ACCESS TO ART AND OTHER ESSENTIAL MEDICINES IN SUB-SAHARAN AFRICA: INTELLECTUAL PROPERTY AND RELEVANT LEGISLATIONS

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EXECUTIVE SUMMARY

Despite major medical breakthroughs there are still significant inequalities in the health status of people between developed and developing countries as well as within developing countries. The case of HIV/AIDS in Sub-Saharan Africa is particularly striking. Though life-prolonging treatments for HIV/AIDS have been available for many years only in the last few years did it become a realistic option for most in Sub-Saharan Africa. Even then, of the over 4.6 million people needing antiretroviral therapy (ART) only 1.04 so far had access to these treatments by the end of 2006.

One major reason for this dismal rate of access to ART in Sub-Saharan Africa relates to the costs of providing the medicines. The cost remained very high for quite a long time and though the cost of first-line treatments has dropped significantly in the last five years the cost of second-line treatments remains prohibitive. To a large measure the high prices are because of the monopoly privileges granted under patent protection. Mandatory patent protection for pharmaceutical products became the global norm based as a result of the rules under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This is the reason why a major part of the efforts to lower the prices of ART and hence improve the level of availability and accessibility has focused on removing the barriers related to patent protection to pharmaceutical products and processes under TRIPS by using the in-built flexibility in the Agreement. These flexibilities permit governments and other stakeholders to deal with the negative consequences of patent protection.

However, a combination of technical and political factors has made it difficult for developing countries including Sub-Saharan African countries to utilise the TRIPS flexibilities to improve access. The Doha Declaration on the TRIPS Agreement and Public Health adopted by the Fourth WTO Ministerial Conference in 2001 was meant to address some of these challenges. The Declaration clarified that all WTO Members had the right to use these flexibilities to the full to promote access. However, obstacles still remain. Looking at the prevalence and treatment figures above, it is clear that nowhere is it more important than Sub-Saharan Africa to utilise the TRIPS flexibilities to improve access to ARVs and other essential medicines. Consequently, there is an important need examine more closely how Sub-Saharan African countries have dealt with these flexibilities in their legislations. This was the objective of this report.

Based on a review of the national legislations of 39 out of the 47 Sub-Saharan African countries, this report finds that though most of the countries, including least-developed countries (LDCs), provide patents for pharmaceutical products, the level of incorporation of the flexibilities in these legislations is very low. In general, a significantly low number of countries have taken advantage of the flexibilities under the TRIPS Agreement to: exclude new use pharmaceutical patents; to implement an international exhaustion regime on patent rights to permit parallel imports from anywhere in the world; to exempt research activities from patent infringement actions; permit the early working (bolar) exception; and to limit the level and type of test data protection. While all the 39 countries provide for compulsory licenses on various grounds and most have government use provisions in their legislations, the actual use of even these two flexibilities remains limited. It notable, however, that full information is not available on the legislative status of the flexibilities in most of the Sub-Saharan African countries. In this regard, though this report makes an important contribution in improving the level of knowledge and has laid a good baseline, significant work remains to be done

understand and improve the legislative uptake of most of the flexibilities as well as their actual use to improve access to ART and other essential medicines.

In light of the above findings and conclusion the report recommends further research, in particular empirical and field research to:

1. Provide a fuller picture on the relevant IP and others laws which have implications for access to ART and other essential medicines;
2. Clarify the extent of the incorporation of the various public health-related TRIPS flexibilities in the relevant laws especially with respect to the 8 countries whose laws were not reviewed due to various difficulties in accessing up to date information or lack of such law; and
3. Determine the actual extent of usage of these flexibilities, their impact on the access situation in the countries and the challenges that may face particular countries in using these flexibilities.

The results in this report also show that interventions by various technical assistance providers such as UNDP in the various Sub-Saharan countries, particularly those that are in the process of reviewing their IP legislations relevant to access to medicines could have significant impact. A focus on the situation in LDCs as well as key countries especially where the incidences of HIV/AIDS are high or rising would also be an area of early action. Additionally, considering the dynamic nature of the laws in this area and the on-going changes occasioned both by TRIPS and other Agreements including FTAs and possibly EPAs, continuous monitoring of developments nationally, regionally and internationally will be required. Also periodic review and updating of Annex 1 and 2 of this report is recommended.

I. INTRODUCTION

The development of antiretroviral therapy (ART) for the treatment of HIV/AIDS, the development of cloning technology, developments in stem cell research, the mapping of the human and other animal genomes, among other breakthroughs in medical research have provided increasing hope for the realization of the right to health in Africa and the rest of the developing world.[1] Despite these major medical breakthroughs, however, there are still significant inequalities in the health status of people between developed and developing countries as well as within developing countries. The case of HIV/AIDS in Sub-Saharan Africa is particularly striking.

As of December 2006, an estimated 39.5 million people were living with HIV/AIDS globally.[2] Sub-Saharan African countries, home to only 10% of the world's population, remained the worst affected with 63% of global HIV/AIDS cases (approximately 24.7 million people) occurring in the region.[3] The levels of prevalence are, however, different across Sub-Saharan Africa with South and East Africa being the worst affected regions. On the other hand, most countries in the West Africa region report a steady HIV/AIDS prevalence rate of between 1-4% though the rates are increasing in countries like Côte d'Ivoire and Mali. In Central Africa, the picture is mixed. For countries like the Central African Republic the infection rate is as high as 11% in the adult population. In Cameroon, on the other hand, the prevalence rate is 5%. Figure 1 below shows the different prevalence rates across Africa.

Unlike before when HIV/AIDS infection spelled death within a short time period after the infected person developed full blown AIDS, the availability of ART provides hope for longer lives for those infected in Africa. Of the over 6 million people living with HIV/AIDS who need ART, over 4.6 million live in Sub-Saharan Africa. However, of those, only 1.04 had access to ART by December 2006.[4] A major reason for this dismal rate of access to ART relates to the costs of providing these medicines. The prohibitive cost of HIV/AIDS and other important essential medicines in the management of the disease is well known and documented.[5] The high prices have seriously compromised the ability of communities, governments and other players to effectively manage the disease. Consequently, over last several years major efforts have been underway to make

[1] The right to health is recognised in Article 25 of the Universal Declaration of Human Rights (UDHR), which provides that: "everyone has the right to a standard of living adequate for the health of himself and his family, including food, clothing, housing and medical care and necessary social services." The concept of health under the UDHR is further defined and given legal standing in international law by Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12.1 of the Covenant recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". Other treaties recognise the right in similar terms including the Constitution of the World Health Organization (WHO).

[2] See the UNAIDS Update on the Global Epidemic of December 2006, available at: http://data.unaids.org/pub/EpiReport/2006/2006_EpiUpdate_en.pdf.

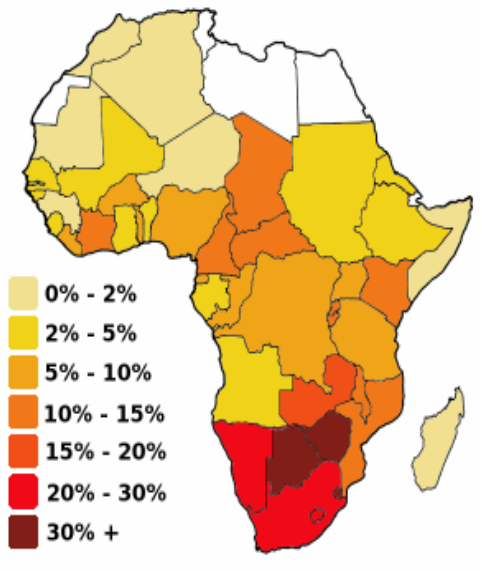
[3] *Id*.

[4] See Tenu Avafia, Jonathan Berger and Trudi Hartzenberg "The ability 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" *TRALAC Working Paper 12/2006* (ICTSD, UNCTAD and TRALAC, Stellenbosch, August 2006), p.1.

[5] See e.g., Médecins sans Frontières (MSF) Access to Essential Medicines Campaign, *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*, 8th Edition, (MSF, Geneva, June 2005).

ART more accessible for developing countries and for poor people especially in Africa.[6] A major part of these efforts has focused on removing the barriers related to patent protection for pharmaceutical products and processes under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[7]. Patent protection under the Agreement which requires the grant of monopoly rights over such pharmaceutical products as medicines for at least 20 years, in particular, inevitably translates into higher prices.

Figure 1: HIV/AIDS Prevalence rates in Africa



Source: UNAIDS 2006

[6] Sisule Musungu, Susan Villanueva and Roxana Blasetti, *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks*, (South Centre, Geneva, 2004), p. 2.

[7] The TRIPS Agreement was adopted as part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations in Marrakesh, Morocco on 15 April 1994. For the full text of the Agreement see WTO, *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations*, (Cambridge University Press, Cambridge, 1999) pp. 320-353.

Recognising and taking into account the significant literature that exists on this subject[8], this report, seeks to review the status of IP and relevant legislation, including legislation being drafted or planned, in Sub-Saharan African countries and their implications for access to ART. The aim of the report is to facilitate better understanding of the state of relevant intellectual property (IP) legislation in Sub-Saharan Africa, the impacts or potential impacts on access to ART and other related essential medicines and to lay a baseline for future analyses. The question the report seeks to address is the following: How have Sub-Saharan African countries approached the question of public health flexibilities in their legislations and what gaps, if any, exist to ensure that the legislations in these countries are supportive of efforts to ensure increased access to ART and other essential medicines such as medicines for opportunistic infections? Among other reasons, answering this question would allow UNDP, which commissioned this study, to better plan its interventions for the region in this area as well as provide crucial information for other stakeholders including civil society organisations in various Sub-Saharan Africa countries.

The report is divided into four main parts. Following this introduction, Part II provides a brief overview and context to the international debate and issues relating to the TRIPS Agreement and access to essential medicines. Part III then provides an analysis of legislation in Sub-Saharan Africa examining the status particularly with respect to the incorporation in those legislations of public health-related flexibilities. The analysis in Part III is based on the detailed information contained in Annexes 1 and 2 to the report. Annex 1 contains detailed information on relevant legislations and availability of patents for pharmaceutical products in Sub-Saharan Africa. Annex 2 contains detailed information on the relevant provisions relating to various public health-related flexibilities. Part IV completes the paper with some conclusions and recommendations for further work and monitoring.

[8] There exists extensive literature on the TRIPS Flexibilities, the Doha Declaration as well as follow-on decisions and it is not necessary to rehash this here. See e.g., Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights* (WHO, Geneva, 2006); Sisule Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* (South Centre and WHO, Geneva, 2006); UNCTAD and ICTSD**,** *Resource Book on TRIPS and Development*, (Cambridge University Press, New York, 2005); Carlos Correa "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", *Health Economics and Drugs, EDM Series No.16* , Essential Drugs and Medicines Policy, (WHO, Geneva, 2004); Paul Vandoren and J. Van Eeckhaute, "The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health-Making it Work", *6 J.W.I.P.*, 779-793 (2003); Commission on IPRs, *Integrating Intellectual Property Rights and Development Policy* (Commission on IPRs, London, 2002); Carlos Correa, "Implications of the Doha Declaration on the TRIPS Agreement and Public Health", *Health Economics and Drugs, EDM Series No. 12*, Essential Drugs and Medicines Policy, (WHO, Geneva, June 2002); Susan Sell "TRIPS and the Access to Medicines Campaign", *Wisconsin International Law Journal*, Vol. 20, No. 3, 481 (2002); and Frederick M. Abbott, "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference", *Occasional Paper 7*, (Quakers United Nations Office, Geneva, September 2001).

II. THE TRIPS AGREEMENT AND ACCESS TO ART AND OTHER ESSENTIAL MEDICINES

The TRIPS Agreement, as part of the World Trade Organization (WTO) framework of multilateral trade agreements puts in place minimum standards for the protection of IP including in the area of pharmaceuticals. These minimum standards have resulted into a significant loss of policy flexibilities by African and other developing countries in regulating the granting and use of pharmaceutical patents and controlling the cost of medicines. For this reason, since the coming into force of the TRIPS Agreement in 1995 and particular in the late 1990s when all developing countries were required to implement its provisions, there has been an intense debate and research on the impact of the TRIPS Agreement on access to essential medicines as well as other essential products such as seeds.

This debate and research has focused on the use of flexibilities that is, taking advantage of the exceptions and limitations to patent rights, compulsory licensing and using the other permitted mechanisms under TRIPS to improve the availability as well as affordability of essential medicines. The focus on flexibilities is logical since the Agreement envisages a balance between the enjoyment of the benefits accruing to the users and producers of technology. It is the flexibilities which guarantee the balance between the rights conferred under Article 28 of TRIPS and the interests of consumers, competitors and the public at large as envisaged in the objectives of the Agreement under Article 7.

The general obligations of WTO Members under the TRIPS Agreement, including their obligations relating to the IP protection for pharmaceutical products are defined in Article 1. Paragraph 1 of the Article provides *inter alia* that WTO Members "may, but shall not be obliged to, implement in their law more extensive protection than is required…" and that they "shall be free to determine the appropriate method of implementing the provisions" of the Agreement. This means that the TRIPS Agreement establishes mandatory minimum standards for IP protection for WTO Members and nothing more. It also means that where there are no prescriptive rules in the Agreement on how to approach a particular issue, say parallel imports, provided the minimum standard is met, each country is free to approach the issue in light of its priorities and national imperatives including access to medicines priorities. This provision, read together with the Preamble and the objectives of the TRIPS Agreement under Article 7 therefore underpins the idea of flexibilities in formulating national legislations.

Notwithstanding the availability of flexibilities and the clear wording of Article 1 of the Agreement, however, these flexibilities have not been used to the full to improve access to essential medicines. The limited use and impact of the flexibilities in improving access can be explained partly by the technical and political challenges which developing countries including African countries face. One of the main challenges at the outset related to defining the scope and interpretation of the flexibilities. Though the language in TRIPS appeared clear, there was significant pressure from major pharmaceutical companies backed especially by the government of the United States for developing countries either not to use the flexibilities or to interpret them very narrowly. It is this pressure and disputes about interpretation which led to the filing of the case in the High Court in South Africa by 39 pharmaceutical companies challenging the South African Medicines Act, 1997 which among other things dealt with generic substitution and parallel imports. Apart from the legal challenge which was later withdrawn in the face of mounting international public outcry, the United States Trade Representative (USTR) had listed South Africa as a priority country in the Special 301 Report leading to

limited sanctions and pressure on the South African government.[9] At the same time, the United States had also filed a WTO case (which was later withdrawn also partly to the mounting public discussion on the impact of United States policy on access to medicines in developing countries) challenging the Brazilian law relating to local working requirements for pharmaceutical patents.[10]

The question on the scope and interpretation of the TRIPS flexibilities was largely resolved by the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration)[11] which affirmed that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement should be used to this end. In particular, the relationship between the TRIPS Agreement and public health (access to medicines) was expressed as follows:

> "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."[12]

Apart from setting out this general approach to public health in the implementation and enforcement of the TRIPS Agreement, the Doha Declaration also gave direction on how to interpret the provisions of the TRIPS Agreement generally and specific clarifications on compulsory licenses and exhaustion of rights. Further, it recognised the challenges faced by Members with insufficient or no manufacturing capacity in the pharmaceutical sector in using compulsory licenses[13] and addressed the special case of LDCs[14].

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[9] See Correa, Sell and Abbot, *supra* note 8.

[10] Also see Correa, Sell and Abbott, *supra* note 8.

[11] The Declaration was adopted at the Fourth Session of the WTO Ministerial Conference in Doha, Qatar on 14 November 2001. See WTO document WT/MIN(01)/DEC/W/2.

[12] Para 4 of the Declaration, *id*.

[13] Paragraph 6 provides that "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002." Though the end of 2002 deadline was missed, the WTO General Council has made two important decisions to implement this paragraph. First in August 2003 the General Council adopted a Decision waiving certain Article 31 obligations and establishing a mechanism to facilitate the import, by countries without manufacturing capacities, pharmaceutical products under compulsory licenses. The Decision, invariably referred to as the paragraph 6 Decision or 30 August 2003 Decision is contained in WTO Document WT/L/539 and Corr. 1 dated 1 September 2003. This decision was adopted as an interim measure pending an agreement on a permanent solution. Subsequently, in November 2005, the General Council adopted a Protocol amending Article 31 of the TRIPS Agreement to incorporate the elements of the 30 August 2003 Decision into the text of the TRIPS Agreement. The protocol is contained in WTO Document WT/L/541 dated 5 December 2005.

However, in addition to the challenge of determining the scope and interpretation of the flexibilities and the use of compulsory licensing for countries without manufacturing capacities in the pharmaceutical sector, there are other challenges that face Sub-Saharan African countries and other developing countries including lack of national and/or regional technical expertise to effectively implement the flexibilities, bilateral and other pressures not to use the flexibilities for public health purposes, lack of political will, and difficulties in obtaining pricing and patent status information.[15] Because of these and other new challenges such as those that arise because of a new wave of Free Trade Agreements (FTAs) as well as the European Communities (EC) and African, Caribbean and Pacific (ACP) Economic Partnership Agreements (EPAs) the debate on IP and access to medicines continues.[16]

The enduring nature of the debate about the effects of IP on access to medicines underscores two important factors. First, it demonstrates the central importance that health plays in every society and the challenges many countries face in fulfilling and ensuring the enjoyment of the right to health. Secondly, the debate underscores the sensitivity of health care products and services to monopoly pricing which is an inevitable consequence of patenting in the pharmaceutical sector.

III. INTELLECTUAL PROPERTY AND ACCESS TO ART AND OTHER ESSENTIAL MEDICINES IN SUB-SAHARAN AFRICA: ANALYSIS OF RELEVANT LEGISLATIONS

The majority of Sub-Saharan African countries, 39 out of 47 were found to have IP statutes (mainly patent /industrial property laws) relevant to access to ART. Of the 39, 26 are LDCs while 13 are developing countries. 35 of out of the 39 are WTO Members while four; Ethiopia, Equatorial Guinea, Liberia and Sudan are not. Ethiopia and Sudan, both LDCs, are in the process of accession to the WTO. 16 out of the 39 are members of African Intellectual Property Organization (OAPI) and hence signatories to the Bangui Agreement on the Creation of an African Intellectual Property Organization.[17] Another 14 are member of the African Regional Intellectual Property Organization (ARIPO) and hence signatories to the

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[14] On LDCs, paragraph 7 of the Declaration provides *inter alia* that "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. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement." Following this instructions the TRIPS Council adopted a Decision in June 2002 extending the transition period for LDCs with respect to implementing patent protection for pharmaceuticals until at least 2016. The Council for TRIPS decision is contained in WTO document IP/C/25 dated 1 July 2002.

[15] For a discussion of some of these challenges see e.g., Musungu *et al, supra* note 6.

[16] For a discussion on the implications of bilateral Agreements on public health see e.g. Musungu and , *supra* note 8; Pedro Roffe and Christophe Spennemann "The Impact of FTAs on Public Health Policies and TRIPS Flexibilities", *International Journal of Intellectual Property Management,* Vol. 1 Nos. 1/2, 2006; and generally http://www.bilaterals.org.

[17] The Bangui Agreement was signed in 1977. It was then revised in 1999 to make it compliant with the provisions of TRIPS. The text of the Agreement and further information about OAPI is available at: http://www.oapi.wipo.net/fr/OAPI/index.htm.

Harare Protocol on Patents and Industrial Designs.[18] The Bangui Agreement is effectively the national law of the Member States and addresses both matters of grant and exploitation (post-grant issues) including public health-related flexibilities.[19] The implications for the 16 OAPI countries is that if the Bangui Agreement does not incorporate a flexibility or otherwise approaches a particular flexibility in a narrow way, if the country does not promulgate a separate national law that would supersede the Bangui Agreement, then such lack of flexibility or narrow interpretation in the Bangui becomes a national problem affecting access to medicines. The Harare Protocol on the other hand addresses only matters relating to the grant of patents but leaves post grant matters to the national jurisdiction of each Member State. The impact of ARIPO membership is therefore felt at the level of determining the availability of patents for various products and processes.[20] In the case of pharmaceutical patents in particular membership of ARIPO has a bearing on the availability of patents for pharmaceutical products and processes as well as whether patents are granted for new uses of products.

Several Sub-Saharan African countries are developing and/or reviewing their industrial property or patent legislations. These include Angola (see WTO document WT/TPR/S/158/Rev.1)[21], Burundi (WTO document IP/N/1/BDI/1), Namibia (according to information obtained from the IP office), Nigeria (WTO document WT/TPR/S/147), Rwanda (WTO document WT/TPR/S/129), Sierra Leone (WTO document WT/TPR/M/143), Sudan, Tanzania (including Zanzibar) and Uganda. There are no patent legislations in Djibouti, Eritrea and São Tomé and Principe. Although Comoros is member of the Paris/PCT, no specific law on industrial property was promulgated after its independence from France.[22]

Cape Verde, Comoros, Ethiopia, São Tomé and Principe, Seychelles, and Sudan are in the process of acceding to the WTO. This means that they will be required to revise their laws in order to comply with the TRIPS Agreement and/or the demands from members of the working parties on the accession of each country. Comoros submitted its request for accession to the WTO only in March 2007 (see WTO document WT/ACC/COM/1). Ethiopia, and São Tomé and Principe are at the early stage of accession and discussion on the respective intellectual property legislation is very limited. Cape Verde confirmed to the Working Party on its accession that the Industrial Property Code, approved by Decree No. 30679 of 24 August 1939 of Portugal that was made applicable to Cape Verde by Ministerial Ordinance No. 17043 of 5 May 1959 will be replaced by a new law that shall be ready by December 2008 (see WTO document WT/ACC/CPV/9/Rev.2, June 2007). However, the draft is not currently

[18] Information about ARIPO including its Member States and the Lusaka Agreement establishing the organisation is available at http://www.aripo.org/articles.php?lng=en&pg=14. The total number of ARIPO members is also 16. However, the Gambia and Sierra Leone which are ARIPO Members are not included in the analysis in the report due to unavailability of information.

[19] Though OAPI Member States are free to promulgate their own national law, which would supersede the Bangui Agreement, on patents or make specific exceptions to the Bangui Agreement, none of the 16 countries has so far taken this approach.

[20] While the Harare Protocol permits Member States to not recognise patents granted by ARIPO on a case by case basis this is not common.

[21] Information on Angola was obtained from WIPO and IIPI, 2000, Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa, http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf. The 2006 Trade review indicate the Industrial Property Law No 3/92 of February 28, 1992 to remain the applicable law in Angola. (WT/TPR/S/158, Trade Policy Review, Angola, p. 15).

[22] WIPO, Country Profile from WIPO Guide to Intellectual Property Worldwide, Comoros, available at http://www.wipo.int/directory/en/region.jsp?region_id=1.

available.[23] Cape Verde was requested by the working party to explain 'whether Cape Verde permitted the registration of generic products; whether the applicant for a generic drug approval needed to provide the same data required for an original product, or could provide an abbreviated drug application; and whether Cape Verde had established any time period after registration of an original product during which generic applications would not be considered.' (See the Draft Working Party Report, WTO document WT/ACC/SPEC/CPV/5/Rev.1). The final report may contain commitment or indication as to whether Cape Verde will provide additional protection other than the protection against unfair competition for test data submitted for approval of pharmaceutical products. The last report on part of Seychelles with respect to intellectual property rights indicate that Seychelles is contemplating to replace the 1901 Patent Act (last amended in 1976) by a new patent law (see WTO document WT/ACC/SYC/8).

Sierra Leone reported that working groups on intellectual property rights and competition policy were being established to develop new legislation. The current Patents Act No. 21, Chapter 247, of 1924, (as last amended by the Laws (Adaptation) Act No. 29 of 1972) is obsolete or exists only on paper.[24] Members of the WTO have offered Sierra Leone technical assistance to support the drafting of legislation on and implementing the IP protection prior to the expiry of the transition period for LDCs. Considering the limited relevance of the existing law on patents in Sierra Leone, its status as LDCs in the WTO and the limited information available with respect to the laws, the study has excluded the analysis on Sierra Leone.

The Gambia has the Industrial Property Act of 1989 in place. However, several sources, including the WIPO database indicate that this law has not entered into force. The Gambia announced its plan to introduce legislation on patents, trade marks and industrial designs in 2004. Yet no laws are notified to the WTO (see WTO document WT/TPR/M/127). For this reason, the Gambia has also been excluded from the analysis.

As is clear, further empirical research will be required to clarify certain issues and gather fuller information on certain countries' legislation. As noted however, the research undertaken and the information gathered on the 39 out of the 47 Sub-Saharan Africa countries permits a reasonable assessment on the approach of these 39 countries to TRIPS flexibilities in the national and regional IP legislations. In the sub-sections that follow, the report reviews the availability of patents for pharmaceuticals and the incorporation of the various public health-related flexibilities, in the laws of Sub-Saharan Africa countries. The flexibilities examined include: the approach to patenting for new uses for pharmaceutical products; parallel imports; compulsory licenses; government use and ex-officio licenses; the research exemption; the early working (bolar) exception; and test data protection.

[23] See blog post at Spoor- Fisher, available at http://www.spoor.com/Publications/Articles/Trademarks/Pages/New_IP_Law_in_Cape_Verde.aspx.
[24] Sarah Perkins, "An analysis of TRIPS flexibilities in West African patent law regimes," (University of Toronto, Toronto, 2007), p. 5.

III.1 Availability of Patents for Pharmaceutical Products

Out of the 39 countries whose legislations were reviewed for this report, all but two, grant patents for pharmaceutical products. The two countries that appear to not grant patents for pharmaceuticals are Angola and Sudan. The latter, which is revising its industrial property law, though not a Member of WTO yet intends to maintain this situation invoking the Doha Declaration and the TRIPS Council decision extending the LDCs transition period with respect to pharmaceutical products till 2016.[25]

By virtue of Article 65.2 and 65.4 of TRIPS, all the developing countries WTO Members are required to make available patents for pharmaceutical products and processes. In that sense all Sub-Saharan Africa developing countries have complied with this obligation. What is striking about the results of the review of laws, however, is the failure of LDCs in Sub-Saharan Africa to take advantage of the 2016 extension to implement protection for pharmaceuticals. Of the 24 LDCs that are WTO Members from the region, only Rwanda, in the context of the paragraph 6 Decision, has declared that it will not enforce pharmaceutical patents. Other LDCs appears not to have taken any legislative measures to enable them take advantage of the extension decision to improve access to ART or other essential medicines. Considering that Africa and the LDCs were in the forefront of advocating for the Doha Declaration which led to the extension decision this fact requires further investigation to determine the reasons for failure to utilise this opportunity by LDCs. While the challenges of implementation outlined in the introduction to the report disproportionately affect LDCs, there is a significant amount of technical assistance that has been provided since the adoption of the Doha Declaration to enable LDCs better promote access to medicines. One would have hoped that this assistance would have made a bigger difference for these countries.

III. 2 Availability of New Use Pharmaceutical Patents

The TRIPS Agreement only requires that patents be granted to products and processes which are new, involve and inventive step and are industrially applicable. The Agreement does not require the patenting of new uses of known products including pharmaceuticals. Countries are therefore free to exclude such products from protection. The majority of the literature on the subject suggests that it is prudent that developing countries exclude new uses of known products or processes from patentability, in order to promote access to medicines. According to the UK IP Commission, “most developing countries particularly those without research capabilities should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products”.

This message from the Commission and other commentators appears not to have had an impact in Sub-Saharan Africa. A review of the legislations in the region indicates that out of the 39 countries reviewed for this report only four; Democratic Republic of Congo (DRC), Malawi, Namibia and Zambia have provisions relating to new uses or second uses. It appears in general that this flexibility has been hugely underutilised by Sub-Saharan African countries in their efforts to improve access to ART and other essential medicines. The reason for this situation are unclear but

[25] See WTO document IP/C/W/25 of 27 June 2002.

there is a clear need for interventions to determine whether this flexibility can be better utilised or if there are some other reasons to justify its underutilisation in the region. One reason for this situation might be related to the approach to this issue by both OAPI and ARIPO which grant new use patents.

III.3 Exhaustion Regime (Parallel Imports)

Exhaustion of IP rights refers to the point at which the IP holder loses legal control over a protected product by virtue of selling or otherwise releasing the product into the channels of commerce. With respect to pharmaceutical patents rights the rules on exhaustion determine whether the patent holder can prevent a third party from importing a pharmaceutical product from abroad in competition with the patent holder or his licensee (parallel import) where the patent holder or his licensee may have sold or released the product into commerce abroad. Exhaustion can be approached from: a national standpoint (where resell within the same country is permitted as in the case of the United States); regionally (where imports are permitted within a regional market as in the case of the European Union or OAPI countries); or international where the rights are exhausted with the placing of the product anywhere in the world market).

Provisions permitting parallel importation can be an important tool enabling access to affordable medicines because there are still substantial price differences for pharmaceutical products in different markets. Permitting some form of parallel imports provides opportunities to shop for better-priced pharmaceutical products for consumers in general and for the government as well. TRIPS and public health literature suggests that there are strong reasons why developing countries should avail themselves of the widest scope in terms of parallel imports and incorporate explicit provisions to put into effect an international exhaustion regime in their national patent laws.[26] In this regard, it is important to remember that while this flexibility exists under the TRIPS Agreement and was confirmed by the Doha Declaration, it does not automatically translate into the national regimes, and it is necessary for specific legal provisions be enacted in national or regional laws.

In Sub-Saharan Africa the use of this flexibilities, particularly in terms of permitting international exhaustion is also not very encouraging. Of the 39 countries whose laws were reviewed for this report, only six; Ghana, Kenya, Mauritius, Namibia, South Africa and Zimbabwe had clear provisions permitting international exhaustion with respect to pharmaceutical products. OAPI countries (16) have a regional exhaustion regime, while 7 other countries have a national exhaustion regime. The situation is unclear in the 10 remaining ones.

III.4 Compulsory Licenses

Compulsory licensing is an important policy mechanism that can be used to address a number of situations in the context of public health including, among others: high prices of medicines; anti-competitive practices; failure to locally work the patent; failure by pharmaceutical patent holders to sufficiently supply the market with needed medicines; emergency public health situations; and, the needs for establishing a

[26] See e.g., the literature referred to in note 8 above.

pharmaceutical industrial base.[27] Compulsory licensing is therefore important both for improving access to essential medicines as well as facilitating the development of innovative capacities and R&D especially in developing countries. For example, a local working requirement, which is a ground for the issue of such licenses, can be important for technology transfer.

The importance attached to compulsory licensing, at least on paper, is confirmed by the review of legislations in Sub-Saharan Africa. All the 39 countries whose laws were reviewed for this report have legislative provisions permitting compulsory licensing to address public health including access to medicines. However, the grounds upon which such licenses could be granted vary widely. Failure to work or insufficient working and failure to supply the domestic market sufficiently are grounds that appear widely across the laws. Overall, at the legislative level, it can be concluded that compulsory licensing is universally recognised as an important tool for improving access to ART and other medicines. Research shows, however, that the use of these licenses for public health purposes in Sub-Saharan Africa is limited raising questions as to whether there are other barriers to effective use.[28]

One barrier which was recognised by WTO Members as impeding effective use of compulsory licensing to improve access to essential medicines including ART is lack of manufacturing capacity in the pharmaceutical sector. This problem was addressed by the 30 August 2003 Decision implementing paragraph 6 of the Doha Declaration[29] and the subsequent amendment to TRIPS in November 2005[30]. From the review of laws no clear picture emerged as to how Sub-Saharan African countries have dealt with incorporating the solution to the paragraph 6 problem into their national legislations. Overall, it appears that none of the 36 Sub-Saharan WTO Members whose laws were reviewed for this report had taken any legislative measures either to implement the 30 August 2003 Decision or to ratify the Protocol amending the TRIPS Agreement. This conclusion is supported by the fact that, except for Rwanda, no Sub-Saharan African country has notified on the WTO website intention to use the paragraph 6 mechanism. None of the 36 countries have notified ratification of the amendment Protocol.[31]

III.5 Government Use and Ex-Officio Licenses

The right of the state to use a patent without the consent of the patent holder (government use or ex-officio licenses) for public health and other public interest purposes is recognized to be an important safeguard by many countries. As in the case of compulsory licensing, this TRIPS flexibility is important both for improving access to essential medicines as well as facilitating the development of innovative capacities and R&D.

[27] For detailed discussion see e.g., UNCTAD and ICTSD and Musungu and Oh, *supra* note 8.
[28] For a discussion on the use of compulsory licensing in developing countries for public health purposes see e.g. Musungu and Oh, *supra* note 8.
[29] *Supra* note 13.
[30] *Supra* note 13.
[31] The status of notifications under the 30 August 2003 Decision is available on the WTO website at: http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm. Information with respect to ratification of the amendment is available at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

The importance of this policy tool is also underscored by Sub-Saharan African country legislations. Although, the legislative status on this flexibility is unclear in 5 countries, 34 countries out of the 39 have specific provisions on government use or as in the case of OAPI countries ex-officio licenses. Again, as in the case of compulsory licensing, Sub-Saharan African countries widely recognise the importance of the flexibility, at least on paper. The actual use of the flexibility, in particular for public health purposes, however, also remains relatively low. Further, research would be required to determine the reasons, beyond the challenges highlighted in the introduction to this report for this low uptake. One reason for the low use, at least in the case of ART may relate to the high levels of donation schemes that currently exist in Sub-Saharan Africa.

III.6 Research Exemption

The research exemption, which is a permissible exception under Article 30 of the TRIPS Agreement, is aimed at ensuring that scientific research aimed at generating new knowledge is fostered and is not impeded by patents. The exemption is also justified on the basis that one of the main aims of patent laws is to facilitate the dissemination of knowledge, promote innovation and thereby facilitate the advancement of science. It is an exception to patent rights that has along history. In the context of public health and access to ART, the research exemption is an important tool in fostering pharmaceutical technological progress and innovation. In some jurisdictions such as the United States, the exemption has traditionally been judicially determined while in other jurisdictions such as Japan, it is a statutory exemption.

In Sub-Saharan Africa of the 39 countries whose laws were reviewed in the report, 28 had specific provisions on the research exemption. The majority of these legislative provisions exempt scientific research and use of patents for experimental purposes from infringement suits. In a number of cases a broad exception exempting all acts undertaken for non-commercial purposes is included in the laws. In the 11 other countries the research exemption is either unavailable or its status is unclear. Further field research will be required to clarify the situation.

Notwithstanding its long history and its importance, however, there is little empirical evidence regarding its impact on domestic R&D generally or in the pharmaceutical sector particularly in developing countries including Sub-Saharan African countries.[32] One challenge relates to the approach to the research exemption based on the commercial/non-commercial dichotomy. An approach based solely on a commercial/non-commercial dichotomy fails to sufficiently account for economic and practical realities of modern research in universities and other research institutions.[33] For those countries currently reviewing or developing their patent laws this might be an issue that requires additional attention and discussion.

[32] Kevin Iles "A Comparative Analysis of the Impact of Experimental Use Exemption in Patent Law on Incentives to Innovate", *Northwestern Journal of Technology and Intellectual Property, Vol 4, No. 1, pp. 61-82* (2005), p. 62.
[33] Iles, *id.*

III.7 Early Working (Bolar) Exception

The early working exception relates to a situation where a potential competitor or other entities use an invention without the authorisation of the patent holder to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term. The exception is intended to ensure that generic versions of the product are available on the market immediately or within a reasonable time after the expiry of the patent. This exception has important benefits for ensuring access to ART and other essential medicines in Sub-Saharan Africa and elsewhere in the developing world. Indeed, the exception is of critical importance also to developed countries as the *Canada Generics* case demonstrates.[34] Generic competition is known to bring down the price of medicines by up to 90% and hence facilitating the quick entry of generics to the market has huge benefits. The early working exception can also be useful in facilitating compulsory licensing by permitting generic manufacturers to test and register their products early.

The importance paid to this flexibility, however, appears to be extremely low in Sub-Saharan Africa. Out of the 39 countries whose laws were reviewed for this study, only 3; Kenya, Namibia and Zimbabwe had specific provisions permitting early working. In 29 of the countries the flexibility was unavailable while in 7 others the permissibility or otherwise of early working was unclear. While field research is required to clarify the situation further, the very low uptake indicates clearly that this important flexibility is woefully underutilised in Sub-Saharan Africa where the need for generics is the greatest. Understanding the reasons for this situation and taking measures to address the situation will be important going forward.

III.8 Test Data Protection

In addition to patent protection for pharmaceutical products, the TRIPS Agreement also requires protection for test data that may be submitted by originator companies to regulatory authorities. Generally, national health authorities as well as agricultural authorities require, as a condition for registering new pharmaceutical products or in the case of agriculture, agro-chemicals, the submission of test data relating to the quality, safety and efficacy as well as information on the composition and physical and chemical characteristics of the product.[35] Once the data is submitted by the originator company, however, a significant number of regulatory authorities do not require companies seeking registration of generic versions of the original product to repeat the studies that are carried out by the originator company but instead rely on bioequivalence tests to grant marketing approval. It is this situation that Article 39 of TRIPS seeks to regulate. The TRIPS Agreement under Article 39, however, only requires protection of test data from unfair competition when such data relates to new chemical entities and where the origination of the data involved considerable effort and provides for exceptions, such as where disclosure is necessary to protect the public. There is therefore room for each WTO Member to determine how to protect test data.

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[34] *Canada – Patent Protection of Pharmaceutical Products*, Report of Panel, WT/DS/114/R, 17 March 2000.

[35] Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, (South Centre and WHO, Geneva, 2002), p. xi.

In Sub-Saharan Africa, 22 out of the 39 countries whose laws were reviewed for this report have some legislative provisions relating to test data protection mainly in the form of unfair competition or medicines regulations. The other 17 countries either have no regulations relating to test data or the legislations are unclear. Most of the laws are, however, unclear in terms of the TRIPS requirements. The clearest legislative provisions on the subject matter are contained in the Bangui Agreement.

In general, except for Mauritius which has five year data exclusivity, other Sub-Saharan African countries do not grant exclusivity for test data. This is encouraging but in light of lack of clarity of the majority of laws it is not possible to conclude whether the situation is positive or not in terms of improving access to ART.

IV. CONCLUSION

Overall, there is a dearth of clear information on which laws apply and in particular the state of the various TRIPS flexibilities in most Sub-Saharan African countries. It is however clear from the available information and from a review of the primary statutes in the majority of the countries (39 out of 47) that IP protection for pharmaceutical products is widespread in the region notwithstanding the fact that the majority of the countries are LDCs permitted not to have such protection at least until 2016. In addition, except for compulsory licensing and government use on which there are legislative provisions in all or the majority of countries respectively, the incorporation of public health-related TRIPS flexibilities in the IP laws of Sub-Saharan African countries is far from ideal. In this regard, it is notable that:

- Only four; the DRC, Malawi, Namibia and Zambia, out of 39 countries have provisions addressing the question of new use pharmaceutical patents;
- Only six, namely, Ghana, Kenya, Mauritius, Namibia, South Africa and Zimbabwe, have an international exhaustion regime to permit parallel imports from anywhere in the world;
- Except Rwanda, no other Sub-Saharan African country has notified intention to use the 30 August 2003 Decision and none has ratified the TRIPS Amendment Protocol aimed at addressing the problem of using compulsory licenses by countries with insufficient or no manufacturing capacity in the pharmaceutical sector;
- There are 11 out of 39 countries which either have no research exemption or its legislative status is unclear and the commercial/non-commercial dichotomy predominate in the provisions of most countries;
- Only three countries; Kenya, Namibia and Zimbabwe has clear provisions permitting early working; and
- Except for OAPI countries, the majority of Sub-Saharan African countries either have no specific legislation on test data protection or the law is vague in terms of the TRIPS rules.

In this context, it is recommended that further research, in particular empirical and field research, be undertaken overtime to:

1. Provide a fuller picture on the relevant IP and others laws which have implications for access to ART and other essential medicines;

2. Clarify the extent of the incorporation of the various public health-related TRIPS flexibilities in the relevant laws especially in the 8 countries that are not included in the analysis in this report due to lack of information; and
3. Determine the actual extent of usage of these flexibilities, their impact on the access situation in the countries and the challenges that may face particular countries in using these flexibilities.

Interventions in the various Sub-Saharan countries that are in the process of reviewing their IP legislations relevant to access to medicines could therefore have significant impact. A focus on the situation in LDCs as well as key countries especially where the incidences of HIV/AIDS are high or rising would also be an area of early action.

Finally, considering the dynamic nature of the laws in this area and the on-going changes occasioned both by TRIPS and other Agreements including FTAs and possibly EPAs, continuous monitoring of development nationally, regionally and internationally will be required in addition to periodic review and updating of Annex 1 and 2 of this report.

ANNEX 1: RELEVANT LEGISLATIONS AND AVAILABILITY OF PATENTS FOR PHARMACEUTICAL PRODUCTS IN SUB-SAHARAN AFRICA

	Country	Domestic Legislations	Applicable Regional and multilateral legislations	Availability of Patent on Pharmaceutical Product	Exclusion of New Use/Second Use Patents
1.	Angola*	Industrial Property Law No 3/92 of February 28, 1992.	TRIPS	No	No
2.	Botswana	Industrial Property, Act, 1996, No. 14 as amended (1997, No. 19).	TRIPS/Paris/ PCT	Yes	While there is no specific exclusion in national law Botswana grants or accepts such grants by virtue of its membership of ARIPO
3.	Burundi*	The Patents Act of 1964, as amended 1968.	TRIPS/Paris	Yes	No
4.	DRC*	Law No. 82-01 of 1982	TRIPS/Paris	Yes	Yes – inventions relating to a medicine may only be patented if the subject matter is a product, substance or compound for the first time presented as constituting a medicine.
5.	Ethiopia*	Inventions, Minor Inventions and Industrial Designs, proclamation, No. 123/1995.	None	Yes	No
6.	Ghana	Patents Act, 2003	TRIPS/Paris/PCT, ARIPO- Harare Protocol	Yes	While there is no specific exclusion in national law Ghana grants or accepts such grants by virtue of its membership of ARIPO
7.	Kenya	Industrial Property, Act, 27/07/2001, No. 3	TRIPS/Paris/PCT, ARIPO- Harare Protocol	Yes	No
8.	Lesotho*	The Industrial Property Order	TRIPS/Paris/, PCT,	Yes	While there is no specific

	Country	Domestic Legislations	Applicable Regional and multilateral legislations	Availability of Patent on Pharmaceutical Product	Exclusion of New Use/Second Use Patents
		(IPO), as amended in 1997	ARIPO- Harare Protocol		exclusion in national law, Lesotho grants or accepts such grants by virtue of its membership of ARIPO
9.	Liberia*	An Act Adopting a New Patent, Copyright and Trademark Law, Title 24, approved May 1972: Chapter 1. Patents (F) IP/PI, November 1977.	Paris/PCT	Yes	No
10.	Madagascar*	Ordonnance No 89-019 instituant un régime pour la protection de la propriété industrielle en République démocratique de Madagascar, de juillet 1989 (Titre I) (Art 3 à 54) (JO D'août 1989).	TRIPS/Paris/PCT	Yes- after 1996.	No
11.	Malawi*	Patents Act, 1992	TRIPS/Paris/PCT/ ARIPO-Harare Protocol	Yes	Allows for exclusion of inventions "capable of being used as food or medicine" which are "a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients" at discretionary basis.
12.	Mauritius	The Patents, Industrial Designs, and Trademark Act No. 25 of 2002	TRIPS/Paris	Yes	No
13.	Mozambique*	Industrial Property Code: Decree No. 4/2006.	TRIPS/Paris/PCT, ARIPO- Harare Protocol	Yes	No

	Country	Domestic Legislations	Applicable Regional and multilateral legislations	Availability of Patent on Pharmaceutical Product	Exclusion of New Use/Second Use Patents
14.	Namibia	Patents, Designs, Trade Marks and Copyright Act 9 of 1916, as amended in South Africa, April 1978. (Only the portions of this Act relating to patents and designs remain in force in Namibia).	TRIPS/Paris/PCT, ARIPO- Harare Protocol	Yes	No
15.	Nigeria	Patent and Design Act, 1971 *A Draft Bill for an Act to provide for the Establishment of the Intellectual Property Commission of Nigeria, repeal of trademarks act CAP 436, LFN 1990 and patents and designs act, CAP 344, LFN 1990 and make comprehensive provisions for the trademarks, registration and protection of trademarks, patents and designs, plant varieties, annual breeders and farmers rights and for matters connected therewith*	TRIPS/Paris/PLT/PCT *The draft Bill provides for compulsory license for importation and exportation of pharmaceutical products that implements the August 2003 Decision of the General Council of the WTO on the implementation of para. 6 of the Doha Declaration on TRIPS and public Health.*	Yes Yes- under the draft Bill.	No *The draft specifically provide patent for invention if it constitutes an improvement upon a patented invention and also is new, involves an inventive step and is capable of industrial application.*
16.	Rwanda*	Patents Act of 1963	TRIPS/Paris	Yes	No- but an improvement patent expires with the principal patent.
17.	South Africa	Patents Act 1978, amended 1997, 2005, Medicines Act 1997	TRIPS/Paris/PCT	Yes	No

	Country	Domestic Legislations	Applicable Regional and multilateral legislations	Availability of Patent on Pharmaceutical Product	Exclusion of New Use/Second Use Patents
18.	Sudan*	Patent Act 1971, Patent, *A new draft bill is under Consideration.*	Paris/PCT	No *Draft bill will invoke 2016 transition period.*	No
19.	Swaziland*	Patents, Utility Models and Industrial Designs Act No. 6 of 1997	TRIPS/Paris/PCT, ARIPO- Harare Protocol	Yes	No
20.	Tanzania* Note that Zanzibar, which is part of the United Republic of Tanzania has a separate patent Law	Patent Act 1987 as amended by Acts Nos. 13 and 18 of 1991. *The 1987 Act is currently under review with the intention of its revision.*	TRIPS/Paris/PCT, ARIPO- Harare Protocol.	Yes	No
21.	Uganda*	The Patents Statute No. 10, December 1991. *A new draft law; an Industrial Property Bill* *Is to be introduced in Parliament soon.*	TRIPS/Paris/PCT	Yes	No
22.	Zambia*	The Patent Act, as last amended in 1987.	TRIPS/Paris/PCT, ARIPO- Harare Protocol	Yes	Generally no exclusion. But specifically excludes any invention which is "capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients."
23.	Zimbabwe	Patents Amendment Act, 1978, as amended	TRIPS/Paris/PCT, ARIPO- Harare	Yes	No

	Country	Domestic Legislations	Applicable Regional and multilateral legislations	Availability of Patent on Pharmaceutical Product	Exclusion of New Use/Second Use Patents
		2002 and 2005.	Protocol		
24-39	The 16 OAPI Countries (Benin, Burkina Faso, Cameroon, the Central African Republic, Chad, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo).	Bangui Agreement	TRIPS and Bangui Agreement	Yes	No

ANNEX 2: RELEVANT LEGISLATIVE PROVISIONS ON VARIOUS PUBLIC HEALTH-RELATED FLEXIBILITIES IN SUB-SAHARAN AFRICA

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
1.	Angola		Compulsory licenses can be issued where a patent is not locally exploited within three years from grant, without legitimate excuse for non-working; the needs of the domestic market have not been met; and where the government believes that exploitation of the patent is of vital importance for the public interest, national security, public health or the economy				No specific legislative provision
2.	Botswana	National	Compulsory licenses can be issued for failure to supply the domestic market on reasonable terms.	Yes	A research exemption exists for experimental purposes	Not available	No specific legislative provision
3.	Burundi		There are no provisions for compulsory licenses, but any interested party may bring a court action for cancellation of a patent if the invention is not exploited in Burundi within two years from the date of first commercial working abroad.			Not available	No specific legislative provision

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
4.	DRC		Compulsory licenses can be issued on the ground of non-working failure to supply the domestic market after five years from filing or three years from the grant.	Yes- In cases where non-working or insufficient working would prejudice the economic development of the country in particular and the public interest in general.			Situation unclear
5.	Ethiopia	National. But the patentee shall not have import monopoly right over the products of the patented invention in Ethiopia	Compulsory licenses can issue where the public interest in particular, national security, nutrition, health or the development of other vital sectors or the national economy so requires and for non/insufficient working.	Yes	Patent rights shall not extend to acts done for non-commercial purposes, the use of the patented invention solely for the purpose of scientific research & experimentation	No	No legislation
6.	Ghana	International	Licenses can be issued on the grounds of non/insufficient local working after three years of grant or four years of filling, for refusal to license, in case of dependant patents, to remedy anti-	Yes. For public interest, including national security, nutrition or health.	Experimental purposes	No	Protection against unfair competition- Protection Against Unfair Competition Act, 2000 (Act 589)

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			competitive practices, and in cases of national emergency or other circumstances of extreme urgency.	(Language unclear on whether prior negotiations with patent holders are required for non-emergency government use.)			
7.	Kenya	International	Compulsory licenses can be issued on the grounds that the market for the patented invention is not being supplied on reasonable terms after three years of grant or four years of filling and in case of dependant patents.	Yes. Where the public interest so requires, in particular, national security, nutrition, health, environmental conservation or the development of any other vital sector of the economy or where it is determined that the manner of exploiting the invention is not competitive.	The law provides that rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.	Yes	Yes, under Pharmacy and Poisons Act and the Pest Control Products Act- No time-limit on data exclusivity currently, but an amending provision is under consideration.
8.	Lesotho		Compulsory licenses can issue on the grounds of non/insufficient Working	Yes- in case of national security, nutrition, health	Exemption for use in research.	No	No specific legislative provision.

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			four years from filing date or 3 years from patent grant.	or the development of other vial sectors of the economy.			
9.	Liberia		There is no specific provision on compulsory licenses but the law provides that foreigners who do not put a patented invention into active operation within three years from the grant date are deemed to have abandoned the patent to the Public- (abandonment of patent)	Government use applies broad public interest grounds including: national security, nutrition, health or development of other vital sectors of national economy or anti-competition	No	No	No specific legislative provision.
10.	Madagascar	National	Compulsory licenses can be issued for non/insufficient working and failure to supply the domestic market after three years from grant or four years from filing or for refusal to license.	Yes- for public interest	Broad exception that patent rights extends only for industrial and commercial purposes, Research and/or experimental exception, and private use.	Yes- Clinical trials for the purpose of obtaining a generic drug's regulatory Approval.[36]	No.
11.	Malawi	Not specified	Licenses can issue to remedy	Yes	None specified.	No	Competition and Fair

[36] WIPO Index of Patent System, Status as of may 2005, Madagascar, available at, http://www.wipo.int/ipstats/en/resources/patent_systems.html.

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			anti-competitive practice, for non/insufficient use and under Section 38 provides that where a patent is in force in respect of –(a) a substance capable of being used as food or medicine, or in the production of food or medicine; (b) a process for producing such a substance as aforesaid; or (c) any invention capable of being used as or as part of a surgical or curative device, the Patents Tribunal shall, on application made to it by any person interested, order the grant to the applicant of a licence under the patent on such terms as it thinks fit unless it appears to such Tribunal that there are good reasons for refusing the application.				Trading Act (Act No. 43 of 1998 and the Pharmacy, Medicines and Poisons Regulations, do not provide for data exclusivity or for unfair competition against IP rights.
12.	Mauritius	International	Licenses can be issued in case of dependant patents, for non/insufficient exploitation or where the public interest including, national security, nutrition, health or the	Yes – for public interest including, national security, nutrition, health or where the	For research and experimental purposes	No	Yes, under The Protection Against Unfair Practices Act, 2002- Data exclusivity for "a reasonable period of

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			development of other vital sectors of the national economy so requires, to remedy anti-competitive practice and in case of national emergency or other circumstances of extreme urgency as well as for public non-commercial use.	development of other vital sectors of the national economy so requires and in case of public non-commercial use.			time" that is "not less than five years", subject to Minister's discretion.
13.	Mozambique	National	Licenses can issue in the case of failure to exploit, demand not being met on reasonable terms, refusal to license and to remedy anti-competitive practice. Other grounds include dependant patent, in case of emergency or in any other circumstances of extreme urgency, either of an economic or a social nature, or for the development of other sectors that are vital to the national economy.	Yes	For the purposes of scientific research.	No	Unfair competition
14.	Namibia	International	Compulsory licenses can be issued in case of non-working/insufficient supply to domestic market after three years from grant or four years from filing, refusal to license, and dependent	Yes	No	Yes	No specific legislation for Protection from unfair competition.

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			patents.				
15.	Nigeria	National *The draft Bill provides for international*	Licenses can issue for non/insufficient working and failure to supply the domestic market, refusal of the patentee to grant licences on reasonable terms, where the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced, and in case of dependant patents. For food & Medicine, if the patented product or process is declared to be of vital importance to the defence or economy of Nigeria, or for public health. This could include: any drugs or pharmaceutical preparations, substances and materials; and any plant, machinery or apparatus, whether fixed to the land or not after importation. *The draft Bill provides detailed provision on grounds for compulsory*	Yes- in public interest, period of emergency, for the maintenance of supplies and services essential to the life of the community. *With regard to national security, nutrition, health, environmental protection or the development of other vital sector*	Broad exception that patent rights extends only for industrial and commercial purposes. *The draft bill provides exemption to an act done privately and on a non-commercial scale, the use of the invention for a scientific research, including experimentation on the invention to test the invention or improve it, the use of the invention for teaching purposes, the preparation of*	*The draft bill provides for exemption to any act including testing making or any other act solely for purposes reasonably related to the development, submission of information required under any law in Nigeria that regulates the manufacture,*	*The draft bill provides for protection against unfair competition and against protection except for public interest and where steps are taken for protection against unfair competition during disclosure.*

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			license that includes: *Non/insufficient working and failure to supply of domestic market- with specific provision on the cases that the interest of public health and nutrition, including that of ensuring access to medicines for all, insufficient quantity or quality or unaffordable prices, where working is being prejudiced by the importation of the patented article and that public interest demands that the patented invention be exploited. Other grounds include refusal of the patentee to grant licences, to remedy the abuse or anti-competitive practices, national emergency or situation of extreme urgency, including public health crises, unfair and substantial prejudiced to the development of sectors of vital importance to socio-economic and technological development and in cases of*	*of the national economy under the draft bill.*	*medicines under individual prescription.*	*construction and use of any product.*	

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			dependant patents. *The draft bill also provided for Compulsory licences for the exportation or Importation of Pharmaceutical Products.*				
16.	Rwanda		There are no provisions on compulsory license. However any interested party may bring court action for the cancellation of a patent if the invention is not exploited in Rwanda within two years from the date of first commercial working abroad.				The 1950 law on unfair competition, provided for the courts to sanction any act contrary to honest practice.
17.	South Africa	International	Grounds for compulsory licensees to issue include dependant patent, abuse of patent (non/insufficient working and failure to supply the domestic market, refusal to license that prejudice the trade, industry or agriculture and excessive pricing)	Yes (upon hearing the patentee beforehand).	No *Draft bill on Intellectual Property Rights from Publicly Financed Research Bill is under consideration*	No	General confidentiality provisions in common law, Medicines and Related Substance Control Act No. 101 of 1965, and Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act No. 36 of 1947
18.	Sudan	National under current law. *International,*	Grounds include failure to work domestically after three years from grant or four	Yes, on grounds of national defence, national		No	No legislation

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
		under new draft bill.	years from filing (Importation does not fulfil the working requirement), refusal to license that unreasonably prejudices the establishment or development of industrial or commercial activities in Sudan , where the patent is declared vital importance for the defence of the economy, and public health. *In the Draft bill it is proposed to redefine conditions considered under national emergency to include: public health crises, "lack of pharmaceutical products at affordable prices", and insufficient manufacturing capacity for pharmaceuticals*	economy, and public health.			
19.	Swaziland		Compulsory licenses can issue in the public interest, including to address national security, nutrition, health.	Yes	The law provides that rights under a patent shall only extend to acts done for industrial or commercial purposes.	No	

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
20.	Tanzania,	National	Licenses can be issued in case of non/insufficient working and failure to supply the domestic market after three years from grant or four years from filing, refusal to license that prejudice the industry and trade and with respect to dependant patents.	Yes – public interest, national security, health or the development of vital sector of the economy.	The law provides that rights under the patent shall not extend to acts done for experimental purposes related to a patented invention.		No legislation
21.	Uganda,	National (International under the draft Bill)	Grounds for compulsory licensing include non/insufficient working and failure to supply the domestic market after three years from grant or four years from filing, refusal to license that prejudices the industry and trade and to remedy anti-competitive practices	Yes – vital public interest, including national security and public health.	The law provides that the rights under a patent shall only extend to acts done for industrial or commercial purposes, in particular, *not to acts done for scientific purposes*.	No	No legislation
22.	Zambia	No explicit provision.	Licenses can issue in case of non/insufficient working and failure to supply the domestic market after three years from grant or four years from filing (Immediately after grant for food- and medicine-related inventions, substance capable of being used as a	Yes. For "service of the State" or during periods of emergency.	Scientific research. *Draft law adds exception for teaching purposes, experimental use for commercial purposes, and,*	No provision in current law. *Yes, in draft law.*	No legislation

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			food or medicine or in the production of food; a process for producing the substance and any invention capable of being used as or as part of a surgical of curative device as well as Food- and medicine-related commodities.), refusal to license that prejudice the industry and trade and to remedy anti-competitive practices.		*exportations to other countries under Compulsory licensing.*		
23.	Zimbabwe	International, "if the cost of importing" a product "is less than the cost of purchasing from the patentee."	Licenses can be issued in case of non/insufficient working and failure to supply the domestic market after three years from grant or four years from filing (Immediately after grant for food- and medicine- related inventions, substance capable of being used as a food or medicine or in the production of food; a process for producing the substance and any invention capable of being used as or as part of a surgical of curative device), refusal to license that	Yes. For "service of the State" or during periods of emergency.	None specified	Yes. "Test batches" of a patented product may be produced, but not put on the market, six months before patent expiry.	No legislation

	Country	Exhaustion regime	Compulsory Licenses	Government Use/Ex-Officio Licenses	Research and other Exemption	Early Working Exception	Data Exclusivity
			prejudice the industry and trade, to remedy anti-competitive practices and in case of dependent patents.				
24-39	OAPI Countries ((Benin, Burkina Faso, Cameroon, the Central African Republic, Chad, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo).	Regional	Compulsory licenses can issue where a patent is not locally worked or the needs of the domestic market have not been met or on account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures; where the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced. (within three years from grant, or four years from filing) and in case of dependant patents.	Where certain patents are of vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the satisfaction of the country's need.	for experimental purposes in the course of scientific and technical research	No	The Bangui Agreement prohibits dishonest use in commerce of confidential data obtained from tests or other confidential data whose production requires considerable effort and which have been communicated to a competent authority for the purpose of obtaining authorization to market pharmaceutical products or chemical products for agriculture comprising new chemical entities, or disclosure of such data, except where necessary to protect the public or unless measures have been taken to ensure that the data are protected against dishonest use in commerce.