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## **DRAFT REPORT**

on development aspects of intellectual property rights on genetic resources: the impact on poverty reduction in developing countries  
(2012/2135(INI))

Committee on Development

Rapporteur: Catherine Grèze

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## MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

**on development aspects of intellectual property rights on genetic resources: the impact on poverty reduction in developing countries  
(2012/2135(INI))**

*The European Parliament,*

- having regard to the 1992 Convention on Biological Diversity (CBD),
- having regard to the 2010 Nagoya Protocol to the CBD on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation,
- having regard to the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture,
- having regard to the 2002 Patent Cooperation Treaty,
- having regard to the United Nations Declaration on the Rights of Indigenous Peoples adopted by the General Assembly on 13 September 2007,
- having regard to the 1989 ILO Indigenous and Tribal Peoples Convention (No 169),
- having regard to the International Convention for the Protection of New Varieties of Plants, as revised at Geneva on 19 March 1991,
- having regard to the 1995 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights,
- having regard to the 2002 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) and the 2011 WHO framework regarding influenza viruses,
- having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions<sup>1</sup>,
- having regard to its resolution of 7 October 2010 on the EU strategic objectives for the 10th Meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD), to be held in Nagoya (Japan) from 18 to 29 October 2010<sup>2</sup>,
- having regard to the Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions entitled ‘Our life insurance, our natural capital: an EU biodiversity strategy to 2020’ (COM(2011)0244),
- having regard to the Report of the Meeting of the Group of Technical and Legal Experts

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<sup>1</sup> OJ L 213, 30.7.1998, p. 13.

<sup>2</sup> OJ C 371E, 20.12.2011, p. 14.

on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing, UNEP/CBD/WG-ABS/8/2, 2009,

- having regard to the study requested by the European Parliament's Committee on Development entitled 'Intellectual Property Rights on genetic resources and the fight against poverty', 2011,
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Development (A7-0000/2012),
- A. whereas 70 % of the world's poor living in rural and urban areas depend directly on biodiversity for their survival and well-being;
- B. whereas the main aims of the Convention on Biological Diversity (CBD) are to foster the conservation and sustainable use of biodiversity and to address the obstacles impeding its use;
- C. whereas genetic resource (GR) providers and holders of related traditional knowledge (TK) frequently belong to developing countries rich in biodiversity;
- D. whereas 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;
- E. whereas Article 27.3 (b) of the WTO-TRIPS entitles governments to exclude from patenting plants, animals and 'essentially' biological processes, while microorganisms and non-biological and microbiological processes are eligible for patents;
- F. whereas the OECD members rely strongly on genetic resources for imported food and agricultural products, thereby making international cooperation on the conservation and sustainable use of genetic resources essential;
- G. whereas the 2007 UN Declaration on the Rights of Indigenous Peoples confirms the right to maintain, control, protect and develop their traditional knowledge;

## **I. Genetic diversity and the MDGs**

1. Recalls the direct link between the protection of biodiversity and the achievement of the MDGs; stresses the importance of healthy biodiversity and ecosystems for agriculture, forestry and fisheries;
2. Stresses that the CBD differs remarkably from other international environmental treaties in that it gives an explicit and prominent role to the questions of fairness, equity and justice in the conservation and use of biodiversity;
3. Underlines the fact that, although there is no general definition of the term 'biopiracy', it usually refers to the industrial practice of privatising and patenting products based on the traditional knowledge or genetic resources of indigenous peoples, without authorisation or providing compensation to source countries;

4. Stresses 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; stresses, accordingly, that EU trade policy related to IPR must be consistent with the objective of Policy Coherence for Development as enshrined in the EU Treaty;
5. Recalls that the CBD and the Nagoya Protocol constitute the main framework for governance of access and benefit sharing (ABS); notes that governance related to IPRs, genetic resources and poverty alleviation also concern the WTO, FAO, WHO and WIPO, thereby raising challenges in terms of ensuring a coherent approach in their support of the CBD regime;

### ***Agriculture and health***

6. Recalls the need for a wide range of Genetic Resources for Food and Agriculture (GRFA) to ensure better ecosystem service provision; emphasises that the use of GRFA is crucial to food security, agricultural and environmental sustainability and facing climate change;
7. Recalls that the wild varieties of cultivated plants which are important for the food security of EU Member States are largely found in developing countries; 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, as this would violate the right to food in developing countries;
8. Stresses that fighting biopiracy entails the implementation and upgrading of the existing arrangements for multilateral access and benefit sharing in the areas of agriculture and health, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) or the WHO's Intergovernmental Meeting on Pandemic Influenza Preparedness;

## **II. Rights of indigenous and local communities over traditional knowledge**

9. Notes that traditional knowledge designates knowledge possessed by specific indigenous and local communities and shared by many segments of the society of a particular region or country;
10. Points out that three quarters of the plants used in modern medicine come from traditional medicine; believes that biopiracy means there is a strong case for protecting traditional knowledge, particularly when it is associated with genetic resources of economic value to the pharmaceuticals industry;
11. Highlights the danger of assessing traditional knowledge only from a mercantile point of view; points out that the existing IPR framework does not fit such a heterogeneous group as traditional knowledge holders; stresses, therefore, the need to define a *sui generis* international IPR regime that preserves the diversity of interest of local communities and reflects customary law etc.;
12. Regrets that traditional knowledge associated with genetic resources is not covered by any of the Nagoya Protocol's monitoring measures; takes the view that the EU should grant

traditional knowledge at least the same level of protection as genetic resources when implementing the Nagoya Protocol;

### **III.Addressing biopiracy – the way forward**

13. 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;
14. Stresses that the CBD's objectives will only be attained if fair and equitable sharing of benefits is granted; urges the EU and its Member States to call for swift ratification of the Nagoya Protocol in order to combat biopiracy and restore fairness and equity in the exchange of genetic resources; stresses the role of EU development cooperation in providing developing countries with assistance with legal and institutional capacity-building on access and benefit sharing issues;

#### ***Improving database and disclosure requirements related to genetic resources and traditional knowledge***

15. Points out the proposal made by developing countries for a binding regulation requiring patent applicants to: (a) disclose the source and origin of genetic resources and associated traditional knowledge (ATK) used in inventions; (b) provide evidence of prior informed consent (PIC) from competent authorities in the provider country and; (c) provide evidence of fair and equitable benefit sharing, to be certified in an international certificate of origin;
16. Regrets the lack of clear statistics on biopiracy and misappropriation, and calls on the EU to support the setting up of an independent body to remedy this situation;
17. Believes that a binding instrument is the surest way to see biodiversity-related measures in the IPR system implemented by user countries; urges 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; stresses 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);

#### ***Working towards a coherent global governance system***

18. Notes with concern that, while the CBD aims at fair and equitable access and benefit sharing between providers and users of genetic resources, for 20 years WTO-TRIPS has favoured users of genetic resources through the WTO dispute-settlement mechanism for patent protection;
19. Insists that WTO-TRIPS should be compatible with the CBD-Nagoya Protocol, and therefore considers it crucial to establish mandatory requirements on disclosing the origin of genetic resources during patent proceedings;
20. Stresses that such requirements could be introduced via an amendment of the WTO-TRIPS Agreement or under WIPO; likewise takes the view that the EU should

establish a clear mandatory requirement to disclose the origin of any genetic resources and associated traditional knowledge in patent applications in EU legislation in the absence of an international agreement;

21. Instructs its President to forward this resolution to the Council and the Commission.

## EXPLANATORY STATEMENT

### Introduction

The protection and preservation of genetic diversity is a key component of the achievement of the Millennium Development Goals. Genetic resources (GR) are particularly essential for sustainable agriculture and food security. Furthermore, genetic diversity is one of the most important components for the survival of the species and the ecosystem's resilience. Therefore, the loss of genetic diversity that occurs as part of the biodiversity erosion process represents a key challenge for humanity. .

In spite of its vital importance for human survival, genetic diversity is being lost at an alarming increased rate. Such erosion of diversity sets new challenges for both holders and users of GR, the former being most often biodiversity-rich developing countries, the latter being usually developed countries

In this context biopiracy has emerged as a major concern for developing countries. Although there is no general definition of the term 'biopiracy', it usually refers to a situation in which biological resources are taken from local communities or indigenous people and are patented while the resulting profits do not benefit the communities which originated the resources, disclosed their properties and have used them.

If clear statistics on biopiracy and misappropriation do not exist, illustrative cases over the last 20 years, including yellow 'Enola' bean, hoodia, rooibos, neem, etc., shed a new light on the challenge to face regarding the illegal use of GR and traditional knowledge (TK) in developing countries. Combating biopiracy represents thus, a major challenge to be addressed by the EU, as such practices run counter EU's commitments towards eradication of poverty, protection of biodiversity and the principle of Policy Coherence for Development enshrined in article 208 of the Lisbon Treaty.

The lack of balance between providers and users of genetic resources has also brought the issue of access to and benefit-sharing from genetic resources onto international stage. In this context, the **Convention on Biological Diversity** (1992) plays a unique role. While it is one of the most important treaties regulating the conservation and use of biodiversity on the international level, it differs from other international environmental treaties in a remarkable way. Questions of fairness, equity and justice play an explicit and prominent role.

In particular, one of the main requirements of the *Access and Benefit-Sharing* (ABS) framework established by the CBD and the Nagoya Protocol, is that benefits shall be granted in exchange for access to GR and traditional knowledge (TK), and that *prior informed consent* (PIC) shall be obtained before access. In addition, *mutually agreed terms* (MAT) for the benefit-sharing (BS) shall also be negotiated.

In light of this, your rapporteur advocates for the quick ratification of the Nagoya Protocol as an important tool to combat biopiracy and to restore fairness and equity in the exchange of GR. This entails, nevertheless, that both developing and developed countries take necessary



steps to make the Protocol effective. While many developing countries have failed or were unable to put into place an adequate legal framework on ABS, developed countries have failed to provide for effective compliance mechanisms that would ensure that fair and equitable BS can be enforced where private actors, under their jurisdiction, utilise genetic resources from biodiversity-rich countries.

To sum up, the Protocol requires the establishment or further elaboration of detailed domestic ABS legislation in developing countries as a precondition for the obligation of user countries to comply with PIC requirements. Given the current lack of ABS legislation in many developing countries, this request poses a real challenge and requires substantial legal and institutional capacity building. Accordingly, EU development aid should be used as a tool to provide developing countries with legal and institutional capacity building assistance on ABS related issue. Concerning compliance, the EU and its Member States must establish effective measures ensuring that GR have been acquired in accordance with PIC and MAT in compliance with provider countries' national ABS legislation. Providing recourse in case of disputes and for access to justice will also require adaptations of domestic legal systems in the EU.

However, to combat biopiracy effectively, it is important to address the following challenges:

### **1) Agriculture and Health**

The use of a wide range of Genetic Resources for Food and Agriculture (CGRFA) is crucial for food security, agricultural and environmental sustainability and to face climate change.

Till now, most developing countries recognise the rights of small farmers to save and exchange seeds. In this context, your rapporteur is particularly concerned about the impact of the 1991 International Convention for the Protection of New Varieties of Plants (UPOV) on food security in developing countries, as it drastically limits the possibility for states to set forth exceptions from plant breeder's rights in favour of farmers' right to re-use and exchange harvested seed.

Your rapporteur deems essential to safeguard the right of farmers to rely on harvested seeds, as an important aspect of the 'right to food'.

Besides, genetic resources from biodiversity-rich countries contribute significantly to pharmaceutical R&D. Unfortunately, it's been proved that intellectual property rights (IPRs) poses a significant challenge on access to medicine in poor countries. Therefore, IPRs should not hinder access to affordable medicines for their populations, especially if such IPRs rely on GR that originate from developing countries. Likewise, it is also crucial to ensure appropriate BS from the pharmaceutical/medicinal utilisation and commercialisation of GR found on their territories.

### **2) Rights of indigenous and local communities and traditional knowledge**

Enabling traditional knowledge holders to maintain, control and protect such knowledge is not

only critical to their economic and cultural survival but to the maintenance of biodiversity that benefits the entire world.

In a context where traditional knowledge provides substantial profits to industries, including pharmaceuticals, cosmetics, and agriculture, protection of traditional knowledge (TK) of indigenous and local communities represents an important challenge to combat biopiracy related to bioprospecting activities.

Although TK protection has been addressed broadly through human rights, indigenous rights and biodiversity preservation concerns, your rapporteur believes that certain improvements at the international institutional level are needed to avoid biopiracy connected to illegal use of TK. Indeed, even if the goals of preservation and human rights are enshrined in a number of international environmental and human rights instruments, these are largely optional and lack in practise the enforcement mechanism of international intellectual property agreements, notably the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

More specifically, if over the last few years, the right of Indigenous and Local Communities (ILCs) have progressively been recognised at the international level, much remains to be done to enforce them effectively. The only legally binding international convention relating to indigenous rights is the 1989 ILO's Convention No 169 on Indigenous and Tribal Peoples. Although the 2007 UN Declaration on the Rights of Indigenous Peoples (UNDRIP) has the merit to address indigenous rights in a comprehensive manner and stresses the fundamental importance of indigenous peoples' right to self-determination, it is a non-binding instrument. However, as a binding international treaty, the Convention of Biodiversity contains, in its Article 8 (j), an obligation for states to protect TK held by ILCs. Furthermore, rules governing TK have been further developed in the 2010 Nagoya Protocol to the CBD.

In this respect, the Protocol establishes/reconfirms similar requirements with respect to PIC by Indigenous Local Communities (ILCs) and the establishment of MAT ensuring fair BS, including measures to address situations of non-compliance and the possibility of recourse and access to justice. However, the requirements related to TK are formulated in a less binding language than those linked to GR. In particular, TK associated with GR is not covered by the Protocol's monitoring measures: there is no obligation to disclose to the 'checkpoint' information on the TK used and the internationally recognised certificate of compliance does not cover TK associated with GR, which limits possibilities of tracing biopiracy related to such TK.

In view of these various shortcomings, your rapporteur deems it essential to grant TK the same level of protection as GR and to define a *sui generis* legally binding international regime of IPR that reflects among others the diversity of interests of local communities as well as customary law. Likewise, it requests adaptation from the WTO-TRIPS and WIPO regime so as to be compatible with CBD and Nagoya Protocol requirements.

### **3) Working towards a coherent global governance system**

The CBD and the Nagoya Protocol constitute the main international forum for the discussions on governance of Access and Benefit Sharing (ABS) from GR. However, the fact the question

of governance related to IPRs, GR and poverty alleviation concern also various international institutions, such as WTO, FAO, WHO and WIPO, raise challenges in terms of ensuring coherence and ‘mutual supportiveness’ between them.

In this context, the relationship between WTO-TRIPS and the CBD as regards ABS is a stumbling block. Based on its sustainable-development oriented objective, the CBD foresees fair and equitable benefit-sharing between providers and users of GR. In contrast, WTO-TRIPS aims to strengthen IPRs, including with respect to biotechnology. Both treaties thus send contradicting signals at the level of implementation. Furthermore, unlike the CBD, the WTO-TRIPS Agreement is supported by the powerful WTO dispute-settlement mechanism. More generally, since the CBD and the Nagoya Protocol are much weaker than WTO-TRIPS or TRIPS Plus standards, there still remains a feeling of imbalance regarding the enforcement and the effectiveness of sanctions.

In accordance with the principle of Policy Coherence for Development, your rapporteur insist that international institutions be supportive of and not run counter to the CBD - Nagoya Protocol regime. In this respect, one needs to bear into account that developing (provider) countries have consistently proposed that binding regulation requires patent applicants to disclose the source and origin of GR and TK used in invention, to give evidence of prior informed consent from competent authorities in the provider country and to provide evidence of fair and equitable benefit sharing to be certified in an international certificate of origin. Acceptance of such claims within the CBD context would require adaptation of WTO-TRIPS.

Since 2008, the EU has in principle accepted the introduction of a **disclosure of origin requirement** into WTO-TRIPS in exchange for enhanced protection of ‘geographical indications’. In the aftermath of the Nagoya Protocol, several developing and emerging countries have submitted a proposal to amend the WTO-TRIPS Agreement by inserting a new Article 29 bis on Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge in accordance with the Nagoya Protocol.

Your rapporteur is of the view that the introduction of a mandatory disclosure requirement in the context of the WTO-TRIPS is needed. In parallel, special attention needs to be paid to the expansion of bilateral trade agreements that may jeopardise further developing countries’ interests, through the enactment of so-called ‘TRIPS plus’ standards for IPRs. It is essential to ensure that the EU refrains from pushing developing countries, especially LDCs, to accept through bilateral agreements far-reaching IP standards regarding seeds/agriculture and health/medicines.