

4th June 2019

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cc. ARIPO Member States

Re: Civil Society Proposals to Address Policy and Legal Incoherencies in the Harare Protocol that Impact Access to Health Technologies in ARIPO Member States

The 16th Session of the Council of Ministers of ARIPO on 23 November 2017, held in Lilongwe, Malawi, mandated the Secretariat to; “*explore and formulate concrete proposals aimed at addressing policy and legal incoherencies that impact access to health technologies and in the Member States of ARIPO, take actions accordingly and report to the Governing Bodies of the Organization*”.

This mandate follows the Outcome document of the High-Level Meeting on Promoting Policy Coherence on Health Technology Innovation and Access in the ARIPO Region that was organized by the Government of Malawi, with the support of UNDP in Lilongwe from November 1 to 3, 2017. In the High-Level Meeting Outcome document, ARIPO Member States identified the following as critical at the Regional Level for improving policy coherence:

- The need for ARIPO Member States to align the Harare Protocol and ARIPO patent practices with the national public health and industrial policy objectives of ARIPO Member States, including the 13 which are least developed countries, recognizing that all ARIPO Member States have the need to increase affordable access to medicines and vaccines and that some have prioritized local pharmaceutical production.
- Examining ways of incorporating TRIPS flexibilities including the WTO LDC Waiver;
- Strengthening the ARIPO patent examination guidelines and practices to incorporate a public health perspective; and
- Including a regional patent opposition mechanism.

In addition, ARIPO Member States are part of many regional and sub-regional initiatives and plans including pharmaceutical business plans focused on addressing the challenge of access to medicines in the region and increasing self-reliance by promoting regional/local generic production. Towards this end, the initiatives and plans consider the full use of TRIPS flexibilities as a prerequisite to the realization of the stated objectives.

We recall that President Mutharika of Malawi stressed during the abovementioned High-Level Meeting that “*We want to promote ways of ensuring affordable essential medicines. This is our sacred duty. We all share the obligation to make Africa a healthy continent. The progress of our nations depends on having healthy and productive citizens.*”

ARIPO administers the filing, examination and grant of pharmaceutical patents for the 18 Contracting States of the Harare Protocol. Hence it has a crucial role in the implementation and use of public health sensitive TRIPS flexibilities. ARIPO’s rules and practices have a direct impact on whether the

population in the region have access to affordable medicines and whether the ambition of a robust generic industry in the region will be realized. We are of the view the ARIPO can and should play a positive role in promoting the well-being of the people of the region.

It is in this spirit, that we attach a CSO Submission with concrete proposals to reflect key TRIPS flexibilities in the Harare Protocol and related Regulations addressing some of the critical gaps at the regional level with respect to implementation of TRIPS flexibilities in particular:

- LDC Pharmaceutical Transition Period
- Improving Patent Procedure
- Preventing Patent Evergreening: Secondary Patents, New Use and Combination Patent Claims
- Sufficiency of Disclosure
- Disclosure of International Non-Proprietary Name for Pharmaceutical Inventions & Foreign Applications and Grants
- Administrative Pre and Post Grant Opposition Systems.

Civil society's previous letters to ARIPO Office to involve public interest civil society and patient groups from the region in discussions pursuant to the Ministerial mandate have thus far been ignored.

We hope with the attached CSO Submission, ARIPO Office and Member States will be more responsive. We are ready to participate, present and discuss these proposals and any other ideas and concerns that exists with regard to the proposals.

We reiterate our intent to engage constructively for the well-being and advancement of the region. We hope that the ARIPO Office and ARIPO Member States will work with us to take advantage of TRIPS Flexibilities for the benefit of the people in the region.

SIGNATORIES

1. Associação SCARJoV, Angola
2. Advocacy Core Team, Zimbabwe
3. AIDS Information Centre (AIC), Uganda
4. AIDS Rights Alliance for Southern Africa (ARASA)
5. Botswana Network on Ethics, Law and HIV/AIDS (BONELA), Botswana
6. Cancer Alliance, South Africa
7. Centre for Health Human Rights and Development (CEHURD), Uganda
8. Centre for Participatory Research and Development CEPARD, Uganda
9. Coalition for Health Promotion and Social Development (HEPS Uganda), Uganda
10. Coalition of Women Living with HIV in Malawi (COWLHA), Malawi
11. East Africa NCD Alliance
12. Fix the Patents Law Campaign, South Africa
13. Foguito
14. Global Coalition of Women against AIDS in Uganda, Uganda
15. Health Gap
16. Health Rights Action Group (HAG), Uganda
17. Hope After Rape, Uganda
18. Human Right Research Documentation Centre (HURIC), Uganda

19. Human Rights Awareness and Promotion Forum (HRAPF), Uganda
20. Initiative for Prisoners Health Rights, Uganda
21. International Community of Women Living with HIV/AIDS (ICW), Uganda
22. IVY Foundation, Malawi
23. Kampala District Forum of PLHIV Networks (KADFO), Uganda
24. KELIN
25. Kenyan Network of Cancer Organizations (KENCO)
26. Life Concern Organization - Malawi
27. Makerere Women Development Association, Uganda
28. Malawi Network of Religious Leaders living with HIV/AIDS (MANERELA+), Malawi
29. Mama's Club, Uganda
30. Mariam foundation, Uganda
31. MPact Global Action, Global
32. National Community of Women Living with HIV, Uganda
33. National Forum for People Living with HIV/AIDS (NAFOPHANU), Uganda
34. Network for Journalists Living with HIV (JONEHA), Malawi
35. Non-communicable Diseases Alliance of Kenya (NCDAK)
36. Pamoja TB group
37. Pan-African Treatment Access Movement
38. Positive Men's Union, Uganda
39. Prevention Care International (PCI), Uganda
40. Rainbow Identity Association – Botswana
41. Rwanda NCD Alliance
42. Pan African Positive Women's Coalition - Zimbabwe
43. SAMASHA, Uganda
44. Southern and Eastern African Trade Information and Negotiations Institute (SEATINI), Uganda
45. Support on AIDS and Life Through Telephone Helpline (SALT), Uganda
46. The Action Group for Health, Human Rights and HIV/AIDS Uganda, Uganda
47. Third World Network
48. Tororo forum for people living with HIV networks
49. Tusitukirewamu, Uganda
50. TRIPS Flexibilities - Advocacy Core Team - Zimbabwe
51. Uganda Network of Young People living with HIV/AIDS
52. Uganda Health Sciences Press Association, Uganda
53. Uganda Network of AIDS Services Organization (UNASO), Uganda
54. Uganda Network on Law Equality and Ethics (UGANET), Uganda
55. Uganda Young Positives (UYP), Uganda
56. Uganda's young positive networks (UNYPA), Uganda
57. WEMIHS NGO, Kenya
58. Women's Coalition Against Cancer (WOCACA), Malawi
59. Yolse
60. Zimbabwe HIV/AIDS Activist Union Community Trust White Ribbon Alliance (WRA), Uganda
61. Zimbabwe National Network of PLHIV (ZNNP+)

CIVIL SOCIETY PROPOSALS TO ADDRESS POLICY AND LEGAL INCOHERENCIES IN THE HARARE PROTOCOL THAT IMPACT ACCESS TO HEALTH TECHNOLOGIES IN MEMBER STATES OF ARIPO

MAY 2019

A. INTRODUCTION

The Communique of the 16th Session of the Council of Ministers of ARIPO on 23 November 2017, held in Lilongwe, Malawi, mandated the Secretariat to; “*explore and formulate concrete proposals aimed at addressing policy and legal incoherencies that impact access to health technologies and in the Member States of ARIPO, take actions accordingly and report to the Governing Bodies of the Organization*”.

This mandate follows the Outcome document of the High-Level Meeting on Promoting Policy Coherence on Health Technology Innovation and Access in the ARIPO Region that was organized by Government of Malawi, with the support of the UNDP in Lilongwe from November 1 to 3, 2017. The meeting was attended by over 50 senior government officials from the ministries of health, trade, industry, commerce, justice and foreign Affairs from 15 African ARIPO Members States as well as representatives of the ARIPO Secretariat, the African Union Commission, the East African Community (EAC), Common Market for Eastern and Southern Africa (COMESA), the World Intellectual Property Organization (WIPO) and the United Nations Joint Programme on HIV/AIDS (UNAIDS), civil society, the private sector and academia.

In the High-Level Meeting Outcome document, ARIPO Member States identified the following as critical at the Regional Level to improving policy coherence:

- The need for ARIPO Member States to align the Harare Protocol and ARIPO patent practices with the national public health and industrial policy objectives of ARIPO Member States, including the 13 which are LDCs, recognizing that all ARIPO Member States have the need to increase affordable access to medicines and vaccines and that some have prioritized local pharmaceutical production.
- Examining ways of incorporating TRIPS flexibilities including the WTO LDC Waiver;
- Strengthening the ARIPO patent examination guidelines and practices to incorporate a public health perspective; and
- Including a regional patent opposition mechanism.

Civil society wish to constructively engage with the ARIPO Secretariat and ARIPO Member States on possible reforms to the Harare Protocol to take advantage of public health flexibilities allowed under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to promote access to affordable health technologies.

In an earlier submission 20th March 2019, we elaborated in detail TRIPS-compliant public health flexibilities that could be enacted at the national level as well as provided comments on Chapter Two of “A Comparative Study of the Industrial Property Laws of ARIPO Member States” commissioned by the ARIPO Secretariat.

This Submission presents concrete proposals to reflect key TRIPS flexibilities in the Harare Protocol to address policy and legal incoherencies that impact access to health technologies.

In Part B, the Submission sets out the context for the proposals, especially the importance for the region. Part C of the Submission identifies critical gaps at the regional level with respect to implementation of the TRIPS flexibilities in the following areas:

- C.1. LDC Pharmaceutical Transition Period
- C.2. Improving Patent Procedure
- C.3. Preventing Patent Evergreening: Secondary Patents, New Use and Combination Patent Claims
- C.4. Sufficiency of Disclosure
- C.5. Disclosure of International Non-Proprietary Name for Pharmaceutical Inventions & Foreign Applications and Grants
- C.6. Administrative Third-Party Opposition Systems
 - C.6.1. Administrative Pre-Grant Opposition System
 - C.6.2. Administrative Post-Grant Opposition System

Part D presents the Conclusion.

B. CONTEXT

Challenge of Access to Medicines in the ARIPO region

Sub-Saharan Africa suffers from multiple communicable and non-communicable (NCD) disease burdens aggravated by many other developmental challenges such as widespread poverty, poor water and sanitation facilities and significant infrastructural, financial and human resource constraints.

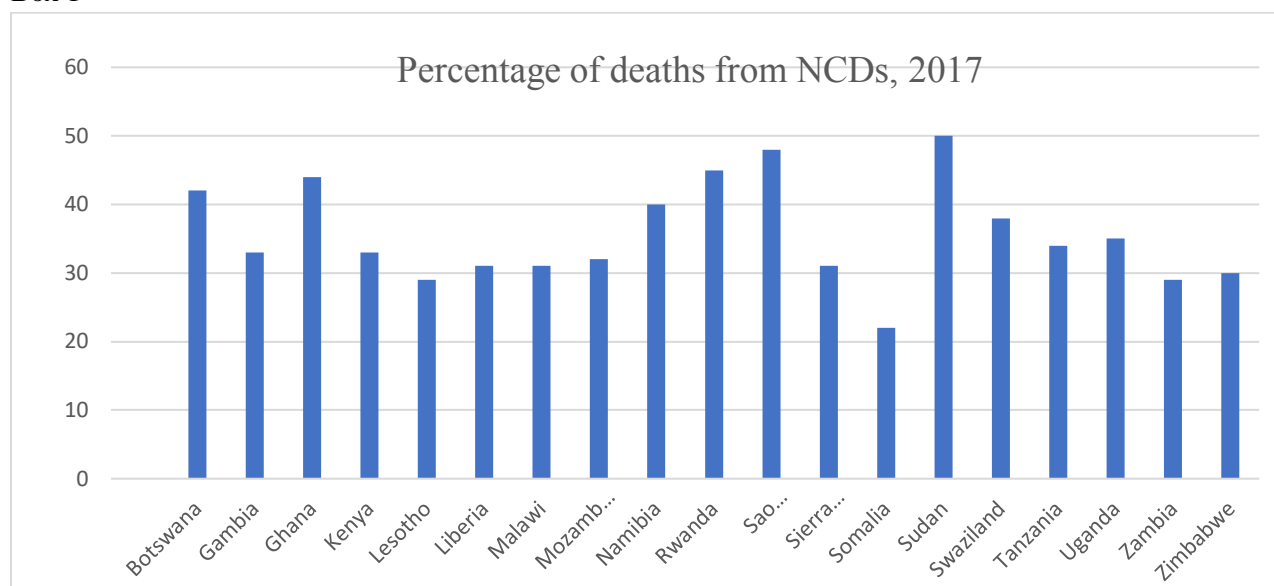
Communicable diseases such as HIV, Tuberculosis (TB) are well-known health challenges in the region. The number of people living with HIV (PLHIV) remains high.¹ For example, in Tanzania there are 1.5 million PLHIV (65000 new infections); in Uganda – 1.3 million PLHIV (50000 new infections); in Kenya – 1.5 million PLHIV (53000 new infections); in Rwanda – 220 000 PLHIV (7400 new infections). While significant strides have been made in increasing access to affordable treatment, persistent gaps in treatment remains. TB is another major infectious disease in the region. The WHO African region has 27% of the world's cases². In particular, Kenya, Uganda, Lesotho, Liberia, Mozambique, Namibia, Sierra Leone, Zambia and Zimbabwe are categorised by WHO as high TB burden countries.³ TB treatment is complex with rise of multidrug-resistant tuberculosis (MDR-TB), hence the need for new drugs such as bedaquiline and delamanid recommended by WHO.

¹ www.unaids.org

² UNITAID (2014). "A Review of the Bedaquiline Patent Landscape A scoping report"

³ WHO (2018) "Global Tuberculosis Report"

Box 1



NCDs are also a major threat in the ARIPO region (see Box 1). In 2016, NCDs were responsible for 41 million of the world’s 57 million deaths (71%). The major NCDs responsible for these deaths includes cardiovascular diseases (44%); cancers (22%); chronic respiratory diseases (9%) and diabetes (4%).⁴ The probability of premature adult NCD mortality is greater in the WHO region of Africa (22%).⁵

WHO notes that “the majority of countries in 2017 did not have all essential NCD medicines and technologies, with only 35% of countries worldwide having all of them”.⁶ WHO also reports that treatment for NCDs can quickly drain household resources, driving families into impoverishment as direct out-of-pocket payments represent more than 50% of total health expenditures in a large number of low-and-middle-income countries.⁷ WHO’s Global report on NCDs refers to a review of medicine prices in two multi-country studies which showed that in the public sector, it cost on average from two to eight days’ wages to purchase one month’s supply of at least one cardiovascular medicine and one day’s wage to purchase one month’s supply of at least one anti-diabetic medicine.

The above provides a snapshot of the severity of the access to medicines challenges facing the ARIPO region. In this context, the cost of treatment and affordability of treatment is evidently an essential aspect that needs to be dealt with if the region is to deal with the numerous health challenges on a long-term sustainable basis.

Currently several countries in the ARIPO region benefit from multilateral health financing programmes such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and Gavi. However, some countries are transitioning out of eligibility as they are becoming middle-income economies, although the burden

⁴ WHO (2017) “Non-Communicable Progress Monitor 2017”

⁵ WHO (2017) “Non-Communicable Progress Monitor 2017”

⁶ WHO (2017) “Non-Communicable Progress Monitor 2017”

⁷ WHO, (2010). “The world health report 2010–Health Systems financing: the path to universal coverage”; WHO, (2011) “Global status report on noncommunicable diseases 2010 Description of the global burden of NCDs, their risk factors and determinants”.

of disease remains high. Countries in transition are expected to increase domestic resources for health, and many will have to pay higher prices for drugs, vaccines and other medical technologies.

In addition, in the region out-of-pocket health expenditure is high. Costly treatment can quickly drive families into poverty through direct out-of-pocket payments. WHO estimated that 150 million people suffered financial catastrophe in 2010. Hence the availability of affordable treatment is essential for the region.

Patents on pharmaceutical products grant the patent holder a monopoly, allowing it to set prices which in many instances are simply unaffordable to patients. The Doha Declaration of the TRIPS Agreement and Public Health explicitly recognizes “concerns about its [patents] effects on prices”. One key strategy to reduce the cost of treatment is the early introduction of generic competition. For example, in 2000, for a triple-combination antiretroviral (ARV) treatment of Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) the price of the lowest branded treatment was about US\$10,439 for a year’s supply⁸. The high price tag meant most patients living with HIV/AIDS would not be able to afford treatment and would be condemned to death. The entry of generic versions of ARVs led to significant price reductions, in 2001 to US\$350 and over time with increased competition to US\$55 per person per year⁹.

The TRIPS Agreement lays out minimum IP-related obligations that WTO Members have to comply with. It also expressly spells out that governments have policy space to implement public health sensitive measures (also known as “TRIPS flexibilities”)

Article 1.1 of TRIPS clarifies that “Members shall be *free* to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” Meaning that there is significant flexibility in interpreting and applying TRIPS provisions. Article 7 of the TRIPS Agreement also directly recognizes that there is a balance of rights and obligations in TRIPS and that intellectual property protection and enforcement should lead to the mutual advance of producers and users, should be conducive to social and economic welfare, and should contribute to the promotion of technological innovation and the transfer and dissemination of technology. Likewise, Article 8 permits Members to adopt measures necessary to protect public health and of vital importance to socio-economic and technological development so long as such measures are consistent with the minimum requirements of TRIPS. Members are also free to take measures to prevent abuse of intellectual property by the holders.

In addition, the WTO Doha Declaration on TRIPS and Public Health in paragraphs 4 and 5 states “the TRIPS Agreement does not and should not prevent measures to protect public health. ... [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member’s right to protect public health and, in particular, to promote access to medicines for all. ... [W]e reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.

International & Regional Instruments Emphasizing Implementation of TRIPS Flexibilities to Promote Access to Medicines & Local Production

⁸ MSF (2007) “*Untangling the Web of Price Reductions*”, (July 2007). Available from <https://msfaccess.org/utw>

⁹ MSF (2013) “*Untangling the Web of Antiretroviral Price Reductions*”, 16th Edition, available at <https://msfaccess.org/utw>

Numerous international, regional and sub-regional instruments and initiatives have highlighted the importance of implementing and using TRIPS flexibilities to facilitate access to affordable medicines, reaffirming Doha Declaration's recognition of the right of WTO Members to take steps to protect public health.

The 2016 UN Secretary General's High-Level Panel on Access to Medicines recommends *inter alia* "World Trade Organization (WTO) Members must make full use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities as confirmed by the Doha Declaration to promote access to health technologies..."¹⁰

The WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property acknowledges "the price of medicines is one of the factors that can impede access to treatment" and that flexibilities "could facilitate increased access to pharmaceutical products by developing countries"¹¹. The Strategy required governments as well as other stakeholders (which would include ARIPO) to *inter alia*: encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products; as well as to promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries.

Other UN Resolutions that encourage and/or recognize the right of countries to use TRIPS flexibilities to promote access to medicines includes the 2011 UN Declaration on HIV and AIDS¹², 2011 UN General Assembly Declaration on the Prevention and Control of Non-Communicable Diseases¹³; the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020¹⁴, the RIO+20 United Nations Conference on Sustainable Development¹⁵ (UNCSD), the 2018 UN General Assembly Declaration on the Prevention and Control of Non-communicable Diseases¹⁶ and the 2018 UN General Assembly Declaration on the Fight Against Tuberculosis.¹⁷

At the African regional as well as sub-regional levels similar initiatives recommending full use of TRIPS-flexibilities have emerged with the aim to improve availability and affordability of medicines in the region and increase self-reliance.

The African Commission on Human and Peoples Rights adopted in 2008 Resolution 141 on "Access to Health and Needed Medicines in Africa" which calls upon States to refrain "from measures that negatively affect access, such as: implementing intellectual property policies that do not take full advantage of all flexibilities in the WTO Agreement on Trade Related Aspects of Intellectual Property that promote access to affordable medicines, including entering "TRIPS Plus" free trade agreements."¹⁸

¹⁰ Available at <http://www.unsgaccessmeds.org/final-report>

¹¹ WHO, (2011) "*Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*". Adopted in 2008 by Resolution WHA61.21

¹² United Nations (2011), "*Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS*" UN General Assembly Resolution A/RES/65/277, 8th July 2011.

¹³ United Nations (2011) "*Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Disease*". UN General Assembly Resolution A/66/2 19 September 2011..

¹⁴ WHO (2013), "*Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020*".

¹⁵ United Nations (2012), "*The future we want*". RIO+20 United Nations Conference on Sustainable Development, A/CONF.216/L.1.

¹⁶ United Nations (2018), "*Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non communicable diseases*" A/RES/73/2 available at https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

¹⁷ United Nations (2018) "*Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis*" A/RES/73/3, available at https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/3

¹⁸ African Commission on Human and Peoples Rights- "*Resolution 141 on Access to Health and Needed Medicines in Africa*" available at <http://www.achpr.org/sessions/44th/resolutions/141/>

In 2012, the Heads of States of Africa adopted a Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Tuberculosis and Malaria Response in Africa. The Roadmap treats the prevalence of AIDS, TB, malaria and other infectious diseases as an emergency for the region, raising concern also that national responses to AIDS, TB and other infectious disease are highly dependent on external financial and foreign produced medicines and that this “dependency poses grave risk to the Continent”¹⁹.

A key pillar of the Roadmap is Pillar 2, under which a suite of high priority actions is outlined to ensure accelerated access to affordable and quality-assured medicines and health-related commodities. This includes investing in regional pharmaceutical manufacturing hubs; greater efforts to ensure that knowledge and technology are transferred to the region and maximum use of flexibilities permitted under the TRIPS Agreement. On the latter point, the Roadmap is supportive of the LDC pharmaceutical waiver to create a sound and viable technological base in the pharmaceutical sector. It also argues for legislative amendment “to better facilitate actions that are needed to import generic drugs from existing suppliers (e.g. from China and India) so that there are no supply disruptions while Africa is building its manufacturing sector”.

Further in 2012, the African Union Commission (AUC), in partnership with the United Nations Industrial Development Organization (UNIDO) developed a business plan to accelerate implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA).²⁰ The business plan states: “One of the key policy and legislative changes needed in order to benefit our continent, its patients and local industry is in the domain of intellectual property rights. Most countries have failed to take advantage of current opportunities presented by TRIPS flexibilities. A few have enacted the TRIPS provisions but the common consensus is that the requirements are too onerous and too time consuming..... The AUC firmly believes that the TRIPS flexibilities present the same opportunity for African pharma as did the Indian Patent Act of 1970 for Indian industry. The Commission is convinced that full exploitation of the flexibilities would lead to a transformation of local industry”. The business plan advocates working together with ARIPO and others for the “simplification of the means by which flexibilities can be exploited” as the “current system is onerous and wasteful”.

The Southern African Development Community (SADC) Pharmaceutical Business Plan (2015-2019) aims to ensure availability of essential medicines to reduce disease burden in the region and in this context has prioritized development of generic pharmaceutical industry production capabilities in the region. The current Pharmaceutical Business Plan requires members to *inter alia* to “[c]ollaborate with development partners to enable countries to protect, include and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude agreements that are not detrimental to public health” and to “strengthen the capacity of Intellectual Property (IP) officers, procurement agencies and Medicines Regulatory agencies on issues of intellectual property and public health”.

¹⁹ African Union (2012) “Roadmap on Shared Responsibility and Global Solidarity For AIDS, TB and Malaria Response in Africa”.

²⁰ African Union (2012) “Pharmaceutical Manufacturing Plan for Africa Business Plan”, prepared as part of the AUC-UNIDO partnership, Addis Ababa, 2012.

The 2nd East African Community (EAC)²¹ Regional Pharmaceutical Manufacturing Plan of Action for 2017-2027²² has as its goal the development of a “globally competitive regional pharmaceutical manufacturing industry that can supply national, regional and international markets with efficacious and quality medicines”. Utilization of TRIPS flexibilities is a core pillar of this Plan of Action. The EAC has also published the “EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation”.²³ Annexed to the EAC Regional Policy are extracts from the “EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities”. These documents expressly urge EAC Member States to adopt and utilize TRIPS health flexibilities and outlines legislative provisions for doing so.

In Conclusion

ARIPO Members are part of numerous international, regional and sub-regional instruments and initiatives mentioned above, sharing the vision, objectives and goals set out in the respective documents. It is apparent that the goal of promoting access to medicines as well as local production of pharmaceutical is dependent on optimal implementation and use of TRIPS flexibilities in the region.

Thus far, the focus has been on incorporation of flexibilities in national patent laws. But this is not sufficient as in the ARIPO region the filing and grant of patents is based on the Harare Protocol and related regulations, centrally managed by the ARIPO Office. Hence, realization of the access to medicines goals and objectives in the region can only be achieved if implementation of selected TRIPS flexibilities is also reflected in the Harare Protocol. Failure to do so, will frustrate full use of flexibilities in the region as observed in the case of use of the LDC Pharmaceutical Transition Period and other flexibilities (see explanation below in Part C).

Analysis shows that the current operations of the ARIPO does not facilitate full use of TRIPS flexibilities and instead appears to be erecting unjustified patent barriers to the importation and local production of affordable medicines.²⁴ This conclusion is supported by the discussions and Outcome document of the High Level Meeting in Malawi in 2017, and consequently ARIPO Ministers calling on the Secretariat to; “*explore and formulate concrete proposals aimed at addressing policy and legal incoherencies that impact access to health technologies*”.

Effective implementation of regional and sub-regional plans to promote access to medicines and local production, necessitates ARIPO Secretariat and Members to amend provisions of Harare Protocol and related regulations to incorporate TRIPS compliant public health sensitive measures to address the incoherencies and to align the Harare Protocol with the public health ambitions of the people in the region.

Against this background, civil society are submitting several key proposals to incorporate relevant flexibilities into the Harare Protocol.

²¹ The East African Community (EAC) is a regional intergovernmental organisation of the Republics of Burundi, Kenya, Rwanda, the United Republic of Tanzania, and the Republic of Uganda. Except of Burundi, the rest are also members of ARIPO.

²² EAC (2017). “*2nd East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action for 2017-2027*” Available at <http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf>

²³ EAC (2013). “*East African Community Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation*”. Available from <http://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf>

²⁴ Shashikant (2014), “The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines”, available at https://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_ENI.pdf

C. PROPOSALS

C.1. LDC PHARMACEUTICAL TRANSITION PERIOD

Majority of ARIPO member states are Least Developed Countries (LDCs) and entitled to transition period under Article 66.1 of the WTO TRIPS Agreement. Of the 18 Contracting States to the Harare Protocol, only six are developing countries (Botswana, Ghana, Kenya, Namibia, Eswatini and Zimbabwe) and thus required to implement the TRIPS Agreement. The remaining 12 Contracting States are categorised by the UN as LDCs. Of the LDCs, several are not members of the WTO (Liberia, Sao Tome and Príncipe and Sudan), and hence under no obligation to implement any aspect of the TRIPS Agreement. LDC WTO members enjoy a transition period pursuant to Article 66.1 of the TRIPS Agreement. For as long as the LDC transition period remains in force (presently until 1 July 2021²⁵), LDCs are generally exempted from TRIPS implementation other than Articles 3, 4 and 5 of the Agreement. This transition period is renewable under Article 66.1 of the Agreement.

The rationale for the transition period is that LDCs have “special needs and requirements”, face “economic, financial and administrative constraints” and “need flexibility to create a viable technological base”. In short, Article 66.1 of the TRIPS Agreement recognizes that TRIPS standards may hinder the development of a technological base, and that LDCs needs policy space (i.e. need not implement TRIPS standards) to address their developmental challenges.

Specifically, with respect to pharmaceutical products, in 2001 the WTO TRIPS Council granted LDCs exemption from patents and the protection of undisclosed data (Sections 5 and 7 of Part II of the TRIPS Agreement) until 2016. In November 2015, this exemption was extended until 1 January 2033 without prejudice to further renewal. The 2015 TRIPS Council decision (see Annex 1) states:

“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 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier.”

The WTO General Council also decided to waive obligations regarding mailbox and exclusive marketing rights (EMR) until 1 January 2033, that would otherwise apply to LDCs pursuant to Articles 70.8 and 70.9 of the TRIPS Agreement (see Annex 2).

Implementation of the LDC pharmaceutical transition period is considered to be key to promoting access to affordable medicines as well as establishing generic production capacity in the region. All pharmaceutical business plans in the region emphasize implementation of the transition period. Hence, several ARIPO members such as Liberia, Rwanda, and Uganda have in recent years introduced the pharmaceutical transition period in their national patent laws. For instance, Uganda’s Industrial Property Act 2013 in Section 8(3)(f) states:

²⁵ 2013 Decision on the Extension of the Transition Period under Article 66.1 for Least Developed Country Members, adopted by the TRIPS Council on 11 June 2013 (official document IP/C/64).

“The following shall not be regarded as inventions and shall be excluded from patent protection... pharmaceutical products until 1st January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on trade related aspects of intellectual property under the World Trade Organization.”

This positive national development, raises two major issues at the regional level. First, the ARIPO Office continues to grant pharmaceutical patents that apply to LDCs (e.g. Uganda) that at the national level do not recognize such patents. Capacity constraints in LDCs mean they struggle to communicate a written objection to the ARIPO Office as required by Section 3(6) of the Protocol when the ARIPO Office decides to grant a patent. A study on “The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines” highlights in its findings:

“According to ARIPO officials, it is not uncommon for the ARIPO office to grant pharmaceutical patents, which are in contravention with the national law as national IP offices often fail to communicate their written objection in a timely manner. [...] The main reason given for the failure to object within the allocated time frame is the lack of capacity and resources in national IP or patent offices.”²⁶

Table 1

Uganda	Rwanda	Liberia
Cobicistat Tablets Patent Grant AP3250(A) ²⁷ Date of Grant: 06/05/2015		
Tenofovir alafenamide hemifumarate Patent Grant: AP 3639 ²⁸ Date of Grant: 13.03.2016	Tenofovir alafenamide hemifumarate Patent Grant: AP 3639 Date of Grant: 13.03.2016	Tenofovir alafenamide hemifumarate Patent Grant: AP 3639 Date of Grant: 13.03.2016
Sofosbuvir Compositions Patent Grant: AP4349 ²⁹ Date of Grant: 25/10/2017	Sofosbuvir Compositions Patent Grant: AP4349 Date of Grant: 25/10/2017	Sofosbuvir Compositions Patent Grant: AP4349 Date of Grant: 25/10/2017
Sofosbuvir/Ledipasvir Combination Patent Grant AP 4613 ³⁰ Date of Grant: 29.07.2018	Sofosbuvir/Ledipasvir Combination Patent Grant AP 4613 Date of Grant: 29.07.2018	Sofosbuvir/Ledipasvir Combination Patent Grant AP 4613 Date of Grant: 29.07.2018

Table 1 features examples of pharmaceutical patents granted by ARIPO and applicable in Uganda, Rwanda and Liberia although the national patents act does not recognize

²⁶ Shashikant (2014) “The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines”, Research Paper 56

²⁷

<https://worldwide.espacenet.com/publicationDetails/originalDocument?FT=D&date=20150531&DB=worldwide.espacenet.com&locale=en-EP&CC=AP&NR=3250A&KC=A&ND=4#>

²⁸ <http://eservice.aripo.org/pdl/pdw/DetailViewBiblio.do?seq=10271&where=ARIPO&selectTab=0>

²⁹ <http://eservice.aripo.org/pdl/pdw/DetailViewBiblio.do?seq=10718&where=ARIPO&selectTab=0>

³⁰ <http://eservice.aripo.org/pdl/pdw/DetailViewBiblio.do?seq=12315&where=ARIPO&selectTab=0>

pharmaceutical product patents. The above listed examples are key treatments for HIV and Hepatitis C infections.

These ARIPO patents are likely to be invalid at the national level as they cover subject matter outside the scope of protection. However, the existence of an ARIPO issued patent certificate creates an ambiguous legal environment, which could hinder importation of generic medicines and deter generic manufacturers from local production. It also negates the intended impact of incorporating the LDC pharmaceutical exemption in national patent legislations.

Secondly the practise of granting of pharmaceutical patents by ARIPO Office that apply to LDCs, is inconsistent with the numerous regional and sub-regional strategies and plans on access to medicines and local production that stress on the urgency to operationalise the pharmaceutical transition period.

Apart from patents, utility models granted with respect to pharmaceutical products could also erect barriers to access to medicines and local production as they operate in the same manner as “patents”. The subject of “utility models” is not regulated by the WTO and hence there are no restrictions to ARIPO members exempting pharmaceutical products from “utility model” protection.

To address these issues and to operationalise the LDC pharmaceutical transition period, two textual proposals are presented. Both proposals clarify that patent or utility model applications and grants by the ARIPO Office with respect to pharmaceutical products, will not have any legal effect in an LDC.

PROPOSAL Option 1(Preferred): *Add Section Iter in the Harare Protocol*

Notwithstanding anything in this Protocol, its Regulations or Administrative Instructions, patent or utility model applications and grants by the ARIPO Office with respect to pharmaceutical products shall not be applicable to, or have any legal effect in any Contracting Party that is designated as a least developed country by the United Nations.

This provision shall be valid until 1st January 2033 or such other period as may be granted to least developed countries by the Council for TRIPS of the World Trade Organization.

Proposal 1 would be the *preferred option* as it automatically extends the pharmaceutical transition period to all LDC Contracting Parties of ARIPO. Adoption of this proposal will immediately facilitate realization of national and regional strategies for access to medicines and local production. **Proposal 2 is an alternative**, that only extends the pharmaceutical transition period to a LDC that issues a “one-time notification” to the ARIPO Office that it does not recognize pharmaceutical product patents or utility models.

PROPOSAL Option 2: *Add Section Iter in the Harare Protocol*

Notwithstanding anything in this Protocol, its Regulations or Administrative Instructions, patent or utility model applications and grants by the ARIPO Office with respect to pharmaceutical products shall not be applicable to, or have any legal effect in any Contracting Party that is designated as a least developed country by the United Nations and that has sent a one-time notification to the ARIPO Office that it does not recognize such patents or utility models. The notification shall be made publicly available by the ARIPO Office within fourteen days of receipt of the notification.

This provision shall be valid until 1st January 2033 or such other period as may be granted to least developed countries by the Council for TRIPS of the World Trade Organization.

C.2. IMPROVING PATENT PROCEDURE

A major problem with the current system is the procedure for granting patents under the Harare Protocol. When the ARIPO Office determines that an application is deserving of a patent, it notifies each designated State, which has 6 months to object to the granting of the patent in its territory by making a written communication to the ARIPO office.³¹ In short, the Harare Protocol has adopted an “opt-out” approach. If the notified states do not communicate their objection to the ARIPO office, the ARIPO office “shall grant the patent, which shall have effect in those designated States which have not made the communication”.³² **Studies confirm that States routinely fail to communicate their objection to ARIPO and consequently patents are granted by default.**

*“Discussions with ARIPO officials, and some IP offices revealed that apart from Kenya, which occasionally communicates its objection, most other Contracting Parties either rarely or have never objected to the granting of the patent, on receiving a notification from ARIPO”.*³³

As noted above, one key reason for the failure is the lack of capacity to object within the limited time-frame. Accordingly, it is proposed that the Harare Protocol adopts an “opt-in” approach i.e. that when the ARIPO Office notifies of its intent to grant a patent, a designated state has to make a written notification to the ARIPO Office confirming that the patent will have effect in its territory. Failure to communicate means that the patent is not applicable to the designated state. This approach is consistent with ARIPO Contracting States maintaining their own sovereignty with respect to granting of patents that are consistent with their national patent laws. It is also proposed that the time-frame of 6 months be extended to 12 months.

PROPOSAL: Amend Section 3(6) and (7) of the Harare Protocol

(6) (a) Before expiration of ~~6~~ **12** months from the date of the notification referred to in Sub-section (7), a designated State may make a written communication to the Office that, if a patent is granted by the Office, that patent shall have ~~no~~ effect in its territory ~~for the reason—~~

~~(i) that the invention is not patentable in accordance with the provisions of this Protocol, or~~
~~(ii) that, because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that State.~~

(b) If the Office decides to grant a patent, it shall notify the applicant and each designated State. A copy of the search and examination report shall be attached to the said notification. The designated State shall have ~~6~~ **12** months within which to respond to the notification.

³¹ Section 3(6) of the Harare Protocol states “Before the expiration of six months from the date of notification. . . a designated State may make a written communication to the Office that, if a patent is granted by the Office, that patent shall have no effect in its territory for the reason: (i) that the invention not patentable in accordance with the provisions of this Protocol, or (ii) that, because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that State.

³² Section 3(7) of the Harare Protocol.

³³ Shashikant (2014) “The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines”, Research Paper 56; See also Osewe P. L., Nkrumah Y.K., & Sackey, E. K. 2008. “Improving Access to HIV/AIDS Medicines in Africa Trade-Related aspects of Intellectual Property Rights Flexibilities”, The World Bank. Available from http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2008/07/30/000333038_20080730041408/Rendered/PDF/448150PUB0Box310only109780821375440.pdf

(7) After expiration of the said ~~6~~-12 months, the Office shall grant the patent, which shall have effect in those designated States which have not made the communication referred to in Sub-section (6). The Office shall publish the patent granted as provided for in the Regulations.

C.3. PREVENTING PATENT EVERGREENING: SECONDARY PATENTS, NEW USE AND COMBINATION PATENT CLAIMS

Development and public policy considerations dictate that ARIPO Members should take steps to safeguard against patent evergreening. Discoveries or trivial improvements are not deserving of patents as they fail to bring any significant added innovative value. Such patents generally held by foreign entities reduce the public domain, hinder legitimate competition, adversely impact domestic entities and consequently affect access to essential goods. This situation is especially apparent in the pharmaceutical sector, although the negative effects are not limited to that sector. In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, for instance, the Supreme Court of Canada stated: ‘[E]vergreening is a legitimate concern and, depending on the circumstances, strategies that attempt to extend the time limit of exclusivity of a patent may be contrary to the objectives of the Patent Act’.

Secondary Patents: Impact on local pharmaceutical production, competition and access to medicines

Over the years, the number of newly developed chemical entities has dramatically fallen³⁴ but the number of patents over simple changes in chemistry/formulation/dosage of existing pharmaceutical products has continuously increased. Thousands of patents are granted per year on these incremental changes, trivial to a person skilled in pharmaceutical research, development and production.³⁵

Lax application of patentability standards results in secondary patents including on the various forms of known chemical entities such as new formulations, dosages, combinations and uses. Such secondary patents, have been known to be used strategically by patent-holding pharmaceutical companies to “evergreen” their patent monopoly by gaining a new 20-year period of exclusivity and thereby unduly delaying the entry of generic competitors.

A case in point is that of a critical HIV medicine – Kaletra – which is a combination of two antiretroviral agents: ritonavir and lopinavir. The basic patent for the underlying compounds was set to expire in 2014 and 2016, respectively, meaning that theoretically generic suppliers should have been able to supply Kaletra beginning in 2016.³⁶ However Abbott filed a number of trivial and follow-on secondary patents (see Box 3) which threatens to keep out generic competition in certain markets until at least 2028, i.e. 12 years after the basic compound patent expired and 39 years after the first patent for ritonavir was filed.³⁷ During the extended patent term Abbott has been able to charge monopoly prices (which have to be borne by public health systems and patients) in countries where the patents apply. Such non-inventive patents also adversely impact useful research around existing drugs³⁸.

Box 2

³⁴ Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, 2006;

Correa, C. (2011). “*Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*”, Research Paper 41, South Centre.

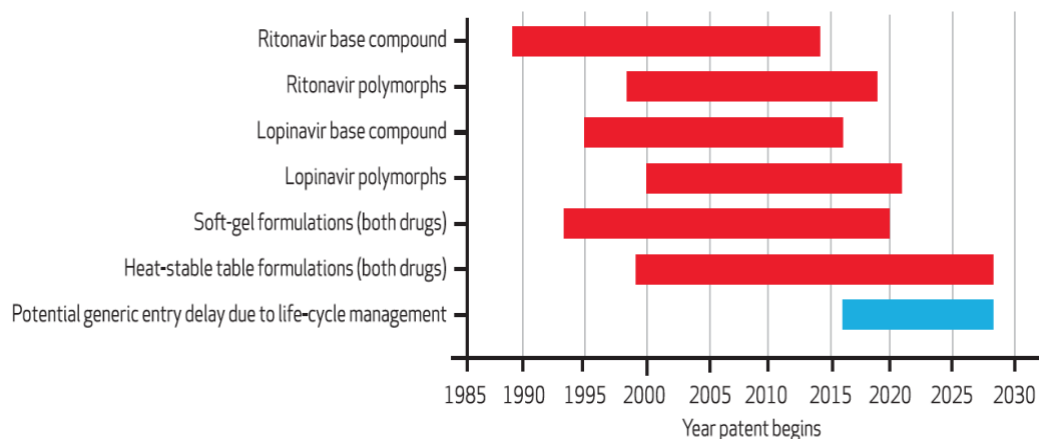
³⁵ Correa, C. (2011). “*Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*”, Research Paper 41, South Centre

³⁶ I-MAK (2012). “*Secondary Patenting A threat to Affordable Generic ARVs*”

³⁷ I-MAK (2012). “*Secondary Patenting A threat to Affordable Generic ARVs*”

³⁸ I-MAK (2012). “*Secondary Patenting A threat to Affordable Generic ARVs*”

Duration Of Patents Covering Ritonavir And Lopinavir/Ritonavir



In the USA it was found that independent formulation patents add an average of 6.5 years of patent life, independent method of use patents add 7.4 years, and independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years, and that late-filed independent secondary patents are more common for higher sales drugs.³⁹ This practice also creates what are known as “patent thickets”, making it extremely difficult for generic competitors to ascertain whether there is an existing valid patent on a medicine or to invent around an operative patent because unworked patents block such efforts.

An inquiry by the European Commission (EC) found that patent holding companies use numerous strategies including creating “patent thickets” around a successful drug (e.g. the filing of up to 1,300 patents EU-wide in relation to a single medicine)⁴⁰. In relation to 219 drugs, the EC found: “...nearly 40,000 patents had been granted or patent applications.....were still pending...Of the nearly 40,000 cases, some 87 percent were classified by the companies as involving secondary patents, giving a primary:secondary ratio of approximately 1:7.” The most common types of secondary pharmaceutical patents filed in relation to the drugs include formulations (57%), combinations (7%), polymorphs (5%), salts (4%). The EC also estimated a loss of around three billion Euros due to delays in the entry of generic products caused by misuse of the patent system.

In 2011, WIPO released its patent landscape report for ritonavir, a compound for HIV treatment which acts as a booster in combination with key ARVs. Over 800 patents were filed since the initial PCT application WO1994014436 to protect different aspects of ritonavir, a HIV/AIDS drug, and its methods of use.⁴¹ The proliferation of ‘secondary’ or ‘spurious’ patents can impose significant costs on patients and public health systems.

A review from a public health perspective of ARIPO’s basic documents and the type of patents that have been granted reveals that the application of patentability standards is lax and the ARIPO Office is open to receiving and granting secondary patents.

³⁹ Anthony Crasto and Ann Newman, “How to Handle Drug Polymorphs... Case Study of Trelagliptin Succinate”, available at <http://newdrugapprovals.org/2014/02/05/how-to-handle-drug-polymorphs- case-study-of-trelagliptin-succinate/>.

⁴⁰ European Commission (2009). “Pharmaceutical Sector Inquiry Report”. DG Competition Staff Working Paper. Available from http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_e n.pdf.

⁴¹ Patent landscape report on Ritonavir. Geneva: World Intellectual Property Organization; 2011 (http://www.wipo.int/export/sites/www/freepublications/en/patents/946/wipo_pub_946.pdf)

Table 2 below shows examples of patent grants by the ARIPO office on select HIV and TB treatment. Patent holder's monopoly on these treatments has been extended by patents granted to new forms (e.g. crystal form, salt), formulations, compositions and combinations of known compounds. These patents over minor changes are aimed at delaying generic competition, with major consequences for local generic production and access to affordable medicine in the region.

Table 2

Compound	Patent Holder	Patent Grant (Expiry Date)
Lamivudine (3TC)		
Lamivudine compound	Iaf Biochem International, Inc	AP136A (08/02/2010)
Crystal form Liquid composition	Glaxo Group Limited	AP300A (02/06/2012)
Liquid composition	Glaxo Group Limited	AP1141A (20/03/2018)
Zidovudine (AZT)		
Zidovudine compound	The Wellcome Foundation Limited, Wellcome Foundation Ltd	AP90A(15/09/2006)
In combination with Lamivudine & Abacavir	The Wellcome Foundation Limited	AP652A (28/03/2016)
3TC + AZT tablets	Glaxo Group Limited	AP1067A (29/10/2017)
Bedaquiline		
Bedaquiline compounds	Jansen Pharmaceutica N.V, Janssen Pharmaceutica NI	AP2421A (18/07/2023)
Bedaquiline to treat MDR TB	Janssen Pharmaceutica N.V	AP2037A (24/05/2025)
Bedaquiline to treat latent TB	Janssen Pharmaceutica NI, Janssen Pharmaceutica N.V	AP2327A (08/12/2025)
Bedaquiline fumarate salt	Janssen Pharmaceutica NI, Janssen Pharmaceutica N.V	A2498A (03/12/2027)

Source: www.medspal.org

Use Claims including Second Indication & Impact on Competition and Access to Medicines

In the pharmaceutical context: “New use” patent claims arise in one of two circumstances; (i) where a new pharmaceutical use is discovered for a product not previously used as a pharmaceutical product (also known as “first medical indication”); (ii) where a product already known to have pharmaceutical use(s) is discovered to have a further pharmaceutical use that is unrelated to the known use(s) (also known as “second medical indication”).

Article 27 of the TRIPS Agreement only obliges grant of patents over products and processes. WTO Members are under no obligation to grant use claims, including second medical indications.

Pharmaceutical companies often use such claims to strategically block the entry of generic products. The patenting of second indications also further de-incentivizes research into neglected diseases especially where the previously-known substance or composition was already in the public domain.⁴²

Section 3(10)(j)(iii) of the Protocol together with Rule 7 recognizes “new use” patent claims. This is apparent from the pharmaceutical product patent grant for bedaquiline (see Table 2). The compound patent granted expires in July 2023. However, the same known compound is then further patented for use in the treatment of multi drug resistant TB and to treat latent TB, extending patent holder’s monopoly until 2027. Provided no further patents are granted, generics will only be able to enter the market in 2028, a delay of about 4 years.

New use of a known product including second medical indications lacks “novelty” and there is no industrial applicability since what is new is an identified effect on the body, not the product as such or its method of manufacture.

Moreover, patents covering new medical indications of a known product is substantially equivalent to a patent over a method of therapeutic treatment, which is generally excluded in national patent laws consistent with Article 27.2 of the TRIPS Agreement. Hence accepting such patent claims contradicts with the application of the exclusion of “method for treatments of the human”⁴³ a common exclusion in most patent laws in the ARIPO region.

Country Experiences

Developing countries are increasingly adopting strict standards of patentability including provisions that explicitly exclude new uses and new forms from patentable subject matter. Such provisions remove uncertainty from patent examinations and provide patent examiners with better guidance on patentability standards. For instance, section 3(d) of the Indian Patents Act 1970 (amended in 2005) restricts patents on new forms of existing substances unless the new form has significantly increased efficacy. In addition, new uses are absolutely excluded from patenting.

Section 3(d) of the Indian Patents Act 1970 (amended in 2005)

“(3) The following are not inventions within the meaning of this Act,—[...]

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

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance.”

⁴² Correa, C. (2008). “A Guide to Pharmaceutical Patents”, Vol. 1 & II, South Centre

⁴³ Correa, C. (2006). “Guidelines for the examination of pharmaceutical patents: Developing a public health perspective”, ICTSD, WHO, UNCTAD.

In 2013, the Supreme Court of India clarified⁴⁴ that efficacy means ‘therapeutic efficacy’ and that the “mere change of form with properties inherent to that form would not qualify as ‘enhancement of efficacy’ of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy”. The Supreme Court held that, “that the physicochemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy”. The Court also held in relation to bioavailability, “just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy” which “must be specifically claimed and established by research data”.

The Indian Section 3(d) approach has been adopted in the Philippines through the Cheaper Medicines Law of 2008 and into recommendations for patent law reforms in Brazil and the East Africa Community.⁴⁵ The EAC recommends that its Partner States are to exclude from patentability: “New medical uses of known substances including micro-organisms” and “Derivatives of medical products that do not show significantly enhanced therapeutic efficacy/significant superior properties”.

The Argentine Patent Guidelines incorporate an even higher “discovery” standard than India, preventing patents on any new form of known substances, regardless of increases in efficacy. On new forms and uses, the Guidelines in summary state:

- New crystalline forms of a substance previously known in the art are not admissible.
- Pseudo-polymorphs (solvates and hydrates) cannot be patented independently from the active ingredient from which they derive.
- Enantiomers and diastereomers are not patentable. even if the application describes different properties.
- New salts of known active ingredients, esters and ethers of known alcohols as well as other derivatives of known substances (such as amides and complexes) are not patentable.
- Active metabolites are not patentable separately from the active ingredient from which they derive.
- Patents over prodrugs, if granted, should disclaim the active ingredient as such, if said active ingredient was previously disclosed or otherwise non-patentable.
- New formulations and compositions, as well as processes for their preparation, should generally be deemed obvious in the light of the prior art. Claims directed to combinations of previously known active ingredients may in practical terms be equivalent to claims over medical treatments, the patentability of which is excluded in this country.
- Claims directed to a new dosage regime are not patentable
- Claims relating to the use of a product, including the second indication of a known product, are not admissible.

Notably, some ARIPO Contracting States have also adopted provisions that limit secondary and new use patent claims. For instance, Zambia’s Patents Act (Section 17) explicitly excludes from patenting “new uses of a known product, including the second use of a medicine” while Zanzibar (part

⁴⁴ *Novartis AG v. Union of India and Ors*, CIVIL APPEAL Nos. 2706–2716 OF 2013, Supreme Court of India, Date of Judgment: 1 April 2013, available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>

⁴⁵ See Section 22.1 of the Intellectual Property Code of the Philippines; Center for Strategic Studies and Debates, Brazil’s Patent Reform: Innovation Towards National Competitiveness (2013) available at http://infojustice.org/wp-content/uploads/2013/09/Brazilian_Patent_Reform.pdf; the East African Community has also directly recommended that its Partners States “are to exclude from patentability ... Derivative of medical products that do not show significantly enhanced therapeutic efficacy/significant superior properties.” Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of Intellectual Property Legislation, Policy Statement No. 3(a)(iii), at 14 (2013) (EAC Regional IP Policy).

of the United Republic of Tanzania) unequivocally excludes “new uses or forms of known product or process” from patenting.⁴⁶ The author of “A Comparative Study of the Industrial Property Laws of ARIPO Member States” commissioned by the ARIPO Secretariat also correctly recommends that ARIPO Member States should deny patents on new uses or methods of use.

Pursuant to these precedents, ARIPO Member States are free to exclude patents on new forms or uses of known substances or to grant such patents on new forms only where there is evidence of significantly enhanced therapeutic efficacy. The proposal below is based on the former approach.

Combinations

Treatment of many diseases, especially infectious diseases, often require attacking the pathogen or disease source with multiple therapeutic agents. When it has become possible to do so, it has become common practice to combine these therapeutic agents into a single pill that is therapeutically equivalent to the medicines dosed separately. Using rational fixed-dose combination medicines is an aid to procurement and supply, enhances patient adherence, and deters patients from splitting their medicines with others.

Although it has become common practice for pharmaceutical manufacturers to make fixed-dose combinations, and the WHO has encouraged them to do so in appropriate cases, i.e., in the case of antiretrovirals, innovators often file new patent applications on the combination medicine even though it is only an admixture of known medicines with known therapeutic effects. As is the case with new uses of known medicines, there is no true novelty in a combination of known medicines without any significantly new and inventive synergistic effects. Nonetheless, ARIPO grants such patents as shown in Table 2 above. Creating combination medicines out of known active ingredients with known effects can be a potent patent evergreening strategy that in the U.S. adds an average of 9.7 years to the patent/exclusivity life of the single active ingredients.⁴⁷

Country experiences

As noted above, Argentina’s Patent Guideline do not allow patents on combinations of previously known pharmaceutical ingredients. Similarly, Section 3(e) of the Indian Patents Act excludes from patentability: “a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such a substance.” **Pursuant to these precedents, ARIPO Member States are free to exclude patents on combinations or admixtures of known substances.**

PROPOSAL: Add to Section 3(10)(h) of the Harare Protocol

(h) The following in particular shall not be regarded as inventions within the meaning of paragraph 10(a):
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(v) a new form of a known substance;

⁴⁶ Zanzibar Industrial Property Act No 4 of 2008

⁴⁷ Hao J, Rodriguez-Monguio R, Seoane-Vazquez E, Fixed-Dose Combination Drug Approvals, Patents and Market Exclusivities Compared to Single Active Ingredient Pharmaceuticals, PLoS ONE 10(10): e0140708. doi:10.1371/journal.pone.0140708.

(vi) any new property, new use or method of use for a known substance or the use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

For the purpose of paragraph (v) and (vi), salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance.

(vii) a substance obtained by a combination or an admixture resulting in the aggregation of the properties of the components thereof or a process for producing such substance.

(viii) the arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way.

PROPOSAL: To Amend Section 3(10)(j)(iii) of the Protocol

(iii) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision ~~shall not apply to products, in particular substances or compositions, for use in any of these methods.~~

PROPOSAL: To Review & Amend Rule 7 and other Regulations/Administrative Instructions to the Harare Protocol to Exclude New Forms, New Use, and Combination Patents, consistent with the proposals made above.

Rule 7 currently facilitates patent evergreening. For example, Rule 7(3) of the Regulations to the Harare Protocol specifies how claims related to medical indications or use claims - first and second medical indications – should be drafted. As mentioned above, presently, the ARIPO office approves of claims relating to use including second indication of a known pharmaceutical product although such claims lack novelty and industrial applicability (since what is new is an identified effect on the body). Further the TRIPS Agreement only obliges grant of patents over products and processes, WTO Members are under no obligation to grant use claims, including second indications.

Explanation: The proposed additions to Section 3(10)(h) of the Protocol is to make explicit that secondary patents and new uses of a known substance or process are not inventions and hence should not be patented.

Proposed paragraph (v) and (vi) are based on precedents mentioned above. The concept of “efficacy” found in Section 3(d) of the Indian Patents Act has not been applied as the efficacy qualification requires a case-by-case assessment and is subjective. Proposed paragraphs (vii) and (viii) are also drawn from the Indian Patents act. The former prevents combination of known active ingredients, which is in any case routine for persons skilled in the art, while the latter prevents patents on arrangements and re-arrangement of known devices (e.g. medical devices). Based on this precedent, ARIPO Member states should also disallow patenting of combinations, admixtures and arrangements or rearrangements of known devices.

Deletion is recommended for Section 3(10)(j)(iii) of the Protocol since that sentence endorses “use” patent claims as it notes that the ban on methods of treatment does not apply to products used in such treatment.

C.4. SUFFICIENCY OF DISCLOSURE

Full disclosure of the invention is a basic principle of patent law. Patents grant temporary monopolies to inventors in exchange for public disclosure of the invention. This issue is important to all sectors including the pharmaceutical sector. At a minimum disclosure of an invention in the patent application should be:

(a) sufficient to be understood and executed by a person with ordinary skills in the discipline concerned. It should be sufficient to teach the invention to a local expert. This standard is lower than the “person skilled in the art” standard used for assessing inventive step to ensure that the manner of disclosure is sufficiently simple and clear to be understood by a person with average knowledge.

(b) the disclosure should contain sufficient information to enable the reproduction of each embodiment of the invention for which protection is sought. This approach prevents excessively broad claims covering embodiments of the invention that have not been described by the applicant in a form that allows their reproduction by a third party.

(c) consistent with Article 29 of the TRIPs Agreement, the disclosure should indicate the best mode for carrying out the invention known to the inventor at the filing or at the priority date of the application.

(d) Lack of sufficient disclosure should be reason for the refusal of a patent application or the revocation of a patent.

In the pharmaceutical sector, pharmaceutical companies often file “Markush” patent applications covering a broad range of possible compounds, indeed sometimes millions of compounds. In such a case, a single patent may potentially block research and development and the commercialization of up to several million molecules.⁴⁸ Recent studies show a growing use of Markush claims in several developing countries, where such claims accounted for more than 50 percent of all patent applications relating to pharmaceuticals.⁴⁹ Patent offices have adopted or proposed different measures aimed at reducing the scope of Markush-type.⁵⁰

With regard to such claims, disclosure is crucial. An application including a Markush claim should contain sufficient information to allow a person with ordinary skill in the art to perform the invention over the whole area claimed, using his common general knowledge, without undue burden and

⁴⁸ UNDP “*Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*”, available at https://www.undp.org/content/dam/undp/library/HIV-AIDS/UNDP_patents_final_web_2.pdf

⁴⁹ Carlos Correa (2013), “*Pharmaceutical innovation, incremental patenting and compulsory licensing*”, South Centre, Geneva.

⁵⁰ For example, Argentina’s patenting guidelines states: “Compounds represented by a Markush formula shall be admissible only if unity of invention is demonstrated; if they comply with the requirements for patentability (novelty, inventive step and industrial application); and if the specification sufficiently describes how to obtain all of the compounds provided by the claimed Markush formula. When an invention involves multiple compounds claimed under a Markush-type formula, a reasonably logical and proportional relationship between the scope of the claims and the related matter disclosed in the description shall be required. The description should include experimental procedures that, taking into account combinations of different substituents or reasonably acceptable equivalents thereof, are representative of the entire scope of the claimed matter. If the working examples are not sufficiently representative of the claimed scope of the invention, and therefore the claims lack sufficient support in the description, the applicant should be required to limit it. For a sufficient description of the compounds included in the claimed Markush formula, the embodiments of the invention described in the working examples should be representative of all the compounds to be protected. In all cases, these embodiments shall be perfectly exemplified by providing all the data characterizing the compound obtained by physico-chemical characterization techniques (such as melting point, boiling point, -IR- infrared spectrum, proton nuclear magnetic resonance -1HNMR- and carbon 13-13CRMN-), indicating whether polymorphic compounds have been detected. Thus, the protection of Markush formulas should be limited to the matter supported by the description, that can be effectively reproduced by a person skilled in the art and whose industrial application comes up unambiguously from the description. Joint Resolution 118/2012, 546/2012 and 107/2012 (Ministry of Industry, Ministry of Health and National Industrial Property Institute), Adoption of Guidelines for the Examination of Patent Applications of Chemical and Pharmaceutical Inventions, 2012, para. (1)(iv)

experimentation, and without needing inventive skill. **The coverage of the patent should be limited to the claimed embodiments that are actually enabled by the disclosure in the specification.**

PROPOSAL: Amend Section 2bis of the Harare Protocol
(1) An ARIPO patent application: (a) Shall relate to one invention only or to a group of inventions so linked that they form a single general inventive concept. (b) Shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person of ordinary skilled in the art. <u>(c) Shall disclose the best mode known, at the date of the application or priority, for the execution of the invention.</u> <u>(d) Shall provide a description sufficient to enable the reproduction of each embodiment of the invention for which protection is sought</u> (2) The claims shall define the matter for which protection is sought. They shall be clear and concise and shall be supported by the description. (3) The abstract shall merely serve for use as a source of technical information; in particular not for the purposes of interpreting the scope of the protection sought.
Regulations
The relevant regulations e.g. Rule 6 should be amended to reflect the above.

C.5. DISCLOSURE OF INTERNATIONAL NON-PROPRIETARY NAME (INN) FOR PHARMACEUTICAL-RELATED APPLICATIONS & FOREIGN APPLICATIONS AND GRANTS

It is usually difficult to identify the subject matter of a patent application as the titles of the application are often technical and/or obscure such as “Therapeutic Nucleosides” or “Quinoline Derivatives And Their Use As Mycobacterial Inhibitors” or “Fumarate salt of (ALPHA S, BETA R)-6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-1-naphthalenyl-beta-phenyl-3-quinolineethanol”. From these titles it is not possible to know which pharmaceutical substance the application relates to. It is thus recommended that the Harare Protocol require mandatory disclosure of International Non-proprietary Names (INN).

INN, also known as a generic name, identifies a pharmaceutical substance or an active pharmaceutical ingredient. It is a unique, globally recognized name that is in the public domain. Ibuprofen, paracetamol and ritonavir are some examples of INN. The aim of the INN system is to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. Selection of INN and its publication is administered by the WHO INN Programme.⁵¹

Evidence suggests that the peak of the number of patent families filed per priority year appears after the publication of the INN.⁵² However for situations where the INNs are published after the filing of the patent application or grant, the applicant should be required to inform the ARIPO office by way of

⁵¹ The INN system as it exists today was initiated in 1950 by a World Health Assembly (WHA) Resolution (WHA3.11).

⁵² Updated Feasibility Study On the Disclosure of International Non-Proprietary Names In Patent Applications and/or Patents, SCP/28/5, available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=408018

a statement, of the INN as soon as it is available, the pending patent applications and patent grants “linked” to the INN. The ARIPO office should then promptly include INN information in its database.⁵³

Disclosure of INN will increase transparency in patent administration, improve prior art search and prevent evergreening, allow health officials, procurement agencies as well as generic companies to promptly identify the patent status related to a particular medicine or biologic. The East African Community has also recommended that its Partner States require disclosure of INNs.⁵⁴

Ideally, INN disclosure should also include the relation between the invention contained in the application and the INN as the claimed invention and the INN substance may relate to each other differently.⁵⁵

PROPOSAL: Add A New Section in Harare Protocol on INN

Section xx

(1) Where a patent application relates to a pharmaceutical substance or product, the applicant shall disclose relevant international non-proprietary names, if available at the time of filing or the priority date.

(2) Where the information in (1) is unavailable at the time of filing, the applicant shall within 30 days of the publication of INN, file a statement disclosing the relevant INN and the linked patent applications and grants.

(3) The Regulations shall specify the nature and form of disclosure.

Rule 16 of the Regulations to the Protocol requires the applicant to provide information concerning corresponding foreign patent applications, patents and other titles of protection. However, such information is only to be provided “at the request of the ARIPO Office, and within the period specified in such request” which means unless requested, the applicant need not provide the information. While the basic premise of Rule 16 is sound, the “on request” qualification frustrates its effective use. Strictly implemented, Rule 16 would significantly increase the burden of ARIPO patent examiners that have to continue requesting information and consequently delay the examination process. As such it is proposed that Rule 16 should be amended to require the applicant to mandatorily provide information about the status of corresponding foreign applications and grants. This approach is consistent with Article 29 of the TRIPS Agreement and it will greatly assist ARIPO Office in its patent examination process and significantly reduce its burden. Once the provision of information is mandated, applicants may use the online system of ARIPO to easily and promptly submit the relevant information as it become available.

PROPOSAL: Amend Rule 16 of the Regulations

Rule 16 should be amended so the applicant is required mandatorily to provide the ARIPO Office within 6 months of filing the application, all information about corresponding patent applications filed.

⁵³ Updated Feasibility Study On the Disclosure of International Non-Proprietary Names In Patent Applications and/or Patents, SCP/28/5, available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=408018

⁵⁴ East African Community Policy Guide, Regional IP Policy on the Utilisation of Public Health-Related WTO- TRIPS Flexibilities and the Approximation of National IP Legislation, p.17, 2013.

⁵⁵ Updated Feasibility Study On the Disclosure of International Non-Proprietary Names In Patent Applications and/or Patents, SCP/28/5, available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=408018

In addition, until the grant of the patent, the applicant should be required to mandatorily provide the ARIPO Office within 3 months of receipt, the following information with respect to corresponding foreign applications and grants:

- Results of search and examination or any other information concerning prior art;
- Any decision rejecting the foreign application
- Any decision refusing the grant of patent.
- Any decision revoking the grant of patent.

C.6. ADMINISTRATIVE THIRD-PARTY OPPOSITION SYSTEMS

The Harare Protocol does not feature any third-party opposition system and in this context, it is “out-of-date”. Such systems are now a common feature in national and regional laws of developed and developing countries including the European Patent Office.

In the ARIPO region, several national patent legislations do have pre- and/or post-grant third party opposition systems. For instance, Zambia’s national patent law allows a third party to file an opposition to grant of a patent application within a specified time frame. The Registrar hears and disposes of the opposition, with the aggrieved party having the possibility to appeal that decision to the High Court.⁵⁶ Post grant, any interested person may file for a revocation of a patent, and this post-grant opposition is heard by the Registrar.⁵⁷ Similar administrative pre- and post-grant oppositions also are available in several ARIPO Member States such as Uganda⁵⁸, Liberia⁵⁹, Zimbabwe⁶⁰ and Botswana⁶¹. In some other Member States (e.g. Mozambique), either administrative pre-grant or post-grant opposition systems are available.

However, at the regional level, the Harare Protocol itself does not provide for any administrative third-party opposition procedures. When the ARIPO Office notifies the national IP office of its decision to grant a patent, according to Rule 18(4) of the Regulations to the Harare Protocol, the notification together with the search and examination report upon which the decision is based should “be made available to the public in each designated State”. However, the link to national pre-grant opposition procedures, where such procedures exists, is not explicitly addressed in the Harare Protocol. Pre-grant oppositions procedures in national legislations are intended to be applicable to patent filings processed nationally and not to applications processed by the ARIPO Office. In any case, the 6-month window given to ARIPO members to object to the patent grant by the ARIPO Office is insufficient for an effective pre-grant opposition system.

Some argue that the Harare Protocol already implements an opposition system as every ARIPO Member has the right to object to the grant of patents by the ARIPO Office. This is a flawed argument as a Member’s right to object is premised on the member state exercising its own sovereign right to conduct examination of the patent application and informing the ARIPO office of its decision. On the other hand, pre-grant oppositions are about third parties (i.e. members of the public) filing an opposition.

⁵⁶ Section 56, Zambia Patents Act 2016

⁵⁷ Section 91-93, Zambia Patents Act 2016

⁵⁸ Section 28 and 32, Uganda Industrial Property Act 2014.

⁵⁹ Section 13.9(k), Liberia Intellectual Property Act 2016

⁶⁰ Section 17 and 45, Zimbabwe Patents Act (Chapter 26:03, as amended up to Act No. 14/2002)

⁶¹ Section 21(5) and Section 36, Botswana Industrial Property Act, 2010

The Harare Protocol also does not provide for post-grant opposition procedures. Once an ARIPO patent is granted, its invalidation is a national matter.

Opposition systems offers third parties an opportunity to oppose the grant of a patent before and after it has been granted. These systems are critical for addressing capacity constraints in patent offices which are often over-stretched or lack access to relevant prior art databases. Participation of third parties who may be well informed about the technology concerned in the examination of patent applications and grants provides an additional layer of review that prevents the grant of invalid patents. Such systems complement the resources available to the patent office, and increase the credibility of granted patents. From a public policy and development perspective, robust administrative pre- and post-grant opposition systems ensure that undeserving inventions are not granted patents, as such patents would unduly block competition and prejudice consumers.

For these systems to be effective, they have to be simple, easy-to-use and inexpensive. Challenging the validity of a granted patent before courts is costly and time-consuming, and most small and medium enterprises as well as the public would be reluctant to take-on the risk and cost of litigation. This means opposition systems should be “administrative”, rather than a judicial process.

There are many different variations of oppositions systems implemented worldwide such as in Australia, Costa Rica, Egypt, Pakistan, Portugal, India and Spain aimed at weeding out frivolous patent applications and grants and improving the quality of patents granted.⁶² For instance, during pre-grant, the EPO allows “Third Party Observations” i.e. any third party to present observations concerning the patentability of the invention to which the application relates, once the European patent application is published. However, the third party does not have a right to be heard. Following the grant, the patent may be opposed by any person within nine months of publication of the grant. The opposition, if successful automatically applies to the European patent in all the Contracting States in which that patent has effect.

India has an administrative third party pre- and post-grant opposition system.⁶³ Where an application for a patent has been published but a patent has not been granted, any person may, in writing, lodge an opposition with the Controller against the grant of a patent and a request for hearing, if so desired. Third parties have at least six months from the publication date of the application to file a pre-grant opposition. Once a patent is granted, “any person interested” has an opportunity to file an opposition within one year from the date of publication of grant of a patent.

The administrative pre-grant opposition system is actively used by generic manufacturers as well as civil society including patient groups, to oppose pharmaceutical patent applications that do not comply with national patent law requirements. In 2006 civil society opposed Glaxo’s application for a patent on a critical ARV combination AZT/3TC, resulting in Glaxo’s withdrawal of all patent applications in all countries.⁶⁴ Indian generic companies also successfully opposed Novartis’s patent application on imatinib mesylate, a life-saving medicine used for the treatment of chronic myeloid leukaemia (CML),

⁶² https://www.wipo.int/scp/en/revocation_mechanisms/

⁶³ Section 25, India’s Patents Act 1970

⁶⁴ MSF (2013). “*Untangling the Web of Antiretroviral Price Reductions*”, 16th Edition. Available from www.accessmed-msf.org.

resulting in generic treatment being available at a more affordable price range of \$100-\$150 per month, rather from Novartis at \$2,500 per person per month.⁶⁵

The EAC has also recommended that its Partner States provide “for effective pre- and post-grant administrative patent application procedures”.

Reviewing these various experiences, it is recommended that the Harare Protocol implements administrative third-party pre- and post-grant opposition systems. Each of these are further discussed below.

C.6.1. Administrative Pre-grant Opposition

An effective pre-grant opposition procedure would:

- Require publication of pending patent applications prior to examination and such applications should be fully and freely available online on a searchable database;
- Allow any person, to file a pre-grant opposition at any time after publication of the patent application but prior to the grant of a patent, with ample time for opponents to submit relevant evidence;
- Establish broad grounds for opposition including failure to meet patentable subject matter, exclusion, or patentability criteria and failure to make required disclosures;
- Opponents should be given full legal standing and they should be able to appear at a hearing in support of their opposition, should they wish to do so;
- The pre-grant opposition procedure should involve simple, expedited administrative procedures.

Some may argue that a pre-grant opposition system would overburden the ARIPO office. However, figures available suggest otherwise. For example, in Australia, in 2010/2011, only 0.5% application of the 26473 applications filed in Australia, were opposed.⁶⁶ In India, in 2016/2017, of the 6,766 patent applications published, only about 0.23% were opposed.⁶⁷

The number of patent applications processed by the ARIPO office annually are significantly lower. In 2017, ARIPO Office received 747 applications. One could reasonably conclude that the rate of opposition is likely to be low and hence implementing such a system is possible.

Some may question the need for an *inter-partes* pre-grant opposition system, instead preferring implementation of a third-party observation system. While the willingness to receive third-party observations is welcomed, it is inadequate to address public policy and development considerations. A third-party observation system merely allows third-parties to submit observations including prior art information with regard to the patent application. The third-party is not involved in the examination of the patent application and a patent examiner is also not obliged to consider the observations.

On the other hand, administrative pre-grant opposition systems could be designed to allow third-parties that wish to only submit relevant information, to do so without requesting for a hearing as well as allow hearings on request as some third-parties may have certain economic or public interests at stake and may wish to challenge the patent application in *inter-partes* procedures, to present evidence and to be

⁶⁵ Gopakumar K.M. (2013). “*What should we learn from the Novartis judgment?*” Third World Resurgence No. 273, May 2013. Available from <http://www.twinside.org.sg/title2/resurgence/2013/273/cover03.htm>.

⁶⁶ SCP/18/4 “Opposition systems and other administrative revocation and invalidation mechanisms” available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=226122

⁶⁷ Annual report 2016-17 of the office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications

heard, before the examiner takes a decision on the application. The patent applicant would also have similar opportunities to respond. Such a system provides the examiner with concrete information and evidence that the examiner needs to consider, in taking a decision on the patent application.

Pre-grant opposition system should be seen as a mechanism that is part of and complementary to the patent examination process. It will be especially supportive of ARIPO's patent examiners that may lack resources to conduct thorough and comprehensive examinations.

It is worth noting that many of the patents granted today, if challenged would be invalidated. In the US, between 2007 and 2011, only 39 out of 283 cases where patent validity was questioned before a US Federal District Court, the claims that were challenged were found to be valid and enforceable.⁶⁸ When the lower court invalidated a patent, the Federal Circuit affirmed that decision more than 70 per cent of the time over the years examined.⁶⁹

This reinforces the need for ARIPO Office to implement a robust administrative opposition system.

PROPOSAL: Add A New Section on Pre-Grant Opposition in the Harare Protocol

Pre-Grant Opposition

(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the ARIPO Office against the grant of patent on the ground—

- (a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;
- (b) that the invention so far as claimed in any claim of the complete specification is a non-patentable invention under Section 3 of the Protocol.
- (c) that the invention as claimed is not novel, is obvious and does not involve an inventive step and is not industrially applicable.
- (d) that the invention so far as claimed is preceded by a claim with an earlier priority date than that of the applicant's claim;
- (e) that in the case of a Patent Cooperation Treaty application, the application was not made within twelve months from the date of the first application for protection for the invention made in a PCT country by the applicant or a person from whom he derives title
- (f) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
- (g) that the patent application has failed to comply with the requirements of the Protocol or has furnished information which in any material respect was false and known to be false or incomplete;
- (h) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;
- (i) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in the ARIPO region or elsewhere.

⁶⁸ White Paper Report, "United States Patent Invalidation Study 2012",

⁶⁹ *ibid*

(2) The ARIPO Office shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed.

(3) No patent shall be granted before the expiry of a period of nine months from the date of publication of the application.

(4) The patent examiner considering the pre-grant opposition shall provide a written decision and the grounds for the decision.

Regulations

The Regulations should specify details about procedures and formats for presenting pre-grant oppositions and evidence and arguments in support thereof. Any procedures adopted should be expeditious and easy-to-use. The patent examiner considering the pre-grant opposition should be required to file a written decision on the merits explaining and justifying its response to the opposition.

C.6.2. Administrative Post-Grant Opposition System

Some key features of an effective administrative post grant opposition system are:

- Information concerning the grant including all information concerning the patent claims granted should be freely available online.
- Any person should be allowed to utilize the post-grant opposition mechanism
- There should be no time limits for a third party to initiate a post-grant opposition
- The grounds for opposition should be broad.
- The composition of the panel/board that will hear the opposition case should be clarified.
- There should be an appeal process, so that any decision of the board may be appealed.

In the case of the European Patent Office (EPO), the rate of patent oppositions (as a percentage of total patents granted) is relatively low: around 5 per cent to 6 per cent (data for 1980-2005) of the European patents granted were opposed. Interestingly, about two thirds of the opposed patents were revoked or amended to survive the challenge. This justifies why the Harare Protocol should also include post-grant opposition proceedings.

PROPOSAL: Add A New Section on Post-Grant Opposition in the Harare Protocol

Post-grant opposition

(1) At any time after the grant of patent, any person may give notice of opposition to the ARIPO Office in the prescribed manner on any of the following grounds, namely: —

- (a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;
- (b) that the invention so far as claimed in any claim of the complete specification is a non-patentable invention under Section 3 of the Protocol.
- (c) that the invention as claimed is not novel, is obvious and does not involve an inventive step and is not industrially applicable.
- (d) that the invention so far as claimed is preceded by a claim with an earlier priority date than that of the applicant's claim;

- (e) that in the case of a Patent Cooperation Treaty application, the application was not made within twelve months from the date of the first application for protection for the invention made in a PCT country by the applicant or a person from whom he derives title
 - (f) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
 - (g) that the patent application has failed to comply with the requirements of the Protocol or has furnished information which in any material respect was false and known to be false or incomplete;
 - (h) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;
 - (i) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in the ARIPO region or elsewhere.
- (2) (a) Where any such notice of opposition is duly given, ARIPO Office shall notify the patentee and provide an opportunity to submit observations on the opposition. The opponent shall have a right to reply.
- (3) On receipt of such notice of opposition, the ARIPO Office shall, by order in writing, constitute a Board to be known as the Opposition Board consisting of three members and refer such notice of opposition along with the documents, patentee's comments and opponent's right to reply to that Board for examination and submission of its recommendations to the ARIPO Office.
- (4) Every Opposition Board constituted shall conduct the examination and hear the parties in such manner and within such period as may be prescribed. The examiner, who has dealt with the application for patent during the proceeding for grant of patent thereon shall not be eligible as member of Opposition Board.
- (5) On receipt of the recommendation of the Opposition Board, the ARIPO Office shall order either to maintain or to amend or to revoke the patent. In case the order is that the patent be maintained subject to amendment of the specification or any other document, the patent holder shall complete the requirements for amendment within such period as may be prescribed, failing which the patent shall be revoked.
- (6) Any order of the ARIPO Office shall have immediate effect in all designated States of ARIPO.

D. CONCLUSION

The ARIPO Secretariat and its Contracting States have a unique opportunity and indeed a human rights obligation to amend the Harare Protocol so as to take full advantage of flexibilities granted to them under the WTO TRIPS Agreement. This Civil Society submission and the proposals herein present a modest set of recommended amendments to the Harare Protocol that would greatly enhance access to affordable medicines in the ARIPO region and further support the development of pharmaceutical manufacturing capacity in the region. The civil society organizations supporting this submission hereby also request that they be formally invited to future consultations undertaken by ARIPO and its Contracting States concerning its mandate to “*explore and formulate concrete proposals aimed at*

addressing policy and legal incoherencies that impact access to health technologies and in the Member States of ARIPO.”

ANNEX 1

IP/C/73

6th November 2015

Council for Trade-Related Aspects of Intellectual Property Rights

EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT FOR LEAST DEVELOPED COUNTRY MEMBERS FOR CERTAIN OBLIGATIONS WITH RESPECT TO PHARMACEUTICAL PRODUCTS
DECISION OF THE COUNCIL FOR TRIPS OF 6 NOVEMBER 2015

The Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS"),

Having regard to paragraph 1 of Article 66 of the TRIPS Agreement;

Recalling the decision of the Council for TRIPS on the Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations With Respect to Pharmaceutical Products (IP/C/25), adopted by the Council for TRIPS at its meeting of 25-27 June 2002 pursuant to the instructions of the Ministerial Conference contained in paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2);

Having regard to the duly motivated request from least developed country Members, dated 23 February 2015, for a further extension of the transition period regarding Sections 5 and 7 of Part II of the TRIPS Agreement with respect to pharmaceutical products (IP/C/W/605);

Decides as follows:

1. 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 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier.
 2. This decision is made without prejudice to the right of least developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.
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ANNEX 2

WT/L/971

2 December 2015

General Council

LEAST DEVELOPED COUNTRY MEMBERS – OBLIGATIONS UNDER ARTICLE 70.8 AND ARTICLE 70.9 OF THE TRIPS AGREEMENT WITH RESPECT TO PHARMACEUTICAL PRODUCTS

DECISION OF 30 NOVEMBER 2015¹

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (the "WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Recalling the decision of the General Council on Least Developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement With Respect to Pharmaceutical Products (WT/L/478), adopted by the General Council at its meeting of 8 July 2002;

Having regard to the request from least developed country Members, dated 23 February 2015, for a waiver from obligations under paragraph 8 of Article 70 of the TRIPS Agreement and a further extension of the waiver from obligations under paragraph 9 of Article 70 of the TRIPS Agreement with respect to pharmaceutical products (IP/C/W/605);

Noting the decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, adopted by the Council for TRIPS at its meeting of 6 November 2015 (IP/C/73);

Recalling the decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products (IP/C/25), adopted by the Council for TRIPS at its meeting of 25-27 June 2002, pursuant to the instructions of the Ministerial Conference contained in paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");

Considering that obligations under paragraphs 8 and 9 of Article 70 of the TRIPS Agreement, where applicable, should not prevent attainment of the objectives of paragraph 7 of the Declaration and the decision of the Council for TRIPS, adopted on 6 November 2015 (IP/C/73);

Noting that, in light of the foregoing, exceptional circumstances exist justifying a waiver from paragraphs 8 and 9 of Article 70 of the TRIPS Agreement with respect to pharmaceutical products in respect of least developed country Members;

1. The obligations of least developed country Members under paragraphs 8 and 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier.

2. This waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.

[1] Adopted in accordance with the Decision-Making Procedures under Articles IX and XII of the WTO Agreement agreed by the General Council in November 1995 (WT/L/93).