Development aspects of intellectual property rights on genetic resources: the impact on poverty reduction in developing countries

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The Committee on Development adopted the report by Catherine GREZE (Greens/EFA, FR) on development aspects of intellectual property rights on genetic resources: the impact on poverty reduction in developing countries.

The committee stresses that the Convention on Biological Diversity (CBD) differs remarkably from other international environmental treaties in that it gives an explicit and prominent role to questions of equity and justice in the conservation and use of biodiversity. Furthermore, genetic resource (GR) providers and holders of related traditional knowledge (TK) frequently belong to developing countries rich in biodiversity, and national access and benefit sharing (ABS) legislation, adopted as part of the CBD process, emerged as a response to the practices of bioprospecting and biopiracy.

Genetic diversity and the MDGs: Members recall the **direct link between the protection of biodiversity and the achievement of the MDGs,** and stress the challenges that intellectual property rights (IPR) over genetic resources and traditional knowledge raise in developing countries in terms of access to medicine, production of generic drugs and farmers' access to seeds. Accordingly, **EU trade policy related to IPR must be consistent with the objective of Policy Coherence for Development (PCD)** as enshrined in the EU Treaty.

The report underlines the fact that there is no generally acceptable definition of the term "biopiracy", but refers to misappropriating and/or illicitly benefiting commercially from the use of traditional knowledge and genetic resources and stresses that further work must be carried out in order to clarify the legal terminology.

Agriculture and health: the committee recalls the need for a wide range of Genetic Resources for Food and Agriculture (GRFA), which is crucial to food security, and that the wild varieties of cultivated plants that are important for the food security of EU Member States are largely found in developing countries. It urges the EU, within the remit of the UPOV Convention, to **refrain from supporting the introduction of legislation that may create obstacles to the reliance of farmers on harvested seeds.**

Members also recall that the 'farmers' exception', under the International Union for the Protection of New Varieties of Plants (UPOV) Convention, allows farmers to save seeds deriving from new varieties and to re-sow them for usual food purposes (thereby enhancing food security). They regret, however, that while it is in the interest of developing countries to extend exemptions from plant breeders' rights, **farmers' rights have become weakened in consecutive reforms of the UPOV Convention.** The report calls on the EU to support developing countries' requests to ensuring appropriate BS in any new sectoral mechanisms/instruments under the Food and Agriculture Organisation (FAO) as well as ensuring consistency with the CDB and its Nagoya Protocol.

Furthermore, it is stressed that GRs, inter alia in the form of herbal medicine, contribute significantly to pharmaceutical R&D and access to medicine, and the report reasserts that **IPRs should not hinder access to affordable medicines, especially where such IPRs rely on GRs that originate from developing countries**. Members call on the EU to refrain from pushing developing countries, especially LDCs, through bilateral agreements to accept far-reaching IP standards regarding e.g. seeds and medicines.

Rights of indigenous and local communities over traditional knowledge: noting with concern that the difficulties faced by TK holders include monitoring and enforcement, Members regret that traditional knowledge associated with genetic resources is not covered by any of the Nagoya Protocol's monitoring measures: there is no obligation to disclose to the 'checkpoint' information on the TK used, while the internationally recognised certificate of compliance does not cover TK associated with GR, which limits the possibility of tracing biopiracy related to such TK. They take the view that **the EU should grant traditional knowledge at least the same level of protection as genetic resources** when implementing the Nagoya Protocol. Furthermore, Members stress that regulations laid down to protect GRs and their associated TK must comply with international commitments, as enshrined in the 2007 UN Declaration on the Rights of Indigenous Peoples (UNDRIP) and the 1989 ILO Convention on Indigenous and Tribal Peoples (No 169). They also point out that three quarters of the world's population depends on natural traditional medicine from plants.

Addressing biopiracy - the way forward: the report points out that biopiracy can be attributed to the lack of national regulations and enforcement mechanisms in developing countries and the lack of a compliance mechanism in developed countries, ensuring that GRs have been acquired in accordance with Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) in compliance with provider countries' national ABS legislation. The committee welcomes, in this context, the draft regulation submitted by the Commission whose objective is to implement the Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing. It notes, however, that the elaboration of ABS legislation in developing countries is a precondition for the obligation of user countries to comply with PIC requirements, but this request poses a real challenge for developing countries as it requires substantial legal and institutional capacity building.

Members urge the EU and its Member States to call for **swift ratification of the Nagoya Protocol** and stress the role of EU development cooperation in providing developing countries with **assistance for legal and institutional capacity building** on access and benefit sharing issues. They believe that support should be given to developing countries in building up databases of TK and understanding patent application systems:

1. Improving database and disclosure requirements related to genetic resources and traditional knowledge: Members believe that a **binding instrument** is the surest way to see biodiversity-related measures in the IPR system implemented by user countries. They urge that steps be taken to make the granting of patents dependent on compliance with a mandatory requirement to disclose the origin of any GR/TK in patent applications, and stress that **such disclosure should include proof that the GR/TK in question has been acquired in accordance with applicable rules** (i.e. prior informed consent and mutually agreed terms). An international instrument comprising disclosure requirements and databases for genetic resources protection is **not a substitute** for an effective access and benefit sharing mechanism at the national level. Members take the view that direct notification by users of companies using genetic resources or associated traditional knowledge, utilisation of certificates compliance and exploration of litigation options within and outside the national jurisdiction, can also effectively contribute to curb potential biopiracy cases.

Lastly, the committee regrets the lack of clear statistics on biopiracy and misappropriation, and calls for more EU research and disclosure of information in this field to remedy this situation.

2. Working towards a coherent global governance system: the report insists that WTO-TRIPS should be compatible with the CBD-Nagoya Protocol, and states that it is crucial to establish mandatory requirements on disclosing the origin of genetic resources during patent proceedings, and thus making it possible to check whether they were acquired legally in accordance with PIC and MAT. Such requirements could be introduced via an amendment of the WTO-TRIPS Agreement or under WIPO. Members call on the EU, in particular, to support, in line with PCD, the request of developing countries to amend the WTO-TRIPS Agreement.

Lastly, Members call on the Commission to instruct its negotiators in the WIPO IGC and the TRIPS review to consider the Nagoya Protocol as their point of departure and to focus on bringing in line the legal framework of relevant Conventions with regard to maritime genetic resources.