The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years after the TRIPS Agreement

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Abstract

Background

It is now 25 years since the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the same concerns raised during its negotiations such as high prices of medicines, market exclusivity and delayed market entry for generics remain relevant as highlighted recently by the Ebola and COVID-19 pandemics. The World Health Organization's (WHO) mandate to work on the interface between intellectual property, innovation and access to medicine has been continually reinforced and extended to include providing support to countries on the implementation of TRIPS flexibilities in collaboration with stakeholders. This study analyses the role of intellectual property on access to medicines in the African Region.

Methods:

We analyze patent data from the African Regional Intellectual Property Organization (ARIPO) and Organisation Africaine de la Propriété Intellectuelle (OAPI) to provide a situational analysis of patenting activity and trends. We also review legislation to assess how TRIPS flexibilities are implemented in countries.

Results

Patenting was low for African countries. Only South Africa and Cameroon appeared in the list of top ten originator countries for ARIPO and OAPI respectively. Main diseases covered by African patents were HIV/AIDS, cardiovascular diseases, cancers and tumors. Majority countries have legislation allowing for compulsory licensing and parallel importation of medicines, while the least legislated flexibilities were explicit exemption of pharmaceutical products from patentable subject matter, new or second use of patented pharmaceutical products, imposition of limits to patent term extension and test data protection. 39 countries have applied TRIPS flexibilities, with the most common being compulsory licensing and least developed country transition provisions.

Discussion

Countries of the WHO African Region operate within a multi-layered – intellectual property regulatory landscape globally and at regional level which is characterized by inconsistencies and misalignment which limit the extent to which countries can implement TRIPS flexibilities.

Conclusions

Opportunities exist for WHO to work with ARIPO and OAPI to support countries in reviewing their legislation to be more responsive to public health needs.

Background

The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights1(TRIPS Agreement) in 1994 by Member States of the World Trade Organization (WTO) was a watershed event, which gave rise to a new global intellectual property protection (IPP) regime with significant effects on access to medicines. Some of these effects include: high prices of medicinal products2, prevention of local manufacture of generic products through reverse engineering of patented products, importation of cheaper medicinal products from off-patent countries or under licensing agreements sand delayed market entry for generic products.

The potential impact of the TRIPS Agreement on access to medicines in developing and least developed countries has caused debate with some commentators arguing that IPP makes it possible for pharmaceutical companies to recoup their Research and Development (R&D) costs and hence act as an incentive for investment in biopharmaceutical research3 and innovation4. However, this incentive structure has failed to spur R&D investments for diseases that predominantly affect people living in countries with a high prevalence of neglected diseases5, leading to the emergence of alternative product development partnership (PDP) models such as the Drugs for Neglected Diseases Initiative (DNDI)6, proposals for global R&D treaty7, and the promotion of public health interests by using existing TRIPS flexibilities8 or through revisions to the TRIPS Agreement9.

Although this paper focuses on the role of intellectual property rights on access to medicines, it is recognized that limited access to medicines in countries of the World Health Organization (WHO) African Region10 is a multidimensional problem. It is affected by other factors such as lack of public financing for health care and over-reliance on out of pocket expenditure11, fragile logistics, storage challenges and high transport and distribution costs12 and inadequate or inappropriate medicines regulatory frameworks13. These factors are further exacerbated by insufficient scientific, technological and local manufacturing capabilities in the Region14.

The occurrence of public health emergencies of global concern such as Ebola15 and COVID1916, have served to highlight further the tensions between IPP and access to medicines17. For example, in March 2020, Gilead Sciences, the makers of remdesivir which is a drug initially studied in clinical trials for Ebola Virus Disease (EVD) and has received USFDA emergency use authorization18 for the treatment of adults and children hospitalized with severe COVID-19 disease, made an application for orphan drug status for the drug, which has since been rescinded19. Orphan drug designation for remdesivir would have granted Gilead Sciences seven years of market exclusivity in addition to the standard 20 years of patent protection guaranteed by the TRIPS Agreement20 and other benefits such as tax credits of up to 50% of qualified clinical development spending, exemption from certain FDA fees and access to special FDA technical advice21. Gilead Sciences has since signed non-exclusive license agreements with pharmaceutical manufacturers in Egypt, India and Pakistan for the supply of remdesivir in 127 low and middle-income countries22, which include all countries of the WHO African Region.

WHO, Intellectual Property and Access to Medicines
The earliest articulation of WHO's mandate to work on the interface between access to medical products, R&D in rare and tropical diseases, and trade can be traced back to 1996, in a World Health Assembly (WHA) resolution on the Revised Drug Strategy which requested the WHO Director-General (DG) to support Member States in their efforts to improve access to essential drugs; to encourage the promotion of R&D of drugs for rare and tropical diseases; and to report on the impact of WTO concerning national drug and essential medicines policies and make recommendations for collaboration between WTO and WHO as appropriate. This mandate has been continually reinforced through assembly resolutions. It has been extended over time to include upon request, providing technical and policy support to Member States, on formulating coherent trade and health policies and the implementation of TRIPS flexibilities in collaboration with other relevant international organizations.

In 2003, WHO member states agreed through resolution WHA56.27 to establish a Commission on Intellectual Property Rights, Innovation and Public Health (CIPiH) which recommended that "WHO should develop a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries" and "...continue to monitor from a public health perspective, the impact of intellectual property rights on the development of new products as well as access to medicines and other health care products in developing countries". These recommendations led to the adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA-PHI) in 2009 and in the same year the WHO-WIPO-WTO trilateral cooperation, which is an interagency collaboration on public health, intellectual property and trade was commenced.

Most recent are assembly decisions WHA71(8) of 2018 on 'Addressing the global shortage of, and access to, medicines and vaccines', which requested the DG to "elaborate a roadmap report, in consultation with Member States, outlining the programming of WHO's work on access to medicines and vaccines including activities, actions and deliverables for the period 2019 – 2023; and WHA71(9) of 2018 on the 'Global strategy and plan of action on public health, innovation and intellectual property (GSPOA-PHI): overall programme review', which requested the DG to "implement the recommendations addressed to the Secretariat ... in an implementation plan, consistent with the global strategy and plan of action on public health, innovation and intellectual property". Additionally, in 2019 resolution WHA72.8 on 'Improving the transparency of markets for medicines, vaccines, and other health products', requested the DG to "continue supporting existing efforts to determine patent status of health products and promote publicly available user-friendly patent status information databases for public health actors, in line with the GSPOA-PHI and to work with other relevant international organizations and stakeholders to improve international cooperation, avoid duplication of work, and promote relevant initiatives".

**Technical Assistance for the implementation of TRIPS and the Role of WIPO**

Within the framework of the WHO-WIPO-WTO trilateral cooperation, the 3 agencies work collaboratively to each fulfill their respective mandates without duplicating efforts and within existing resource constraints. By virtue of the 1995 Agreement between WIPO and WTO, and recommendations of the WIPO Development Agenda (2007), WIPO plays an important role in providing developing countries with technical assistance to implement the TRIPS Agreement. Recommendation 1 states that "WIPO technical assistance shall be development-oriented, demand-driven and transparent, taking into account the priorities and the special needs of developing countries, especially LDCs". An analysis of information provided on the WIPO website indicates that 24 countries, 30 of the WHO African Region have received technical assistance specific to the development of national IP strategies, policies and/or for legislative assistance. Based on the same information, Gabon, Ghana and South Sudan have not received any form of WIPO technical assistance.

**Aims of the study**

The WHO commitments highlighted above and the fact that it is 25 years since the adoption of the TRIPS Agreement provide a good backdrop for reviewing the status of intellectual property rights and the use of TRIPS flexibilities in WHO African Region Member States. The study presents a situational analysis of patenting activity and trends at the African Regional Intellectual Property Organization (ARIPO) and the Organisation Africaine de la PropriétéIntellectuelle (OAPI), the two African regional patent offices. It reviews the intellectual property regulation and governance landscape affecting countries of the WHO African Region, including regimes established by ARIPO and OAPI. Finally, the study provides an assessment of the Region's preparedness to respond to public health emergencies by analyzing how countries have implemented available TRIPS flexibilities in national legislation, including the disincentives and challenges experienced. The findings of the study provide a baseline for WHO's work towards the implementation of the Health Assembly's decision WHA 71(8) and resolution WHA72.8 mentioned above.

**Methods**

**A. Patenting trends**

The patent data used in this study was obtained from the ARIPO and OAPI offices in April 2019. Face-to-face meetings were organized with officers of the two organizations to explain the objectives of the study and to clarify that the data required was in the areas/fields that can potentially be applied in medical inventions using the World Intellectual Property Organization (WIPO) international patent classification (IPC) codes. Table 1 (see Appendix A) presents the codes for patents falling within the scope of this study.

Officers of both patent offices conducted a data search using parameters defined and provided the requisite data as downloaded files in MS Excel. The total number of health-related patents registered in ARIPO and OAPI databases as of April 2019 was 3458 and 2811 respectively. This study only reviewed and analysed patents that had been granted within the past 20 years. Consequently, the patents analyzed were 960 (28%) for ARIPO and 2274 (81%) for OAPI. In order to identify the specific disease(s) a patent can be associated with, we used the patent short title, and in instances where the short title did not mention the disease, the patent abstract was consulted. Those that did not mention a specific disease were left out of the analysis. In doing the analysis the diseases covered by the patents were clustered in broad categories namely: inflammatory diseases, cancers, tumors and abnormal cell proliferation, cardiovascular
diseases viral infections, neurodegenerative diseases, diabetes and diabetes-related conditions, infections, pain, HIV/AIDS, tuberculosis, malaria, mental disorders, nervous system disease, digestive system disease, weight related disorders, lung diseases, eye diseases and vaccines.

B. Application of TRIPS flexibilities

This study conceptualizes flexibilities as understood within the context of the TRIPS Agreement, its amending Protocol and the Doha Declaration on the TRIPS Agreement on Public Health (Doha Declaration)34. We define TRIPS flexibilities through the lens of Articles 1.135 and 8.136, which provide policy space for countries to implement the TRIPS Agreement in a manner appropriate and responsive to their contexts, as different options which consider national interests and can be transposed into national law.

The study conducted a desk review of available patent laws and policy frameworks37 of WHO African countries with the aim of analyzing whether or not they have implemented TRIPS flexibilities within their national legal frameworks. To supplement this analysis, the study used data from The TRIPS Flexibilities Database, found on http://tripsexibilities.medicineslawandpolicy.org/, which is a searchable publicly accessible database maintained by the Medicines Law and Policy group38. The database contains records of instances when national authorities of WTO member countries have invoked the application of a TRIPS flexibility for public health reasons since 2001 to 2020. Finally, the study analyses information elicited from an online questionnaire administered by WIPO and available on https://www.wipo.int/scp/en/exceptions/ to identify the most often cited challenges by respondent WHO African countries39, in implementing TRIPS flexibilities.

The TRIPS Agreement uses the term flexibility in paragraph 6 of the preamble and in Article 66.1 in the context of the need for least developed countries (LDC) to create a viable technological base and their readiness to implement it. Paragraph 440 of the Doha Declaration reaffirms the right of WTO members to use full provisions of the TRIPS Agreements and provides a contextual basis for understanding flexibilities while Paragraph 5 clarifies that they include:

- applying customary rules of interpretation of public international law so that all provisions of the TRIPS Agreement are read in light of the object and purpose as expressed in its objectives (Article 7) and principles (Article 8);
- the right of each member to grant compulsory licenses and the freedom to determine the grounds for granting such licenses;
- the right of each member to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises includethose relating to HIV/AIDS, tuberculosis, malaria and other epidemics; and
- the freedom of each member to establish its exhaustion of IPR regime without challenge subject to the national treatment (Article 3) and most-favored-nation treatment (Article 4) provisions.

Given that Paragraph 5 does not provide an exhaustive enumeration of flexibilities, the study highlights a number of applicable TRIPS flexibilities that African Region countries may evoke to enhance access to medicines. These flexibilities, which are discussed in detail in Table 2 (see Appendix B), include:

1. An interpretation of Article 27.1 of the TRIPS Agreement in national legislation in a manner that excludes new uses, formulations, dosages or combinations of previously patented medicines from patentability criteria. This legislative measure coupled with the implementation of substantive patent examination procedures would serve to prevent frivolous patent applications, evergreening and creation of patent thickets around one invention.

2. Allowing limited exceptions to exclusive rights conferred by patents for purposes of scientific experimentation (research exception); and for facilitating regulatory and market entry approval (Bolar exception) in accordance with Article 30 of the TRIPS Agreement. The research exception makes it possible for countries to develop their scientific and technological capacities and competencies to reverse engineer pharmaceutical products for generic production and for developing them further to better suit local conditions. On the other hand, the Bolar exception allows the use of a patented invention during the patent term without consent of the patent holder for purposes of developing information to obtain market approval and facilitates market entry by competitors immediately after the patent term expires hence ensuring early access to generic medicines.

3. Compulsory licensing under Article 31 of the TRIPS Agreement, which allows for the exploitation of patented subject matter through government authorization without the patent holder's consent, for reason of national emergency and public non-commercial use.

4. Exhaustion of rights and parallel importation under Article 6 of the TRIPS Agreement and Paragraph 5 (d) of the Doha Declaration which make provision for importation and resale in a country without consent of the patent holder of a patented medicine put on the market of the exporting country by the patent holder or in a legal manner.

5. Patent term extension – Countries may consider disallowing/limiting patent term extension in national law for pharmaceutical products.

6. Limits on test data protection – Article 39.3 of the TRIPS Agreement allows countries to determine how to protect test data in the public interest. This provision demands protection from unfair commercial use and does not demand data exclusivity. Countries may therefore incorporate in domestic legislation the right of regulatory authorities to rely on available data to assess new drugs for market entry.

7. Least Developed Countries (LDCs) transition periods – These include the TRIPS Council decision41 for the extension of the transition period for LDCs under Article 66.1 of the TRIPS Agreement to 1 July 2021; the TRIPS Council decision42 and TRIPS General Council decision43 stating that LDC member states are not obliged to protect pharmaceutical patents, or to provide means for filing patents and provide exclusive marketing rights for pharmaceutical products until 1 January 2033.

8. Creation of patent opposition (pre and post patent grant), as required by Article 62.4 of the TRIPS Agreement, to serve as an additional administrative layer of patents review to prevent the grant of invalid patents.

Results
A. Patenting trends

Graph 1 below depicts health-related patent application trends at ARIPO and OAPI. Data show that there was a sharp increase in patent applications at both offices from 1994 to 1999, which started to decline in the period 1999 - 2000. This trend matches reports in a study on inventions and patenting in Africa44. The observed increase in patent applications in the late-1990s may have been caused by developments in molecular biology, genetics and genomics and their application in the biopharmaceutical sector45.

According to the 2018 Report on the State of Health in the WHO African Region46, the main five causes of morbidity and mortality in the Region, are lower respiratory infections, HIV/AIDS, diarrheal diseases, malaria and tuberculosis. Other top causes of morbidity and mortality include stroke and ischemic heart diseases, preterm birth complications, birth asphyxia and congenital anomalies.

An analysis of the top 10 diseases covered by patents granted at ARIPO and OAPI corresponds to a certain extent, with the top 10 causes of morbidity as illustrated by graphs 2 and 3 below. In both repositories the three top categories of diseases covered by granted patents were inflammatory diseases; cancers, tumors and abnormal cell proliferation; and cardiovascular diseases. Within the inflammatory diseases category, there were patents for lower respiratory diseases such as chronic obstructive pulmonary disease and asthma. HIV/AIDS, which was the second cause for morbidity and mortality, was 7th among the top 10 ARIPO patents and 10th for OAPI. Stroke and ischemic heart diseases which ranked 4th and 5th as causes of mortality respectively, fall within the broad category of patents covering cardiovascular diseases, which ranked 3rd on the list of top 10 diseases covered by patents at ARIPO and OAPI.

Diarrheal diseases, tuberculosis and malaria, which are among top causes of mortality and morbidity did not appear among the top diseases covered by patents in the Region. There were only 23 TB patents at ARIPO and 25 at OAPI, while there were only 37 malaria patents at ARIPO and 47 at OAPI.

The top 10 categories of diseases covered by patents taken at ARIPO and OAPI were the same, the only difference being in the ranking. Another interesting finding, whose implications meri further interrogation, is the ranking of cancer-related patents, which was 2nd at both patent offices.

An analysis of the countries of origin of health-related patents at ARIPO and OAPI shows that the top 10 sources of patents at ARIPO were USA, Great Britain, the European Patent Office, France, India, China, South Africa, Germany, Italy and Denmark. South Africa was the only African country in the top 10 list. The top 10 sources of patents at OAPI were USA, France, Great Britain, Germany, India, Belgium, Japan, Cameroon, Switzerland and Ireland. Cameroon was the only African country in the top 10 list. The African Region countries that had health-related patents at ARIPO were Kenya, Mauritius, Namibia, Zambia, and Zimbabwe and Egypt from the Eastern Mediterranean Region (EMRO) of the WHO. While in OAPI the African Region countries were Burkina Faso, Benin, Central African Republic, Congo Republic, Cote d'Ivoire, Cameroon, Guinea, Mali, Mauritius, Namibia, Nigeria, Senegal, Togo, South Africa and Egypt and Morocco from EMRO.

An analysis of the African country patents shows that the top three disease categories covered are HIV/AIDS, cardiovascular diseases, and cancer and tumors. Table 3 below provides a summary of the main diseases covered by African country patents.

Table 3: Summary of main diseases covered by African country patents

| Disease                | Number of mentions in patents | Disease               | Number of mentions in patents |
|------------------------|-------------------------------|-----------------------|-------------------------------|
| HIV/AIDS               | 20                            | Tuberculosis          | 5                             |
| Cardiovascular diseases| 18                            | Bacterial infection   | 5                             |
| Cancer and Tumors      | 14                            | Antimicrobial         | 4                             |
| Diabetes               | 14                            | Antiviral             | 4                             |
| Malaria                | 13                            | Ulcers                | 4                             |
| Skin                   | 10                            | Hemorrhoids           | 4                             |

B. The Intellectual Property Regulation and Governance Landscape in the WHO African Region

Countries of the WHO African Region operate within a multi-layered IP regulation and governance landscape. The Paris Convention for the Protection of Industrial Property (1883) and the TRIPS Agreement (1994) regulate the global IP framework within which African Region countries operate. Most countries (40 out of the 47) in the Region are members of the World Trade Organization (WTO) and are Parties to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provides a minimum standard for the regulation of intellectual property. Article 1.1 of the TRIPS Agreement states that signatory Members States may, but shall not be obliged to, implement in their law more extensive protection than is required by TRIPS, making it open for them to determine the appropriate level of implementing it within their own legal system and practice. At the time of writing this article Algeria, Comoros, Equatorial Guinea, Eritrea, Ethiopia, Sao Tome and Principe, and South Sudan were not members of the WTO. All countries with the exception of Eritrea had commenced accession discussions leading to eventual membership.

At the Regional level, countries are either signatories to the Harare Protocol on Patents and Industrial Design (1982), which is administered by ARIPO or the Bangui Agreement (1977) administered by OAPI.

The African Regional Intellectual Property Office (ARIPO) System and TRIPS Flexibilities
The African Regional Intellectual Property Office (ARIPO) was established by the Lusaka Agreement in 1976; and has 20 member states, 1847 of whom are members of the WHO African Region. The objective of ARIPO is to promote the harmonization and development of intellectual property laws appropriate to the needs of its member states, fostering the establishment of a close relationship between its member states on intellectual property matters and establishing such common services or organs as may be necessary or desirable for the co-ordination, harmonization and development of intellectual property activities affecting its member states.

The Harare Protocol on Patents and Industrial Designs (Harare Protocol) was adopted in 1982 and came into force in 1984. There are 18 contracting parties to the Harare Protocol namely Botswana, Eswatini, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Sudan, Tanzania, Uganda, Zambia and Zimbabwe. Of these, Gambia, Lesotho, Liberia, Malawi, Mozambique, Rwanda, Sao Tome & Principe, Sierra Leone, Uganda, Tanzania and Zambia are classified as LDCs.

Under the Harare Protocol, an application for the grant of a patent is made with any Contracting Party or directly with ARIPO, in which the applicant designates any one of the Contracting Parties in which they wish the invention to be accorded protection. The Protocol establishes a regional mechanism that administers the filing, examination and grant of patents, in all fields of technology, including the pharmaceutical field (section 3.10.a). A review of how the TRIPS flexibilities identified in the methods section above are implemented by the Harare Protocol shows that patentability criteria extend to cover pharmaceutical products under Rule 10 of the Regulations to the Harare Protocol. Additionally, Rule 7 (3) on drafting patent claims implies that ARIPO allows claims relating to second uses of known and already patented pharmaceutical products, which is likely to encourage frivolous patent applications and ever-greening. 48495051

Rule 3.3 of the Regulations to the Harare Protocol makes provision for ARIPO to, upon request, undertake or arrange for the substantive examination of a patent application. According to one of the ARIPO officials interviewed for this study, substantive examination is ordinarily conducted at ARIPO. However, ARIPO has bilateral agreements with the European Patent Office (EPO), the Australian, German and Swedish patent offices as well as with WIPO, for the conduct of substantive examination in technical fields or for complex inventions that ARIPO may not have adequate examination capacity. A study conducted in 201453 revealed that ARIPO had only 6 patent examiners at the time, which is a grossly low number of examiners. Rule 19bis of the Regulations to the Harare Protocol provides for the publication of patent applications as soon as possible after the expiry of 18 months from the date of filing or from priority date, and does not make provision for opposition of patents granted by ARIPO.

The Organisation Africaine De La Propriété Intellectuelle (OAPI) System and TRIPS Flexibilities

The Organisation Africaine De La Propriété Intellectuelle (OAPI) was created in 1977 by the Bangui Agreement and has the objective of implementing and applying common administrative procedures deriving from a uniform system for the protection of industrial property, providing services related to industrial property, and promoting the economic development of Member States by means of effective protection of intellectual property and related rights, according to Article 2.1 of the Agreement. According to Articles 2 (2), 8 (1) and 8 (2) of the Bangui Agreement OAPI serves as both a national and central patent documentation body for all its member countries and for Member States party to the Patent Cooperation Treaty (PCT). In this case, OAPI serves as the national, designated, elected, and/or receiving office within the context of Article 254 of the PCT, and the Bangui Agreement is the law governing industrial property rights in each of its member states. This being the case, patent applications at OAPI are designated for protection in all OAPI member countries.

The countries signatory to the Bangui Agreement are Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo Republic, Cote d'Ivoire, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo. Out of the 15 Member States, only 4 countries are not LDCs namely Cameroon, Congo Republic, Cote d'Ivoire, and Gabon.

According to the Bangui Agreement a patentable invention is defined as a product or process that is new, involves an inventive step and is industrially applicable. This broad definition of patentability criteria is construed to cover both pharmaceutical products and processes. In accordance with provisions of Article 20 of the Annex to the Bangui Agreement, OAPI is a formality and not a substantive examination office. Therefore all patent applications that meet the formality examination requirements namely, Articles 655, 14, 15, and 1557 of the Annex to the Agreement, are granted under Article 22. The Bangui Agreement just like the Harare Protocol does not make provision for a patent opposition system that would serve to prevent granting of invalid and or frivolous patents.

C. Implementation and Application of TRIPS Flexibilities by WHO African Region Countries

Table 4 (see Appendix C below) presents a summary how the TRIPS flexibilities identified in the methods section and discussed in table 2 (on Appendix B below) have been enacted into law by African Region countries. The summary is based on a review of all WHO African countries’ patent legislation and IP policies as accessed through the WIPO Lex depository.

The analysis shows that 3 countries, namely Namibia59, Rwanda60 and Zambia61 have specific legislation on patentability of pharmaceutical products based on what constitutes novelty to limit ever-greening of patents. These countries have explicit legislation against new or second use patents of already patented pharmaceutical products. Twenty one (21) countries62 make provision for limited exceptions to exclusive patent rights for purposes of research and scientific experimentation (research exception), while twelve63 allow for the use of patented knowledge during the patent term for purposes of developing information necessary for obtaining regulatory and market-entry approval (bolar exception). The Bangui Agreement as currently enforced, does not make provision for research and bolar exceptions for signatory member states.

The most commonly legislated flexibilities are compulsory licensing and parallel importation where 45 out of the 47 (95%) countries have enacted legislation to allow for compulsory licensing, and 40 (85%) for exhaustion of rights and parallel importation. The 2 countries that do not legislation on
compulsory licensing were Eritrea and Madagascar and the 7 without legislation on parallel importation are Angola, Cabo Verde, Comoros, Ethiopia, Eritrea, DRC and Malawi.

The least commonly legislated flexibilities were those imposing limits to patent term extensions and on test data protection. Only Angola64 and Zimbabwe65 were found to have legislative provisions that could be used to limit pharmaceutical product patent term extensions, while only Uganda has legislation which allows the medicines regulatory authority to rely on available data to assess new generic drugs for market entry.

Out of the 30 WHO African Region member states who are classified as LDCs66 and qualify for pharmaceutical product patent waivers, until 1 January 2033, on the mailbox provision and exclusive marketing rights for pharmaceuticals relating to Articles 70.8 and 70.9 of the TRIPS Agreement, only Angola67, Madagascar68, Liberia69, Rwanda70 and Uganda71 have explicitly excluded pharmaceutical products from patentability criteria in their national laws. Burundi's Industrial Property law72 states that this exemption was valid until 1 January 2016. Least developed countries signatory to the Bangui Agreement and members of OAPI do not exempt pharmaceutical products from patentable subject matter.

Algeria, Angola, Eritrea, Ethiopia, Madagascar, Nigeria, Sierra Leone and all OAPI countries were found not to have any patent opposition procedures (whether pre and/or post grant) in place.

The analysis shows that only three flexibilities are recorded in the database as having been applied, namely Article 31 of TRIPS which allows for compulsory licensing including for non-commercial use; paragraph 7 of the Doha Declaration on LDC country transition periods and paragraph 5(d) of the Doha Declaration allowing for parallel importation. The most commonly applied flexibility is paragraph 7 of the Doha Declaration on transition provisions with 27 countries having applied it, followed by Article 31, allowing compulsory licensing, which has been applied by 16 countries. Parallel importation has only been used by Kenya once (in 2002) for the importation of generic medicines.

Some countries have applied flexibilities more than once; the highest being five times by Kenya, four times by Zimbabwe, and three times by Benin, Congo, Gabon, Ivory Coast, Mozambique, Togo and Zambia. Central African Republic, Chad, the Gambia, Guinea, Lesotho, Malawi, Niger, Rwanda and Sierra Leone have all applied flexibilities twice respectively. Guinea, Mozambique and Zambia adopted a mixed approach of using both Article 31 and paragraph 7, and Kenya both Article 31 and paragraph 5 at different times. In the case of Kenya, it did not execute 4 of its applications which were under Article 31 for HIV/AIDS medications. The pharmaceutical companies involved in these cases GSK and BoehringerIngelheim entered into voluntary license agreements with a Kenyan manufacturing company Cosmos Ltd. The 5th application by Kenya, and the only one to be executed was under paragraph 5 and related to sourcing of generic drugs. Cameroon and South Africa too did not execute their flexibilities applications which were both under Article 31 and were both for HIV/AIDS drugs. The database does not record why Cameroon did not execute its application. In the case of South Africa, the concerned pharmaceutical companies GSK and BoehringerIngelheim entered into a voluntary license with Cipla, an Indian manufacturing company.

An analysis of responses provided by twelve WHO African countries77 to an online questionnaire administered by WIPO78, identifies a number of challenges that countries experience in applying TRIPS flexibilities to meet public health needs. The most often cited challenge in the survey was insufficiency or no local manufacturing capacity79 to produce generic pharmaceutical products in relation to the use of compulsory licensing. This arose from the fact that Article 31 (f)80 and (h)81 of the TRIPS Agreement, before entry into force of Article 31bis in 2017, which made it impossible for countries with insufficient or no pharmaceutical manufacturing capacity to use compulsory licensing to access patented medicines. It was however noted from the survey that the considerable burden of proof on governments and potential users of the Article 31bis system82 remains to be a challenge. Another challenge identified from the WIPO survey and literature, is the risk of having counterfeit pharmaceutical products introduced into the market through parallel importation.

**Discussion**

The WHO African Region is characterized by what could be termed as a collage of member states as far as IP regulation and governance is concerned. To begin with, we have countries such as Algeria, Comoros, Equatorial Guinea, Eritrea, Ethiopia, Sao Tome and Principe and South Sudan who are not yet signatories to the TRIPS Agreement and are exempt from any intellectual property protection requirements imposed by the Agreement that may hinder access to medicine. Out of the other 40 WHO African Region Member States, 2184 signatories to the TRIPS Agreement are unlikely to benefit from the LDC transition waivers under Article 66.1 for fully implementing the TRIPS Agreement until 1 July 2021, and on obligations under Article 70.885 and 70.986, with respect to mailbox applications and provision of exclusive marketing rights of pharmaceutical products until 1 January 203387 since they are signatories to the Harare Protocol or the Bangui Agreement (1977). The Harare Protocol and the Bangui Agreement require these Member States to attain a TRIPS – plus standard, where patentability criteria extends to pharmaceutical products and process, hence more onerous than the one required under TRIPS.

The IP frameworks imposed on ARlPO and OAPI Member States are inconsistent and misaligned with the TRIPS Agreement and are more onerous than the minimum standard provided by TRIPS. Areas of misalignment that have an impact on access to medicines in countries is the uniform treatment of LDC member states with non LDCs hence the lack of differentiation between obligations for LDCs and non LDC; the absence of capacity to conduct substantive patent examination to ensure that patentability criteria are met prior to granting patents, the absence of patent opposition procedures, failure to impose limits on pharmaceutical patent term extension and on test data protection to prohibit data exclusivity especially in the public health interest.

In the years following the adoption of the TRIPS Agreement, developing countries experienced challenges in applying TRIPS flexibilities such as compulsory licensing (Article 31) and parallel importation (Article 6) of drugs in their bid to address the HIV/AIDS crisis that was facing most developing countries towards the end of the 20th century. One such example in the African Region was South Africa, which enacted the Medicines and Related Substances Control Amendment Act 1997 that allowed for parallel importation and compulsory licensing of pharmaceuticals in the country. These amendments to the law led to a backlash from pharmaceutical companies and culminated into legal action against the South African government, which was later withdrawn. Over time
and with a lot of public pressure on the pharmaceutical industry African countries have been able to put in place legislation allowing them to exploit some available TRIPS flexibilities to address public health needs. Though some positive strides have been made by WHO African Region countries, a lot more can be done by legislating for a wider range of flexibilities such a more rigorous application of the LDC transition waivers, adopting rigid patentability criteria which prohibits new or second use of already patented pharmaceutical products, limiting patent term extensions and limiting test data protection to facilitate faster entry of generic medicines into the market.

Compulsory licensing was a commonly evoked flexibility by countries, which in some instances was not executed, hence the conclusion that these may have served to encourage pharmaceutical companies to enter into voluntary licensing arrangements.

We observe that exhaustion of rights and parallel importation is not commonly applied in the Region, despite being one of the most legislated flexibility. This could be due to the fact that some countries have adopted a national exhaustion approach such, while those governed by the Bangui Agreement have precluded international exhaustion and restricts parallel importation to the regional exhaustion regime within OAPI countries. It could also be due to fears of proliferation of substandard and counterfeit medicines into the market.

Conclusions

The experiences of the HIV/AIDS pandemic in the nineties, and most recently, the search for an effective treatment and vaccine for COVID-19 highlight the tensions between intellectual property rights and public health interests. There is evidence that learning has taken place from the lessons of the HIV/AIDS pandemic. Some of these lessons include the willingness by pharmaceutical companies such as Gilead Sciences to enter into voluntary licensing agreements with manufacturing companies in developing countries to serve less developed markets. The speed with which countries such as Canada, Germany, Chile and Ecuador have amended their respective patent laws to prohibit market exclusivities and to allow for compulsory licensing, should it become necessary, of COVID-19 medicinal products are examples of how TRIPS flexibilities can be deployed to address health needs.

The low levels of patenting activity by African Region countries calls for the need to develop and strengthen health innovation systems in the Region. This can be done through policies that support health research systems and a local incentive structure that focuses research on local health challenges. Other aspects of developing health innovation systems would include developing local scientific and biomedical research capacities and local manufacturing capabilities.

The findings of this study provide an opportunity for the WHO Regional Office for Africa to work closely with ARIPO and OAPI to develop and promote a Regional IP framework that is responsive to public health challenges of the Region; and to support countries in reviewing national IP laws taking into account available flexibilities especially the LDC transition waivers and those not commonly used in the Region such as research exception, regulatory review exception and patent term extension.

Declarations

Ethics approval and consent to participate

Since this research does not include human participants, no permission was needed from the WHO African Region Ethics Review Committee.

Consent to publish

Not applicable as manuscript does not include details, images or videos relating to individual persons.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to the fact that they are held by ARIPO and OAPI patent depositories but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

MM contributed to conception and design, data collection, analysis and writing of the manuscript. JBN and OMJK contributed by providing inputs to the study conception and design and in data collection. SK, AL, AS and PT provided inputs in the analysis of the manuscript. All authors read and approved the final manuscript.
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Abbreviations

3TC Lamivudine
AIDS Acquired Immune Deficiency Syndrome
ARIPO African Regional Intellectual Property Organization
ARV Antiretrovirals
AZT Azidothymidine
COVID-19 Corona Virus Disease of 2019
D4T Stavudine
DG Director General
DNA Deoxyribonucleic Acid
DNDi Drugs for Neglected Diseases Initiative
EFV Efavirenz
EMRO Eastern Mediterranean Region
EVD Ebola Disease Virus
GSK GlaxoSmithKline
GSPOA-PHI Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
HIV Human Immuno Deficiency Syndrome
IP Intellectual Property
IPC International Patent Classification
IPP Intellectual Property Protection
IPR Intellectual Property Rights
LDC Least Developed Countries
MS Microsoft
NVP Nevirapine
OAPI Organisation Africaine de la Propriete Intellectuelle
PDP Product Development Partnership
R&D Research and Development
RNA Ribonucleic Acid
TDF Tenofovir Disoproxil Fumarate
TRIPS Agreement on Trade-Related Aspects of Intellectual Property
USA United States of America
US FDA United States Food and Drug Administration
WHA World Health Assembly
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Appendices

Appendix A

Table 1: IPC Codes of patents with potential application in the pharmaceutical sector

| IPC Classification | Description                                                                 |
|--------------------|-----------------------------------------------------------------------------|
| A61K               | Preparations for medical purposes                                           |
| A61P               | Therapeutic activity of chemical compounds or medicinal preparation         |
| A61B               | Diagnosis - analyzing biological material covering processes for diagnostics. |
| A01N               | Medicinal preparations (for pharmaceutical use) containing materials from mammals or birds |
| C01H               | Sugars, derivatives thereof, nucleosides, nucleotides, nucleic acids with therapeutic activity further classified in subclass A61P, which covers DNA or RNA concerning genetic engineering, vectors or the isolation, preparation or purification |
| C12N               | Micro-organisms or enzymes; compositions thereof; propagating, preserving or maintaining micro-organism, mutation or genetic engineering; culture media |
| C12P               | Fermentation or enzyme using processes to synthesize a desired chemical compound or composition or to separate optical isomers from racemic mixture; particularly processes for producing enzymes, DNA or RNA concerning genetic engineering, vectors e.g. plasmids or their isolation. |
| C12Q               | Measuring or testing processes involving enzymes or micro-organisms (immunoassays) compositions or test papers thereof; processes of preparing such composition; condition responsive control in microbiological or enzymological process. |
| C08B               | Polysaccharides, derivatives thereof; those with therapeutic activity are further classified in subclass A61P. |
| C07F               | Acyclic, carbocyclic, or heterocyclic compounds containing elements other than carbon, hydrogen, halogen, oxygen, nitrogen, sulfur, selenium or tellurium. Therapeutic activity in A61P. |
| C01G               | Compounds containing metals and whose therapeutic activity is further classified under A61P. |
| C07I               | Steroids particularly those whose therapeutic activity is further classified in subclass A61P. |
| C08L               | Compositions of macromolecular compounds which include pharmaceuticals under A61K. |
| C07G               | Organic chemistry/compounds of unknown constitution. Those with therapeutic activity further classified in subclass A61P. |
| C07B               | General methods of organic chemistry; apparatus therefore (preparation of carboxylic acid esters by telomerization) |
| C07C               | Acyclic or carbocyclic compounds |
| C07D               | Heterocyclic compounds. Those with therapeutic activity further classified in subclass A61P. |
| C08G               | Macromolecular compounds obtained otherwise than by reactions only involving carbon-to-carbon unsaturated bonds. |
| C08N               | Investigation or analyzing materials by determining their chemical or physical properties. |
| C01B               | Non-metallic elements; compounds thereof; whose therapeutic activity is further classified in A61P. |
| C08F               | Macromolecular compounds obtained by reactions only involving carbon-to-carbon unsaturated bonds; which include therapeutic activity under A61K, A61P. |

Appendix B

Table 2: Summary of available TRIPS flexibilities
### Appendix C

#### Table 4: Implementation of available TRIPS Flexibilities by WHO African Region Countries

| Flexibility | Legal Basis | How and Why to Implement the Flexibility |
|-------------|-------------|----------------------------------------|
| Article 31 of TRIPS | Countries may opt to interpret ‘novelty’ in domestic legislation in a manner that excludes new and second uses of medicines. This flexibility is applied to prevent frivolous patent applications from new uses, formulations, dosages or combinations of known or previously patented medicines, evergreening, or the creation of patent thickets around one invention. |
| Article 30.3 of TRIPS | The terms limited exceptions have been defined by the WTO Dispute Settlement Panel33 as “exception under which use of the patented product for scientific experimentation, during the term of the patent without consent is not infringement.” Countries can therefore allow this exception in their national law in order to allow for the development of local scientific and technological knowledge and competence or to manufacture pharmaceutical products for generic production and for developing them further to better suit local conditions. |
| Article 66.1 to 1 July 2021 | This provision allows importation and resale in a country without consent of the patent holder of a patented product put on the market of the exporting country by the patent holder or in a legal manner. International level of exhaustion provides the most flexibility, followed by regional and lastly national. It is a legal doctrine according to which an IP right holder cannot prevent further distribution or resale of goods after consenting to the first sale. In such a situation the right holder is considered to have exhausted its right over those goods. |
| Article 6 of TRIPS | This provision allows to determine how to protect test data in the public interest. This provision does not demand data exclusivity, which has the potential of blocking entry of generic versions of patented medicines. Rather, it demands protection from unfair commercial use. TRIPS does not define unfair commercial use nor does it provide guidance on how protection can be achieved. Countries may therefore incorporate in domestic legislation the right of regulatory authorities to rely on available data to assess new drugs for market entry. |
| Article 6.1 of TRIPS | In 2013 the TRIPS Council decided to extend the transition period for LDC members to fully comply with the TRIPS Agreement to 1 July 2021. LDC Members are exempt from the patentability requirement under Article 27.1 of TRIPS covering pharmaceutical products until 2033, also known as the pharmaceutical product transition period |
| Article 39.3 of TRIPS | This provision allows to determine how to protect test data in the public interest. This provision does not demand data exclusivity, which has the potential of blocking entry of generic versions of patented medicines. Rather, it demands protection from unfair commercial use. TRIPS does not define unfair commercial use nor does it provide guidance on how protection can be achieved. Countries may therefore incorporate in domestic legislation the right of regulatory authorities to rely on available data to assess new drugs for market entry. |
| Article 66.1 of TRIPS | In 2013 the TRIPS Council decided to extend the transition period for LDC members to fully comply with the TRIPS Agreement to 1 July 2021. LDC Members are exempt from the patentability requirement under Article 27.1 of TRIPS covering pharmaceutical products until 2033, also known as the pharmaceutical product transition period |
| Paragraph 5(d) of the Doha Declaration | This exception facilitates market entry by competitors immediately after the end of the patent term and is therefore an instrument that is specifically designed to ensure early access to generic medicines. |
| Article 31 of TRIPS | Article 31 of TRIPS stipulates conditions for the issuance of a compulsory license by a member state. Provisions of Article 31 (f) and (h) make it impossible for countries with insufficient or no manufacturing capacity to use this flexibility. Questions of market viability for a single national market made it unattractive to use this flexibility. |
| Article 31 of TRIPS | This provision allows importation and resale in a country without consent of the patent holder of a patented product put on the market of the exporting country by the patent holder or in a legal manner. International level of exhaustion provides the most flexibility, followed by regional and lastly national. It is a legal doctrine according to which an IP right holder cannot prevent further distribution or resale of goods after consenting to the first sale. In such a situation the right holder is considered to have exhausted its right over those goods. |
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| Article 6 of TRIPS | This provision allows importation and resale in a country without consent of the patent holder of a patented product put on the market of the exporting country by the patent holder or in a legal manner. International level of exhaustion provides the most flexibility, followed by regional and lastly national. It is a legal doctrine according to which an IP right holder cannot prevent further distribution or resale of goods after consenting to the first sale. In such a situation the right holder is considered to have exhausted its right over those goods. |
| Ability | WHO African countries with relevant legislation | Observation |
|---|---|---|
| Ability to stop | Namibia, Rwanda and Zambia have specifically legislated against new or second use of already patented pharmaceutical products to stop “ever-greening” of patents | OAPI countries – Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo do not provide legislative exceptions for regulatory review purposes. |
| Country from which | Algeria, Botswana, Burundi, Cabo Verde, Democratic Republic of Congo, Eswatini, Ethiopia, Ghana, Kenya, Lesotho, Liberia, Madagascar, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome & Principe, Seychelles, Sierra Leone, Tanzania, Uganda, | |
| Ability | Botswana, Cabo Verde, Kenya, Liberia, Namibia, Rwanda, Sao Tome & Principe, Seychelles, South Africa, Uganda, Zambia, Zimbabwe | OAPI countries – Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo do not provide legislative exceptions for regulatory review purposes. |
| Exception | Algeria, Angola, Botswana, Burundi, Cabo Verde, Democratic Republic of Congo, Eswatini, Ethiopia, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Nigeria, Rwanda, Sierra Leone, Sao Tome & Principe, Seychelles, South Africa, South Sudan, Tanzania, Uganda, Zambia, Zimbabwe, and OAPI countries namely Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Mauritius, Niger, Senegal and Togo. | |
| Exception | Botswana, Cabo Verde, Kenya, Liberia, Namibia, Rwanda, Sao Tome & Principe, Seychelles, South Africa, Uganda, Zambia, Zimbabwe | |
| Exception | Botswana, Cabo Verde, Kenya, Liberia, Namibia, Rwanda, Sao Tome & Principe, Seychelles, South Africa, Uganda, Zambia, Zimbabwe | |
| Exception | Botswana, Cabo Verde, Kenya, Liberia, Namibia, Rwanda, Sao Tome & Principe, Seychelles, South Africa, Uganda, Zambia, Zimbabwe | |
| Exception | International exhaustion – Botswana, Burundi, Ghana, Kenya, Liberia, Mauritius, Namibia, Seychelles, Sierra Leone, South Africa, Zambia, Zimbabwe | |
| Exception | Regional exhaustion – Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo Republic, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo – essentially all OAPI countries. | |
| Exception | National exhaustion – Eswatini, The Gambia, Lesotho, Rwanda, Madagascar, Mozambique, and Tanzania, Nigeria, Sao Tome & Principe, South Sudan, Uganda | |
| Exception | Algeria – legislation does not specify applicable level of exhaustion whether national or international | |
| Term | Angola, Zimbabwe | |
| International exhausti | Angola, Botswana, Burundi, Cabo Verde, Democratic Republic of Congo, Eswatini, Ethiopia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Nigeria, Senegal, Togo do not provide patent opposition legislation. | |
| International exhausti | Angola, Burundi, Madagascar, Liberia, Rwanda, Uganda have excluded pharmaceutical products from patentability criteria | |
| International exhausti | Countries with a pre-grant opposition system: - Botswana, Burundi, Cabo Verde, Lesotho, Liberia, Malawi, Mozambique, Namibia, Seychelles, Uganda, Zambia, Zimbabwe | |
| International exhausti | Countries with a post-grant opposition system: - Botswana, Comoros, DRC, Eswatini, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome & Principe, Seychelles, South Africa, South Sudan, Tanzania, Uganda, Zambia, Zimbabwe | |

**Appendix D**

Table 5: Summary of application of TRIPS flexibilities by African Region countries
| Country          | Date  | Flexibility | Product     | Patent filed/granted | Disease | Executed | Reason executed | if not filed/granted |
|------------------|-------|-------------|-------------|----------------------|---------|----------|-----------------|----------------------|
| Angola           | 2005  | Par7        | All medicines | Yes                  | All     | Yes      |                 |                      |
| Benin            | 2004  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Benin            | 2007  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Benin            | 2009  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Burkina Faso     | 2005  | Par7        | ARVs +      | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Burundi          | 2005  | Par7        | ARVs +      | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Cameroon         | 2005  | Art 31      | NVP, 3TC, 3TC/AZT | Yes               | HIV/AIDS| No       | No response    |                      |
| Cape Verde       | 2004  | Par7        | All medicines | Unknown             | All     | Yes      |                 |                      |
| CAR              | 2004  | Par7        | ARVs +      | Yes                  | HIV/AIDS| Yes      |                 |                      |
| CAR              | 2005  | Par7        | ARVs +      | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Chad             | 2005  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Chad             | 2007  | Par7        | All medicines | Yes                 | All     | Yes      |                 |                      |
| Comoros          | 2007  | Par7        | ARVs +      | Unknown             | HIV/AIDS| Yes      |                 |                      |
| Congo            | 2007  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Congo            | 2014  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Congo            | 2005  | Art 31      | ARVs +      | Yes                  | HIV/AIDS| Yes      |                 |                      |
| DRC              | 2005  | Par7        | ARVs        | No                   | HIV/AIDS| Yes      |                 |                      |
| Eritrea          | 2005  | Par7        | ARVs        | No                   | HIV/AIDS| Yes      |                 |                      |
| Ethiopia         | 2004  | Art 31      | ARVs        | No                   | HIV/AIDS| Yes      |                 |                      |
| Gabon            | 2005  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Gabon            | 2006  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Gabon            | 2013  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Gambia           | 2004  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Ghana            | 2005  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Guinea           | 2004  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Guinea           | 2005  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Guinea Bissau    | 2005  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Guinea Equatorial| 2009  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Ivory Coast      | 2004  | Art 31      | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Ivory Coast      | 2007  | Art 31      | 3TC, 3TC/AZT, 3TC/AZT/NVP, 3TC/D4T, 3TC/D4T/NVP, DDI, EFV, IDV | Yes | HIV/AIDS| Yes      |                 |                      |
| Kenya            | 2002  | Par5d       | Generics    | Yes                  | All     | Yes      |                 |                      |
| Kenya            | 2004  | Art 31      | 3TC         | Yes                  | HIV/AIDS| No       | Voluntary licence |                      |
| Kenya            | 2004  | Art 31      | 3TC/AZT     | Yes                  | HIV/AIDS| No       | Voluntary licence |                      |
| Kenya            | 2004  | Art 31      | AZT         | Yes                  | HIV/AIDS| No       | Voluntary licence |                      |
| Kenya            | 2004  | Art 31      | NVP         | Yes                  | HIV/AIDS| No       | Voluntary licence |                      |
| Lesotho          | 2004  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Lesotho          | 2006  | Par7        | All medicines | Yes                 | All     | Yes      |                 |                      |
| Liberia          | 2005  | Art 31      | ARVs        | No                   | HIV/AIDS| Yes      |                 |                      |
| Malawi           | 2004  | Par7        | All medicines | Yes                 | All     | Yes      |                 |                      |
| Malawi           | 2005  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Mauritania       | 2004  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Mozambique       | 2004  | Art 31      | 3TC/D4T/NVP | No                   | HIV/AIDS| Yes      |                 |                      |
| Mozambique       | 2005  | Art 31      | EFV         | No                   | HIV/AIDS| Yes      |                 |                      |
| Mozambique       | 2005  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Niger            | 2004  | Par7        | All medicines | Yes                 | All     | Yes      |                 |                      |
| Niger            | 2008  | Par7        | ARVs        | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Rwanda           | 2007  | Par7        | 3TC/AZT/NVP | No                   | HIV/AIDS| Yes      |                 |                      |
| Rwanda           | 2007  | Par7        | All medicines | Yes                 | All     | Yes      |                 |                      |
| Senegal          | 2006  | Par7        | ARVs +      | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Sierra Leone     | 2009  | Par7        | IDV, LPV/r, NVP, TDF | No   | HIV/AIDS| Yes      |                 |                      |
| Sierra Leone     | 2009  | Par7        | DDI, IDV, LPV/r | No       | HIV/AIDS| Yes      |                 |                      |
| South Africa     | 2003  | Art 31      | AZT, 3TC, AZT/3TC, NVP | Yes | HIV/AIDS| No       | Voluntary licence |                      |
| South Sudan      | 2007  | Par7        | All medicines | Yes                  | HIV/AIDS| Yes      |                 |                      |
| Eswatini         | 2005  | Art 31      | NVP, AZT    | Yes                  | HIV/AIDS| Yes      |                 |                      |
| São Tomé and      | 2006  | Art 31      | ARVs        | No                   | HIV/AIDS| Yes      |                 |                      |
| Country     | Year  | Paragraph | Medicines      | Available | Condition   | Available |
|-------------|-------|-----------|----------------|-----------|-------------|-----------|
| Príncipe    |       |           | All medicines  | Yes       | All         | Yes       |
| Tanzania    | 2008  | Par7      | All medicines  | Yes       | All         | Yes       |
| Togo        | 2004  | Par7      | TDF/3TC        | Yes       | HIV/AIDS    | Yes       |
| Togo        | 2008  | Par7      | EFV, NVP, 3TC/AZT | Yes | HIV/AIDS    | Yes       |
| Uganda      | 2006  | Par7      | 3TC/D4T/NVP    | Yes       | HIV/AIDS    | Yes       |
| Zambia      | 2004  | Art 31    | 3TC/D4T/NVP    | Yes       | HIV/AIDS    | Yes       |
| Zambia      | 2004  | Par7      | ARVs +         | Yes       | HIV/AIDS    | Yes       |
| Zambia      | 2006  | Par7      | ARVs +         | Yes       | HIV/AIDS    | Yes       |
| Zimbabwe    | 2002  | Art 31    | ARVs +         | Yes       | HIV/AIDS    | Yes       |
| Zimbabwe    | 2003  | Art 31    | ARVs +         | Yes       | HIV/AIDS    | Yes       |
| Zimbabwe    | 2004  | Art 31    | ARVs           | Yes       | HIV/AIDS    | Yes       |
| Zimbabwe    | 2005  | Art 31    | ARVs +         | Yes       | HIV/AIDS    | Yes       |

**Figures**

![Graph 3: Top 10 diseases covered by patents granted by OAPI](image)

**Figure 3**

Graph 3