the Indian example by providing the requirement for patent applicants to not only disclose information relating to any corresponding foreign application, but to also continuously inform OAPI of the status of the evolution of the foreign application.

OAPI could draw inspiration from the Indian Patent Act by replicating the provisions of section 8 of this Act in the Revised Bangui Agreement. Section 8 of the Indian Patent Act provides:

> (1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or within the prescribed period as the Controller may allow –
>
> (a) a statement setting out the detailed particulars of such application; and
>
> (b) an undertaking that, up to the date of grant of the patent, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

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19 Art 29(1) of the TRIPS Agreement provides: 'Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.'

20 UNDP (n 13 above) 47.

> (2) At any time after an application for a patent is filed in India and until the grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

Lastly, OAPI could link the failure to disclose a foreign application as a ground for pre-grant and post-grant opposition, as has been done by the Indian Patent Act.[21]

5.2.2 Government control and local ownership should be ensured

OAPI is a supra-national organisation comprising 17 countries. It is an independent body with its own Chairperson and institutional framework. OAPI rules take precedence in all matters related to intellectual property rights in all its member states. In fact, the drafting, implementation and supervision of intellectual property rights remain the sole preserve of OAPI. Power is heavily centralised, with only a very limited role allowed for national intellectual property organisations. This means that member states have little or no say in OAPI's trans-national decision-making processes. The effect of this has produced very limited opposition from member countries to most of the OAPI laws and policies. To compound matters, since OAPI receives funding from the WIPO, France and other developed countries with very stringent IP protection systems, cultures and agendas, OAPI laws are drafted to heavily favour the position of these countries. At the same time, there has been very limited opposition and oversight of OAPI member countries.[22] The discussions in chapter 4, which highlight the role of developed countries,

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21 Secs 25(1)(h) (pre-grant) and 25(2)(h) (post-grant) of the Indian Patent Act (as amended).

22 *Medicins Sans Frontières* alledged that the revised Bangui Agreement was 'inspired by WIPO whose budget is partially funded by industrialists' and was 'revised under pressure exerted by pharmaceutical industries of the north'. See C Deere 'TRIPS implementation in Francophone Africa' in *The implementation game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries* (2009) 241.

especially France, to ensure that the Bangui Agreement of 1999 contains TRIPS-plus provisions, are eloquent testimony to this fact.[23]

Therefore, it is recommended that member countries become more involved in the redesign, articulation and implementation of regional IP policies. This is one of the ways of cultivating and inspiring informed national discussions and debates. Such involvement would include expert scrutiny and analysis of draft laws, open national and parliamentary discussions of these laws and ensuring the maintenance of regular contact with OAPI officials. In addition, the promotion of transparency and increased involvement by members will ensure local ownership. The study as examined in chapter 4 indicates that the current laws were simply prepared by experts and nationals of countries strongly in favour of stringent IP protection, and sent to OAPI for adoption. With transparency and openness, such perceptions would be assuaged as national constituencies will assume greater local ownership. In this way, practical solutions to problems related to access to medicines that nationals face would be obviated by solutions generated through local discussions and involvement.

5.2.3 The role of NGOs in the OAPI region in access to medicine issues should be enhanced/increased

Unlike countries in East and Southern Africa, NGOs in the OAPI region have not been fully involved in advocating for and promoting access to medicine issues. Several reasons can be advanced for this state of affairs. First, OAPI has historically been a very centralised and domineering organisation. There has been a serious problem of information flow as well as a lack of consultation and involvement of NGOs in policy discussions and law reform processes. The lack of information has meant that most NGOs are neither aware of impending policies

[23] The national IP Institute of France gave OAPI technical and financial support before and during the negotiations of the Bangui Agreement. In fact, it even had a co-operative agreement with OAPI dating as far back as 1982. See Deere (n 22 above) 250.

and laws, nor able to actively lobby OAPI to get involved in major IP discussions. Besides *Medicins Sans Frontières*, it appears that international NGOs active in the access to medicine sphere have not found the OAPI region interesting - or promising - enough to get involved in advocacy campaigns related to access to medicines.[24] The consequence is that there have been very limited discussions on IP issues regarding access to medicines, as well as a dearth of information in most areas of the OAPI region.

To get involved in IP discussions, NGOs in the OAPI region need to have technical training so as to strategise. They would need to build alliances with other NGOs and civil society networks in Eastern and Southern Africa[25] so as to benefit from the latters' knowledge, expertise and experience. Knowledge and skills gained from such exchanges would enable them to get involved in policy discussions. One way of getting involved is to pressurise their respective governments to enable OAPI to become more transparent. For instance, NGOs can lobby their local parliamentarians and senators to request parliamentary and senatorial inquiries on the role of OAPI in facilitating access to medicines and, more importantly, creating an avenue for NGOs to make inputs in any regional IP policy (that can negatively impact access to medicines) formulation and implementation. Another way is to lobby their governments to create a forum or similar space for NGOs to have a say in major IP policy discussions and reforms. Furthermore, NGOs and civil society should co-ordinate their activities to avoid duplication so as to ensure the effective use of time and resources.

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24 Eg, during the negotiations of the Revised Bangui Agreement of 1999, NGOs did not start to get involved until the middle of the negotiating process when they started voicing concerns about the potential impacts of the Agreement on public health and access to medicines. See Deere (n 22 above) 265.

25 As discussed in ch 3, the Treatment Action Campaign of South Africa has been very instrumental in leading pro-access to medicine campaigns. It was very instrumental during the case pitting pharmaceutical companies against the South African government.

5.2.4 OAPI countries should undertake research and development on access to medicines

Research and development are critical in the health system of any country. Research is the main driver of invention and innovation. With little or no research, there is a high risk that there would be very limited progress and sufficiency in the production of medicines. Limited progress in technological advancement will have an impact on access to medicines. In the context of OAPI, research and development should be geared towards innovation. This is because very little pharmaceutical capacity exists. Regardless of the fact that it requires a considerable budget to develop a medicine plant, it is recommended that OAPI countries pool their funds and embark on an initiative which will concentrate on the production of generic medicines to cater for the most common diseases and those with the most devastating impact. There are current discussions in East and Southern Africa for the development of a common regional medical plant to cater for the needs of the countries of these regions. OAPI could learn from this and should start looking at ways to emulate the example.

5.2.5 OAPI should use a human rights-based approach to access to medicines

Human rights instruments have been used, either through advocacy or litigation, in some parts of the continent to protect, promote and facilitate access to medicines. However, this has not been the case with members of OAPI. OAPI member states are all signatories to the Universal Declaration of Human Rights, and state parties to the African Charter on Human and Peoples' Rights, the ICESCR, as well as a host of other regional and international human rights instruments. The most distressing aspect, however, is the inexplicable non-use and non-implementation of these instruments, especially with regard to the right to health and, in particular, access to medicines.

It is recommended that human rights NGOs working in the field of HIV in the OAPI region should increase their involvement in the human rights sphere by submitting shadow reports to UN and AU human rights treaty bodies, under the Universal Periodic Review (UPR) and the African Peer Review Mechanism (APRM), highlighting the failure of their governments to ensure the protection and the realisation of the rights of access to medicines and to health. Human rights laws, and specifically UN and African human rights monitoring bodies, are an under-utilised site of engagement for access to medicines and the right to health campaigns. Human rights bodies, such as the United Nations Human Rights Committee, the Committee on the Elimination of Discrimination Against Women and the Committee on the Rights of the Child, offer great opportunities for pushing access to medicines and right to health issues in the OAPI region. Unfortunately, as discussed in chapter 4, very few NGOs have used the opportunity that these fora present to submit shadow reports highlighting violations of the right to health committed in their countries. This situation is the same for regional fora such as the African Commission. Indeed, very few human rights NGOs working in the field of HIV in the OAPI region have ever interacted with African regional human rights bodies. Greater involvement in human rights issues, especially the right to health and the correlative right of access to medicines, will allow these NGOs to take advantage of these fora to frame access to medicines issues into the language of human rights. This would be an example of progressive 'regime shifting'. It would help shift the debate over TRIPS, IP and access to medicines in Africa from the opaque interiors of trade and commerce ministries and international institutions into the more participatory, transparent and progressive realm of human rights law.

Strong involvement in access to medicines issues will help NGOs in the OAPI region to further build on the momentum from the adoption of the resolution on access to medicines and the right to health by the African Commission, by devising strategies for follow-up and greater dissemination and awareness about this resolution. In addition, it will help them to engage with their respective

governments and the African Commission on its Guidelines for State Reporting on socio-economic rights, by making submissions on further drafts of this document.

5.2.6 Universities in the OAPI region should play a more pronounced role with regard to IP and access to information

It is not until recently - 2004 - that the major universities in the OAPI region have started offering a major course on intellectual property rights.[26] IP was often taught as a sub-set of international trade law or commercial law. In addition, OAPI was not very interested in research and did very little in terms of promoting intellectual property rights, be it at the national or the regional level. As a result, there was very little interest on the part of the public, lawyers, judges and NGO representatives to get involved in IP issues. This is one of the reasons why there was a very low involvement of these groups during the negotiations of the successive Bangui Agreements.[27]

However, the tide began to turn in mid-2000 with the inauguration of a training centre at OAPI and the creation of a course on intellectual property rights at the University of Yaoundé II, sanctioned in partnership with OAPI. This notwithstanding, more still needs to be done. For instance, OAPI should actively engage universities in other countries and develop curricula on IP, generally, and its impact on access to medicines, more specifically. One of the ways to implement such engagement might be by starting and sponsoring clinical research and advocacy projects at local universities.

In addition, universities could be encouraged to develop courses in IP, human rights and access to medicines. The primary goal of such courses would

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[26] The first fully-fledged postgraduate programme in intellectual property rights in the OAPI region only commenced in Cameroon in 2004 when the University of Yaoundé launched a Master's degree in IP law.

[27] See ch 4 which contains a detailed analysis on why NGOs did not actively participate when the Bangui Agreement was being revised in 1999.

be to conduct training on access to medicines and the right to health for post-graduate students, legal practitioners, government officials and parliamentarians from across the OAPI region. The training will focus on the human rights implications of the international trade regime. It will examine the intellectual property flexibilities that are necessary to meet public health requirements, including those permitting compulsory licensing, parallel importation and local or regional production.

OAPI might encourage universities to learn from the University of Pretoria that has developed specialised short courses on many topical and thematic issues, including IP, human rights and access to medicines. One-week short courses are a standard feature of the Centre for Human Rights' LLM and Advanced Human Rights Short Courses programmes.[28] The courses are taught in intensive format through six to eight hours of classroom instruction per day with a graded examination on the afternoon of the last day. Borrowing this format from the University of Pretoria, universities in the OAPI region might structure such a course so that it has the equivalent class time of a two-credit seminar (approximately 28 hours).[29]

Lecturers in such courses could be drawn from NGO representatives and academics in the Central African sub-region. At a later stage, the institutionalisation of the course within the faculties at these universities would be considered so as to ensure sustainability.

5.2.7 OAPI countries should actively participate in international trade fora

OAPI member states have not actively participated in international trade fora such as the WTO, unlike their East and Southern African counterparts, in terms of

[28] For more information on the Centre for Human Rights and its short courses, visit http://www.up.ac.za/chr.

[29] A particular advantage of the format is the ability to attract professionals for a week of instruction that may not be available for a longer period.

making contributions to debate or making a case for particular positions. During the negotiations of the Doha Declaration and the August 2003 Decision on medicines, Zimbabwe and Kenya played significant roles under the banner of the Africa Group.[30] In fact, at the level of the WTO, the Africa Group took centre stage in pressing for reforms that would facilitate access to medicines.[31] This has not been the case with OAPI member states.[32]

The advantages of taking centre stage in such fora are many and varied and include a clearer understanding of the issues; a clearer articulation of problems and concerns relative to access to medicines; as well as the creation of an enabling atmosphere for collaboration with civil society organisations and NGOs that will be in the position to support and provide inputs to their respective governments' and regions' positions. In addition, the involvement in such fora will generate support for particular positions and policies from LDCs and developing countries facing similar problems and concerns.

5.2.8 Synergy between regional trade and human rights organisations should be ensured

There are many regional trade organisations to which OAPI member states belong. For instance, Chad, Cameroon, Gabon, Central African Republic, Equatorial Guinea and the Republic of Congo belong to the Central African Economic and Monetary Community (CEMAC), while Benin, Côte d'Ivoire, Togo, Senegal, Mali, Burkina Faso, Niger and Guinea belong to the Economic Community of West

30 As discussed in ch 2 and 3, during the negotiations of the Doha Declaration between 2000 and 2001 and the August 2003 deal, Zimbabwe and Kenya played a key role in mobilising African countries under the Africa Group at the level of the WTO.

31 T Kongolo 'WTO Doha Declaration and intellectual property: African perspectives' (2002) *African Yearbook of International Law* 185-201.

32 In fact, there is no evidence that OAPI countries were particularly active as part of the Africa Group during the negotiations of the Doha Declaration. See TRIPS and Public Health, submission of the Africa Group and other developing countries to the Special TRIPS Council Meeting of June 2001, 5, http://www.twnside.org.sg/title/twr131d.htm (accessed 12 June 2012). See also J Gathii 'The legal status of the Doha Declaration on TRIPS and public health under the Vienna Convention on the Law of Treaties' (2002) 1 *Harvard Journal of Law and Technology* 296.

African States (ECOWAS). These trade organisations deal with intellectual property issues and enter into intellectual property rights negotiations, especially in bilateral trade agreements.[33] In many cases, their intellectual property negotiation mandates and agenda are not aligned with those of OAPI. As such, these organisations could enter into binding treaties that provide more stringent intellectual property protection than the OAPI Bangui Accord. For instance, these organisations are currently negotiating economic partnership agreements with the EU that may subsequently include stringent IP provisions. The finalisation of such regional treaties might impact on access to medicines initiatives, especially if they contain TRIPS-plus provisions.

It is therefore recommended that OAPI as an institution should exchange and constantly share experiences with CEMAC and ECOWAS, especially on the relationship between IP and access to medicines. The advantage of this approach is that OAPI may benefit from the international trade and negotiation experiences of these organisations, and these organisations may in turn learn and appreciate more of what OAPI is doing and may better align their programmes with that of OAPI. In addition, OAPI should also liaise and work together with regional human rights and health organisations, such as the African Commission, regional UN offices and the regional WHO office in Brazzaville. Knowledge gained from working and interacting with these institutions will help OAPI to take a human rights approach to the framing, drafting, articulation and implementation of its patent policies that relate to access to medicines.

5.2.9 The dangers of economic partnership agreements, in respect of CEMAC and UEMOA, should be recognised

OAPI members that belong to CEMAC and ECOWAS are currently negotiating economic partnership agreements (EPAs) with the EU. Following the attainment

[33] Eg, in the negotiations of economic partnership agreements with the EU, African countries negotiated as regional blocs with the EU.

of independence by most ACP countries, the European Economic Community (EEC) entered into a series of trade and development agreements with its former colonies. This was evident from the entry into force of the Yaoundé, Lomé and Cotonou Agreements. In these agreements, the EU granted ACP countries unilateral trade preferences on agricultural produce.

With the expiry of the last Lomé Agreement imminent, the EC proposed a new trade and development regime. The Cotonou Agreement, entering into force in 2000, envisaged the creation of reciprocal trade agreements between the EU and regional blocks of ACP countries by establishing so-called economic partnership agreements. EPAs are supposed to be asymmetrical trade agreements covering not only trade in goods and services, but other issues, such as competition, government procurement and intellectual property. Regarding intellectual property, the EU included it in the EPAs with Caribbean countries. One of the dangers of IP provisions in the EPAs would be that African countries (including OAPI member countries) could be pushed to agree to higher levels of patent protection than required by the WTO. In addition, the EU may push for stringent IP enforcement and border measures which, if implemented, may negatively affect access to medicines. For instance, border measures may make it difficult for generic medicines to transit through EPA signatory countries to the importing countries. Such generic medicines can be seized or generic importers may be required to fulfil burdensome administrative and regulatory requirements to import generic medicines. Taking into account the dangers the EPAs may pose in inhibiting access to medicines, it is recommended that OAPI member states do the following:

(i) Since proposed bilateral and regional free trade agreements could limit the ability of developing countries to use the TRIPS flexibilities, governments in both developed and developing countries should ensure that all free trade agreements comply with the principles of the Doha Declaration.[34]

34 http://www.unaids.org/en/media/unaids/contentassets/documents/pressrelease/2011/20110315_

(ii) Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.

(iii) A public health justification should be required for data protection rules, going beyond what is required by the TRIPS agreement.

In a worst case scenario, OAPI member countries should refuse to enter into any agreement having intellectual property provisions, and should refer any negotiations to the negotiation at the TRIPS Council at the level of the WTO.

5.3 How the recommendations stated above can be taken forward

The recommendations discussed above could be taken forward by:

(i) actions at the national level;
(ii) actions at the regional level;
(iii) actions at the continental level; and
(iv) actions at the international level.

5.3.1 Actions at the national level

At the level of OAPI member states, a number of action points can be pursued. This will mean activism by every branch of government of member states and active involvement by civil society organisations.

As has been discussed above, OAPI leaves certain policy spaces for its member states. The member states can make use of these spaces and enact access to medicine-friendly laws. For example, the ministries of health and commerce could come together and set out a policy document that would

PR_TRIPS_en.pdf (accessed 1 February 2014). See also World Health Assembly (WHA) Resolution 57.14.

encourage the grant of compulsory licences. First, administrative units could be set up with personnel trained in the issuing of compulsory licences. In addition, the document detailing the ways of issuing compulsory licences would have to be written in clear and simple language, accessible to all.

In addition, member states should reform their criminal laws and reduce sanctions for intellectual property violations, especially where it is not wilful.

Furthermore, the parliaments of member states should be vocal in requesting reforms of the Revised Bangui Agreement. Ministers who sit on the OAPI Board of Directors should be brought to task and should answer questions as to why the current OAPI regime has not been reformed to promote and protect access to medicines.

5.3.2 Actions at the regional level

There should be a co-ordinated approach at the regional level in terms of hamonisation of trade policies. OAPI countries should ensure that they have the same position in the negotiation of any bilateral investment treaty introducing stringent intellectual property rights protection which could be detrimental to access to medicine initiatives. OAPI member countries should exchange ideas on trade policy initiatives, especially policies dealing with intellectual property rights.

Local civil society organisations involved in access to medicine issues should reach out to their counterparts in other OAPI member states. This will ensure that there a common position and that a united front is taken when advocating for reforms.

5.3.3 Actions at the continental level

OAPI member countries should be active on the continental front. This would mean attending continental meetings on intellectual property rights and rights to health. They should also take an active part in the current discussions at the African Union for the creation of the Pan-African Intellectual Property Organisation.

In addition, civil society organisations from OAPI member countries should establish alliances with their continental counterparts, especially those from Eastern and Southern Africa that have been very active in access to medicine issues. This will ensure that civil society organisations from OAPI member countries exchange notes and advocacy materials and learn from best practices from their Eastern and Southern African counterparts.

5.3.4 Actions at the international level

OAPI member countries should very attentively follow intellectual property and access to medicine developments in other parts of the world, such as India and Brazil. These two countries have been very active in access to medicine debates, either through national litigation or the enactment of national legislation, and have vibrant generic medicine-manufacturing companies. OAPI members could learn from the intellectual laws and policies that have been put in place by these countries.

In addition, OAPI member countries should be very active in multilateral discussions on intellectual property rights, especially at WTO TRIPS Council meetings and discussions. Active participation would cause them to be abreast of current developments and will give them the chance to make inputs in Council discussions. Furthermore, it will give them the opportunity to align their interests with the Africa Group.

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Annex 1: List of questions[35] and interviewees

Questions

A) Revised Bangui Accord

1 What were the reasons for the revised Bangui Accord, especially the patent (relating to public health) provisions?

2 Have the reasons/expectations been achieved?

3 Were citizens and non-governmental organisations (NGOs) from the OAPI member countries consulted during the negotiations and drafting of the revised Bangui Agreement? If yes, how successful were their contributions?

4 Do you think that the revised Bangui Agreement has increased foreign direct investment in Francophone African countries?

B) Role of foreign countries and international organisations and institutions

1 Do you think foreign countries and international organisations/institutions were involved in the negotiations and drafting of the revised Bangui Agreement? If yes, which ones?

2 What do you think were the reasons for their involvement?

3 Was their involvement/participation necessary?

4 Would the outcome of the negotiations and the final text of the revised Bangui Agreement have been different without the participation of foreign countries and international organisations/institutions? If yes, why?

C) Role of national intellectual property co-ordinating offices

1 In your opinion, do you think national intellectual property offices were involved in the negotiations and drafting of the Revised Bangui Agreement?

2 How successful was their involvement?

D) General questions

1 From a public health and access to medicines perspective, what are the advantages and disadvantages of having OAPI regulating intellectual property in many Francophone African countries?

[35] Note that the questions were open-ended and were used as guidelines depending on the individuals. They were not structured as they could change depending on the answers given.

2 Has regionalisation of intellectual property promoted access to medicines?

3 Do you know whether there have been efforts from OAPI to conduct research/study on the impacts of its patent provisions on access to medicines in its member countries?

Interviewees

1 Constantin Ondoa, OAPI Certified IP Lawyer, Douala, Cameroon and former student of the OAPI/University of Yaoundé IP Academy

2 Denis Abessolo, OAPI Certified IP Lawyer, Douala, Cameroon and former student of the OAPI/University of Yaoundé IP Academy

3 Halleson Durrell, IP and Environmental Lawyer, World Wide Fund for Nature, Cameroon, formerly of the South African Institute of International Affairs

4 Dr Maurice Betanga, General Counsel, OAPI

5 Professor Tshimanga Kongolo, World Intellectual Property Organisatio,

6 A former consultant (would like to remain anonymous) with Medecins Sans Frontières' access to medicines campaign

7 Pagob Aurelien, Legal Officer OAPI

8 Dr Stephen Kingah, Professor, United Nations University, Brugge, Belgium and former researcher on EU and African Trade Relationship at the EU headquarters, Brussels, Belgium

9 Anonymous forms completed by some of the 2009, 2012 and 2013 LLM students at the Centre for Human Rights, University of Pretoria, on what they thought were the problems of access to medicines in Africa and why

10 Emmanuel Chesami, Commonwealth Trade Policy Analyst, Mauritius

11 Discussions with students from the University of Buea (during a lecture in March 2013)