

### 3. INTELLECTUAL PROPERTY POLICY & LEGAL FRAMEWORK

This section looks at the key issues and challenges related to the legal and policy framework in LDCs, before setting out a detailed checklist to guide an assessment, based on available evidence, about the capacity of a country to formulate policy and legislation on intellectual property and to participate in international IP standards setting and negotiations.

#### ***3.1 Key issues and challenges***

Most LDCs are members of the World Trade Organisation (WTO) or are in the process of accession. The objectives, principles, rights and obligations of the WTO TRIPS Agreement need to be well-understood by policymakers and legislators in LDCs, as do the flexibilities, safeguards and S&DT provisions available to them to build a sound and viable technological base and ensure their national IPR regime contributes to social and economic development goals.

For LDCs, implementation of the TRIPS Agreement is a significant challenge and will often require the preparation or updating of a full range of industrial and intellectual property policies, laws and regulations, as prescribed under the Agreement. At the same time, many countries are finding themselves increasingly involved in negotiations that are occurring in parallel at the international, regional and bilateral levels, negotiations that are constantly reshaping the global IPR regime. LDCs are increasingly concerned about the TRIPS-plus agreements at the regional and bilateral level, as these tend to require commitments that go beyond the minimum standards set out in the TRIPS Agreement.<sup>i</sup>

The capacity of LDCs to participate effectively in international and regional IPR rule making and standard setting varies considerably, from influential to virtual spectator.<sup>ii</sup> Effective IPR policy development and implementation requires specialized technical and analytical skills and also a capacity to coordinate the policy development process in the national capacity so as to ensure the participation of key stakeholders both within and outside of government. Responsibility for IPR policy in LDCs generally falls to ministries of international trade or foreign affairs. The subsequent development of IP legislation and regulations is often delegated to ministries or departments that are, or will be, responsible for the actual administration of the IP system.

Important IPR issues facing national in general policy makers and legislators in LDCs include:

- how to utilize the flexibilities, safeguards and S&DT provisions available under TRIPS;
- how to ensure the national IPR regime can best promote innovation, creativity, access to knowledge and transfer of technology;

- How to better implement the Doha Declaration, the waiver on article 31 f) of TRIPS (also called paragraph 6 solution); and any future amendment of the TRIPS agreement in light of the Doha Declaration and the waiver;
- how to generate synergies with WHO Resolutions and discussions on Public Health, Intellectual Property and innovation;
- how to regulate access and protect plant varieties and plant genetic materials;
- how to best exploit national biological resources as envisaged under the Convention of Biological Diversity (CBD);
- whether and how to design and implement appropriate systems to protect traditional knowledge; and
- how best to continue to adopt administrative systems and processes to keep pace with rapidly evolving international and regional IP systems and standards.

To ensure that national IPR reform processes are effectively linked to related areas of development policy, and that stakeholders participate effectively in these reform processes, IPRTA donors and providers should be mindful of the need to build sustainably the capacity of local institutions to carry out policy research, analysis and dialogue with these stakeholders, in addition to providing international expert and legal advice.<sup>iii</sup>

In recent years, concerns have been expressed from a number of different sources regarding the role of donors in providing advice and technical assistance to developing countries and LDCs for reform of IPR policy and legislation. While LDC IP offices typically value the technical assistance provided by institutions such as WIPO or bilateral donors, a number of experts and organisations have raised substantial concerns about whether this assistance has always been appropriately tailored to the circumstances of the developing country concerned and the local absorptive capacity for such assistance.

Such concerns demonstrate the potential sensitivity and importance of this area of domestic regulatory policymaking in developing countries. As many LDCs will continue to depend on technical assistance in this area for some time to come, particularly as they proceed in the future with implementation of the TRIPS Agreement, IP technical assistance should be mindful of the need to respond positively to these concerns.

***In particular, IPRTA donors and providers should ensure that advice on legal and policy reform to LDCs in relation to implementation of the TRIPS Agreement, always fully takes into account the possible options and flexibilities to accommodate public policy objectives and the possibilities, according to the Agreement, to request further extensions to the application of TRIPS in a LDC context.***

### **3.2 Diagnostic assessment checklist**

#### **Key national concerns and issues**

- What are the key national concerns in relation to IPR policy and legislative framework (e.g. economic development, trade etc)?
- How well have such concerns been manifested or articulated by stakeholders in the country? Are these concerns based on actual documented evidence?
- Are some potentially important concerns and issues likely to surface in the near future? What are these? What measures are being taken or planned to address these?
- To what extent have the objectives and principles of the TRIPS Agreement, Articles 7<sup>iv</sup> and 8<sup>v</sup> been taken into account in formulating national IP strategy?

#### **National policymaking/legislative processes & stakeholder map**

- What ministry or agency has the lead role in IPR policy coordination and making?
- What is the general policy coordination/making process particularly with respect to public participation in the area of IPR?
- To what extent does lobbying by particular interest groups influence policy making and legislative processes generally and in respect of IPR policy/legislation in particular?
- If the development of policy and the preparation of legislation for the various forms of IPR are the responsibilities of different ministries or agencies, what are these?
- What ministry or agency has the lead role in the drafting of IPR legislation?
- What role do IPR administrators play in policy development and the drafting of legislation and regulations?
- What is the process for developing IPR legislation, regulations and procedures (e.g. are discussion papers prepared, are stakeholders solicited for input, etc.)?
- Who are the key stakeholders in the country's process for IP policy and legislation development? (An outline for a national and international stakeholder map is presented at Annex A).
- What Ministry has the lead role in ensuring the country's implementation of the objectives, principles, rights and obligations under the TRIPS Agreement, including giving due consideration to use of flexibilities, safeguards and S&DT provisions for LDCs?

### **Existing legal framework for industrial and intellectual property protection, enforcement and regulation**

- Does a statement of national policy (i.e. purpose) with regard to intellectual and industrial property exist that forms the basis for IPR laws and the administration of IPRs in the country?
- If there is no explicit statement of purpose, where can the government’s expression of such purpose best be found (e.g. government decrees, jurisprudence, etc)?
- What is the nature and scope of the national legal framework for the establishment and enforcement (including private dispute resolution) of IP rights? (A template for analysing national IPR legislation is presented at Annex C).
- Does the national legal framework for IP meet all TRIPS requirements at the present time? If national legislation does not meet all TRIPS requirements, what areas require further attention?
- To what extent have TRIPS flexibilities, safeguards and S&DT provisions for LDCs been considered and reflected in national legislation and regulations?

### **Public Health and access to essential medicines**

- To what extent have the Doha Declaration on TRIPS and Public Health and the waiver of Article 31 (f) of the TRIPS Agreement been considered in national legislation and regulations reform?
- To what extent have TRIPS flexibilities, safeguards and Special & Differential Treatment provisions for LDCs that are relevant for addressing public health concerns been considered and reflected in national legislation and regulations (i.e. compulsory licensing, parallel importation, exceptions to patent holder rights, patentability guidelines for pharmaceutical products, etc)?
- What type of technical assistance has been received in relation to the TRIPS Agreement and Public health? Who have been the main providers?
- Does the country participate in regional or international “common interest” blocs in connection with any of these issues (regional legislation, regional procurement/aid schemes or cooperation frameworks)? If yes, what ministry or agency has the lead role? What role do the health ministries and IP offices play in this?

### **Protection of traditional knowledge, folklore and biodiversity**

- What are the broad national interests and/or concerns with respect to protection of traditional knowledge, folklore and biodiversity?
- What activities are currently under way in the country that have led or will lead to the definition of national positions (e.g. in international rule making) with respect to each?

- Are there specific issues that are of particular domestic concern or interest (e.g. “basmati” rice, “Maldives” Tuna, traditional textiles, Geographical Indications)? Who are the key stakeholders with respect to each issue?
- Does the country participate in regional or international “common interest” blocs in connection with any of these issues? If yes, what ministry or agency has the lead role? What role do the IPR administrators play in this?
- Is the country actively participating in related discussions in WTO and WIPO? Is the country a member of the CBD and/or the 2004 FAO Treaty on Plant Genetic Resources and if so has it adopted national laws implementing the principles of these treaties?

#### **Recent legal changes**

- What changes in IPR legislation have been promulgated since 1990?
- Why were these changes made? Was it due to internal processes or in response to external forces such as the need to implement treaties etc?
- Did the country require TA to undertake these changes? If so, from whom was the TA obtained and under what conditions, if any, was the TA provided?
- Have the above legislative changes been implemented in practice? That is, are there implementing rules and regulations or administrative guidelines in place, and are these being actively implemented by administrators, courts and enforcement authorities?

#### **Planned legal changes**

- What legal changes that will impact IPRs are planned or pending?
- Are the planned legal changes due to internal demands/processes or is it because of international obligations or other external factors?
- When are they expected to be promulgated?

#### **Membership of international treaties and agreements**

- Is the country a Member of the WTO? Is the country acceding to the WTO?
- Is the country a member or observer at the World Intellectual Property Organisation (WIPO)?
- Is the country a member of other key intellectual property protection, global protection system and classification treaties? (A list of the main WIPO global protection systems and treaties is presented at Annex B). If so, which ones?
- Is the country a member of bilateral or regional trade agreements that include an IP component or provisions? If so, which ones?
- The additional question could be – Have all these treaties been implemented nationally, e.g., is there evidence of implementing legislation-decrees, regulations etc.?
- Is the country a member of regional IPR treaties or agreements (e.g. OAPI, ARIPO, EAPO, etc.)? Is membership regarded as successful by the country concerned?

### **Participation in international IP standard setting and negotiations**

- To what extent does the country participate in international IPR standard setting (e.g. WIPO, WTO)?
- Is the country currently involved in international, regional or bilateral negotiations that have an IPR component? If yes, what are these?
- Does the country have permanent representation at WTO and WIPO in Geneva?
- Who are the key IP agencies and officials in the capital? What are the mechanisms for consulting with stakeholders and co-ordinating policy positions across government?
- Does the country participate in regional trading bloc deliberations on IPRs (e.g. ASEAN, APEC, SAARC, ANDEAN Community, COMESA, CEMAC, EAC, UMEOA, and ECOWAS)?
- What role does the IP office play in supporting IPR discussions and negotiations at the regional and international levels? What resources does the IPR office have for this (e.g. skills, travel budget)?

### **Technical assistance and capacity building programmes**

- What donors have been or are presently actively providing IP-related technical assistance in support of the development of the national IP policy and legal framework?
- How will new proposed IPRTA projects or programmes be co-ordinated with, learn lessons from and complement such other donor-supported activities?