TRIPS flexibilities in Africa: Are countries equipped to protect public health?

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Outline

- Introduction & Methodology
- Key Takeaways
- Main Findings
- Preparedness for COVID-19 Response

Introduction & Methodology

- Access is a huge problem in Africa
  - Burden of both communicable & NCDs
  - Ailing health systems
  - Price barriers to health technologies
- Methodology
  - Focus on English-speaking countries (28)
  - Review of regional policies & national laws
  - Review of literature on use of flexibilities
  - Analysis of trends and challenges

Key Takeaways

- Majority of countries are LDCs (60%)
- Role of regional organisations critical
- Capacity & other constraints
- Surge of use of flexibilities during the HIV epidemic
- Question of political will

Role of Regional Organisations

- Positive
  - Continental initiatives: Roadmap on Shared Responsibility & Global Solidarity for AIDS, TB & Malaria response in Africa (2012); PMPA; Agenda 2063)
  - Regional: EAC TRIPS Policy; SADC Pooled Procurement Strategy.
  - 2nd decade of Doha – at least 10 countries revised IP laws → Flexibilities.
- Negative
  - ARIPO Patents:
    - Examines on behalf of members: members also have own legislation; can opt out of recognizing the patent.
  - OAPI Patents:
    - OAPI office grants patents on behalf of its members; do not have individual national laws.

Capacity Constraints

- Limited capacity to receive and process applications.
- Dependence on ARIPO process.
  - Many members have pre-grant opposition in their national legislation, but ARIPO does not use this flexibility.
  - Examination of patents is not rigorous because of, among others, its own capacity constraints.
  - Countries struggle to comply with the 6-month opt-out rule.
  - ARIPO patents are then applicable, even in LDCs.

Reform: Amend Harare Protocol to include blanket exemption of LDCs from recognizing patents on pharmaceutical products; itself adopt more rigorous patent examination standards, to weed out evergreening.

Question of Political Will

- Even where the legislation exists, not used to benefit public health.
- Conversely, in some states, even where no express legal provisions relating to certain flexibilities, they were still able to take the necessary steps.
- For instance, Comoros, Mozambique, and Sao-Tome and Principe reportedly made use of Article 31 of TRIPS despite the absence of relevant provisions in their respective patent laws.
- African countries face additional pressures to include higher protections in FTAs; as well as to adopt anti-counterfeiting legislation(EAC; ECOWAS).

Snapshot of Flexibilities in Legislation

- **LDC Transition**: 28 of 33 countries have incorporated into law.
- **Patentability Criteria**: New uses, methods, forms excluded in 4 countries (Namibia, Rwanda, Zambia, Zanzibar).
- **Substantive Examination**: In most legislation, but effectively non-examining.
- **Pre-Grant Opposition**: Available in 9 countries, but mostly non-examining.
- **Post-Grant Opposition**: Available in 23 countries; no evidence of use.
- **Bolar Exception**: Available in 11 countries; no evidence of actual use.
- **Compulsory Licences/Government Use**: Available; 19 countries reference public health or emergency; used fairly often in 2002-2009 period.
- **Research Exception**: Available in 19 countries; no evidence of use.
- **Parallel Importation**: Available in some form in 23 countries; only 1 use.

73 Uses of Flexibilities 2002-2009

(Adapted from Medicines, Law & Policy, TRIPS Flexibilities Database)

Flexibility	No. of Uses	Countries Utilising the flexibility
Para 6 Doha	1	Rwanda, 2007.
Para 7 (LDC) Doha	40	Benin, Burundi, Burkina Faso, Cape Verde, CAR, Chad, Comoros, Djibouti, DRC, Eritrea, Gambia, Guinea, Guinea-Bissau, Lesotho, Malawi, Mauritania, Mozambique, Niger, Rwanda, Senegal, Sierra Leone, S Sudan, Sudan, Tanzania, Togo, Uganda, Zambia. (27) – Majority for ARVs; some for all medicines (11).
Art 31 (CL/GU) TRIPS	25	Cameroon, Congo, Ethiopia, Gabon, Ghana, Equatorial Guinea, Ivory Coast, Liberia, Mozambique, Swaziland, Sao Tome & Principe, Zambia, Zimbabwe. (13) – Majority government use.
VL	6	Kenya, South Africa.
Parallel Import	1	Kenya.

What Does this Tell Us?

- Necessity is a key driver for use of flexibilities.
- This period was the height of the global HIV/AIDS pandemic:
  - 28 CL uses for ARVs; 11 for all medicines.
- Not all countries availed themselves of flexibilities:
  - Only 30 of 55 countries: and 27 of 33 LDCs.
- No other reported uses of flexibilities, despite access problems.
- Many countries have some experience of using flexibilities.
- A crisis or pandemic is an opportune moment to adopt and use them.

COVID-19: Are countries equipped?

- What does the response need?
  - PPEs: in short supply (many patents on respirators etc.)
  - Diagnostics: tests in short supply (limits on exports).
  - Treatments: none approved (all but one candidate patented).
  - Vaccines: none approved (likely to be patented).
  - Legal frameworks that are fit for purpose.
- Opportunities:
  - Open science/resources for equitable access to public goods.
  - Not to be exploited to create market monopolies.
  - Leaps in science & tech, but no short cuts in eg clinical trials.

COVID-19 & Beyond

- COVID-19 Emergency Access Act?
  - LDCs
    - Blanket exemption for pharmaceutical products.
    - Other flexibilities?
  - Developing Countries
    - All available flexibilities
    - Strict patentability standards + detailed guidelines
    - Quick, easy government use provisions
    - Cover data exclusivities, trade secrets, know-how etc.