



EUROPEAN PARLIAMENT

2009 - 2014

Plenary sitting

A7-0423/2012

14.12.2012

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

CONTENTS

	Page
MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION.....	3
EXPLANATORY STATEMENT	12
OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE.....	16
OPINION OF THE COMMITTEE ON LEGAL AFFAIRS	19
RESULT OF FINAL VOTE IN COMMITTEE.....	22

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 inventions¹,
- 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 2010²,
- 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 activities and reports of the WIPO Intergovernmental Committee on

¹ OJ L 213, 30.7.1998, p. 13.

² OJ C 371E, 20.12.2011, p. 14.

Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,

- having regard to the Report of the Meeting of the Group of Technical and Legal Experts 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 Parliament's Committee on Development, entitled 'Intellectual Property Rights on genetic resources and the fight against poverty' (2011),
 - having regard to the 1971 Ramsar Convention on Wetlands,
 - having regard to the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES),
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on Development and the opinions of the Committee on International Trade and the Committee on Legal Affairs (A7-0423/2012),
- 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 a common definition of biopiracy is the industrial practice of privatising and patenting the traditional knowledge or genetic resources of indigenous peoples, without obtaining authorisation from or providing compensation to source countries;
- F. whereas the CBD and its Nagoya Protocol requires bioprospectors to obtain 'prior informed consent' (PIC) from and reach 'mutually agreed terms' (MAT) with countries of origin or indigenous and local communities in relation to TK associated with GR, and to share the benefits from bioprospecting with them;
- G. whereas the evolving ABS regime under the CDB operates in a complementary fashion with the WTO and its Trade-Related Aspects of Intellectual Property Rights (WTO-TRIPS), the World Intellectual Property Organisation (WIPO), the Food and Agriculture Organisation (FAO), the International Union for the Protection of New Varieties of Plants (UPOV) and the World Health Organisation (WHO);
- H. whereas ABS governance is also reflected in a number of human rights instruments,

including the 1948 Universal Declaration of Human Rights, the 1966 International Covenant on Civil and Political Rights and the 1966 International Covenant on Economic, Social and Cultural Rights;

- I. whereas Article 27(3)(b) of the WTO-TRIPS entitles governments to exclude from patentability plants, animals and ‘essentially’ biological processes, while microorganisms and non-biological and microbiological processes are eligible for patenting;
- J. whereas biodiversity provides a great range of ecosystem services, such as local water, food provision, materials for sustaining livelihoods and climate regulation; and whereas environmental degradation poses new challenges for the conservation and sustainable utilisation of a wide range of species and GRs as a base for food security and sustainable agricultural development;
- K. whereas the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), which was negotiated within the ambit of the Food and Agriculture Organisation of the United Nations (FAO), is aimed at the conservation and sustainable use of plant GRs for food and agriculture and the fair and equitable sharing of the benefits arising from their use, in harmony with the CBD;
- L. whereas the OECD members rely strongly on genetic resources from abroad especially for crops, thereby making international cooperation on the conservation and sustainable use of genetic resources essential;
- M. whereas estimates indicate that three-quarters of the world’s population depends on natural traditional medicines and that approximately half of synthetic drugs have a natural origin;
- N. whereas several international conventions and agreements, including the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), the Declaration of the Rights of Indigenous Peoples (DRIPS), the UNESCO Convention for the Safeguarding of Intangible Cultural Heritage, address the subject of traditional knowledge;
- O. whereas article 8(j) of the CBD commits parties to respect, preserve and maintain TK and to ‘encourage the equitable sharing of the benefits arising from the utilisation’ of such knowledge;
- P. whereas the 2007 UN Declaration on the Rights of Indigenous Peoples confirms the right to maintain, control, protect and develop their traditional knowledge;
- Q. whereas in 2009, the WIPO General Assembly instructed its Intergovernmental Committee (IGC) to develop an international instrument to protect genetic resources, traditional knowledge and traditional cultural expressions;

I. Genetic diversity and the MDGs

- 1. Recalls the direct link between the protection of biodiversity and the achievement of the

MDGs, in particular MDG 1 focused on the eradication of extreme poverty and hunger; stresses the importance of healthy biodiversity and ecosystems for agriculture, forestry and fisheries within a sustainable development perspective;

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 generally acceptable definition of the term 'biopiracy', it may refer 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 and consolidate the legal terminology, in particular with a view to a definition of the term 'biopiracy' based on authoritative figures;
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; insists that these international institutions should be supportive of and not run counter to the CBD regime;
6. Reiterates its respect for the milestones achieved in the international protection of indigenous peoples' rights over their genetic and other resources and associated traditional knowledge, enshrined in the UN Declaration on the Rights of Indigenous Peoples, in the ILO Convention No 169, in Article 8(j) of the CBD and in the Nagoya Protocol; expresses its concern at the genetic erosion occurring as a consequence of the almost exclusive dominance on the market of industrially produced seeds, i.e. seeds protected by intellectual property rights, to the detriment of traditional seed varieties;.

Agriculture and health

7. 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;
8. Highlights the fact that the achievement of MDG 1 depends, among other things, on how we manage agricultural ecosystems; stresses, in this context, that while reducing the negative impact that agriculture may have on the environment requires a wide range of crop genetic diversity to ensure better ecosystem service provision, crop diversity enables specifically poor and small-holder farmers to diversify their diets and incomes; stresses equally that crop genetic diversity confers resilience regarding climate change;
9. 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;

10. Recalls that the ‘farmers’ exception’, under the UPOV Convention, is especially important for developing countries as it allows farmers to save seeds deriving from new varieties and to re-sow them for usual food purposes (thereby enhancing food security); regrets however that, while it is in the interest of developing countries to keep and extend exemptions from plant breeders’ rights, farmers’ rights have become weakened in consecutive reforms of the UPOV Convention;
11. Notes that the FAO is taking a leading role in developing specialised ABS regimes relevant to food and agriculture; calls on the EU to support developing countries’ requests to ensuring appropriate BS in any new sectoral mechanisms/instruments under the FAO as well as ensuring consistency with and enhancing synergy with the CDB and its Nagoya Protocol;
12. Recalls that GRs, inter alia in the form of herbal medicine, contribute significantly to pharmaceutical R&D and access to medicine; reasserts that IPRs should not hinder access to affordable medicines, especially where such IPRs rely on GRs that originate from developing countries;
13. Calls 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, in line with the EU’s Policy Coherence for Development (PCD);
14. 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) – e.g. by considering new ways to raise resources for the Benefit-Sharing Fund – or the WHO’s Intergovernmental Meeting on Pandemic Influenza Preparedness;
15. Takes the view that future bilateral and multilateral agreements aiming at harmonisation, and in particular those concerning the scope of exceptions and limitations to patent rights, will require careful scrutiny from a development perspective, with a view to achieving global equity for public health in the spirit of the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement, safeguarding local knowledge and, in relation to plant breeders’ rights, securing access to seeds;

II. Rights of indigenous and local communities over traditional knowledge

16. 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; points out that traditional knowledge includes ‘intangible values’ and that the maintenance of the cultural heritage is in fact of primary importance in all its expressions, including social, religious, cultural and landscape values;

17. Points out that three quarters of the world's population depends on natural traditional medicine from plants; believes accordingly that biopiracy means there is a strong case for protecting traditional knowledge, particularly when it is associated with genetic resources of economic value to industry;
18. 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.;
19. Notes with concern that the difficulties faced by TK holders include monitoring and enforcement, i.e. learning that violations have taken place and obtaining timely remedies; regrets in this context that traditional knowledge associated with genetic resources is not covered by any of the Nagoya Protocol's monitoring measures, given that 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; 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;
20. Stresses that regulations laid down to protect GRs and their associated TK must comply with international commitments on promotion of and respect for the rights of indigenous peoples, 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);
21. Recognises the potential role of the intellectual property and patent system in promoting innovation, transfer and dissemination of technology to the mutual advantage of stakeholders, providers, holders and users of genetic resources, their derivatives, and of associated traditional knowledge in a manner conducive to welfare and development, while emphasising the necessity of preventing the adverse effects of the IPR and patent system on indigenous peoples' and local communities' application of traditional knowledge, their laws, practices and knowledge system and their ability to use, develop, create and protect their knowledge in relation to genetic resources; points out that, under certain circumstances, contracts between the parties may be identified by indigenous peoples or local communities as a more feasible solution to share benefits and to protect their interests while preserving the environment and preventing social and economic harm, e.g. by means of safeguard clauses;

III.Addressing biopiracy – the way forward

22. 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 PIC and MAT in compliance with provider countries' national ABS legislation; 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; insists equally upon the importance to provide effective recourse mechanisms in case of disputes and access to justice;

23. Recalls that effective implementation of the Protocol depends on actions to be taken both in developing and developed countries; notes that the elaboration of ABS legislation in developing countries is a precondition for the obligation of user countries to comply with Prior Informed Consent (PIC) requirements; points out, however, that this request poses a real challenge for them as it requires substantial legal and institutional capacity building;
24. 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 enhance fairness and equity in the exchange of genetic resources; stresses the role of EU development cooperation in providing developing countries with assistance for legal and institutional capacity building on access and benefit sharing issues; believes that support should be given to developing countries in building up databases of TK and understanding patent application systems;
25. Reiterates that, against the background of its recent resolution on the patenting of essential biological processes¹, excessively broad patent protection in the area of breeding can hamper innovation and progress, to the detriment of small and medium-sized breeders, by blocking access to genetic resources;

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

26. Draws attention to 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;
27. 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; stresses also that better data is needed on the number and content of ABS contracts; considers that this could be gathered by setting up a notification and database system through the CBD Clearing-House Mechanism;
28. 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);
29. Stresses that 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;

¹ European Parliament resolution of 10 May 2012 on the patenting of essential biological processes, P7_TA(2012)0202.

30. Takes 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;
31. Considers that a clear and coherent system of proprietary rights would contribute to the creation of knowledge and its dissemination to developing countries, to the benefit of local entrepreneurship, research, education and poverty alleviation;

Working towards a coherent global governance system

32. 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, and thus to make it possible to check whether they were acquired legally in accordance with PIC and MAT;
33. Stresses that such requirements could be introduced via an amendment of the WTO-TRIPS Agreement or under WIPO, within the context of the ongoing discussions on the setting-up of (a) new international legal instrument(s) for the effective protection of genetic resources, traditional knowledge, and traditional cultural expressions; calls on the EU, in particular, to support, in line with PCD, the request of developing countries 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; welcomes, as a first step, the fact that the EU proposal for a regulation on access to genetic resources and benefit sharing provides for a mandatory requirement to disclose the origin of any genetic resources and associated traditional knowledge;
34. Calls 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 in the negotiations on bringing in line the legal framework of the CBD¹ and its Nagoya Protocol, WIPO, TRIPS, the ITPGRFA² and UPOV³, as well as UNCLOS⁴ with regard to maritime genetic resources; notes that the TRIPS agreement transitionally excludes Least Developed Countries⁵; stresses that this approach must be preserved with regard to any revisions that may result from the CBD-Nagoya process;
35. Welcomes initiatives providing an alternative option to strictly trade-based bodies, such as the Global Biodiversity Information Facility (GBIF), which promotes free and open access to biodiversity data through global cooperation between different governments, organisations and other international stakeholders;
36. Notes the work of the World Intellectual Property Organisation (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, and encourages similar measures to be taken and consistent definitions to be used at EU level;

¹ Convention on Biological Diversity.

² International Treaty on Plant Genetic Resources for Food and Agriculture.

³ International Union for the Protection of New Varieties of Plants.

⁴ United Nations Convention on the Law of the Sea.

⁵ Art. 66.1, TRIPS; Decision of the Council for TRIPS of 29 November 2005.

37. 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.

27.11.2012

OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE

for the Committee on Development

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

Rapporteur: Helmut Scholz

SUGGESTIONS

The Committee on International Trade calls on the Committee on Development, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Regards the fair and equitable sharing of benefits arising from the utilisation of genetic resources as a key objective; emphasises the need to provide transparency and legal certainty for resource providers, inventors and investors; considers it essential to develop a common understanding among international institutions governing trade and trade-related issues regarding the meaning in law of the term ‘biopiracy’; deplores the slowness of proceedings in the ongoing negotiations in the WIPO IGC¹ and the TRIPS² review process regarding Article 27.3 (b);
2. Urges the EU and the Member States to ratify the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity; commends the Commission for presenting a draft regulation for the implementation of the Nagoya Protocol; calls 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 in the negotiations on bringing in line the legal framework of the CBD³ and its Nagoya Protocol, WIPO, TRIPS, the ITPGRFA⁴ and UPOV⁵, as well as UNCLOS⁶ with regard to maritime genetic resources; notes that the

¹ World Intellectual Property Organisation Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore¹.

² Agreement on Trade-Related Aspects of Intellectual Property Rights.

³ Convention on Biological Diversity.

⁴ International Treaty on Plant Genetic Resources for Food and Agriculture.

⁵ International Union for the Protection of New Varieties of Plants.

⁶ United Nations Convention on the Law of the Sea.

TRIPS agreement transitionally excludes Least Developed Countries¹; stresses that this approach must be preserved with regard to any revisions that may result from the CBD-Nagoya process;

3. Agrees with the position of stakeholders that a rules-based international trade system requires preventing the wrongful granting of patents, which in turn requires establishing requirements on disclosing the source and origin of genetic resources during patent proceedings; insists that WTO-TRIPS should converge with the aim of being compatible with the CBD-Nagoya Protocol;
4. Welcomes initiatives providing an alternative option to strictly trade-based bodies, such as the Global Biodiversity Information Facility (GBIF), which promotes free and open access to biodiversity data through global cooperation between different governments, organisations and other international stakeholders;
5. Recognises the potential role of the intellectual property and patent system in promoting innovation, transfer and dissemination of technology to the mutual advantage of stakeholders, providers, holders and users of genetic resources, their derivatives, and of associated traditional knowledge in a manner conducive to welfare and development, while emphasising the necessity of preventing the adverse effects of the IPR and patent system on indigenous peoples' and local communities' application of traditional knowledge, their laws, practices and knowledge system and their ability to use, develop, create and protect their knowledge in relation to genetic resources; reiterates that, against the background of its recent resolution on the patenting of essentially biological processes², especially in the area of breeding, excessively broad patent protection can hamper innovation and progress and become detrimental to small and medium breeders by blocking access to animal and plant genetic resources; points out that, under certain circumstances, contracts between the parties may be identified by indigenous peoples or local communities as a more feasible solution to share benefits and to protect their interests while preserving the environment and preventing social and economic harm, e.g. by means of safeguard clauses;
6. Reiterates its respect for the milestones achieved in the international protection of indigenous peoples' rights over their genetic and other resources and associated traditional knowledge, enshrined in the UN Declaration on the Rights of Indigenous Peoples, in the ILO Convention No 169, in Article 8j of the CBD and in the Nagoya Protocol; expresses its concern at the genetic erosion occurring as a consequence of the almost exclusive dominance on the market of industrially produced seeds, i.e., seeds protected by intellectual property rights, to the detriment of traditional seed varieties.

¹ Art. 66.1, TRIPS; Decision of the Council for TRIPS of 29 November 2005.

² European Parliament resolution of 10 May 2012 on the patenting of essential biological processes, P7_TA(2012)0202.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	27.11.2012
Result of final vote	+: 13 -: 0 0: 12
Members present for the final vote	Laima Liucija Andrikiienė, Daniel Caspary, María Auxiliadora Correa Zamora, Christofer Fjellner, Metin Kazak, Franziska Keller, Bernd Lange, Paul Murphy, Cristiana Muscardini, Helmut Scholz, Peter Šťastný, Gianluca Susta, Henri Weber, Jan Zahradil
Substitute(s) present for the final vote	Josefa Andrés Barea, George Sabin Cutaş, Mário David, Elisabeth Köstinger, Marietje Schaake, Inese Vaidere
Substitute(s) under Rule 187(2) present for the final vote	Isabelle Durant, Francisco José Millán Mon, José Ignacio Salafranca Sánchez-Neyra, Ivo Strejček, Renate Weber

6.11.2012

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on Development

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

Rapporteur: Françoise Castex

SHORT JUSTIFICATION

The report of the Committee on Development aims at considering the effects of intellectual property rights on genetic resources with regard to human rights and global food security, primarily by drawing on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. The main issue raised in this respect is that of ‘bio-piracy’, which could refer to either the unauthorised extraction of genetic resources, such as plants with medical properties, or to the patenting of spurious inventions based on such resources or traditional knowledge from indigenous peoples without compensation.

Your rapporteur welcomes a reflection on these issues, in the interest of developing countries with the end goal of poverty alleviation, but stresses that the practical implementation of any set of rules for avoiding bio-piracy involves problems of a legal nature which are not easily solved without a proper reflection on, and a correct interpretation of, the current legal framework as mentioned above.

The legal terminology in the area of intellectual property rights on genetic resources needs to be clarified and consolidated, not least the term ‘bio-piracy’. Any definition of this term needs to have a solid foundation, requiring extensive fact-finding and research. The international community should also define the *sui generis* systems in force at international level for plant protection in those cases where patent protection is not applicable.

It is furthermore essential to safeguard the interests of small and medium breeders, taking into consideration that excessively broad patent protection in the area of breeding can hamper innovation and progress and become detrimental to these breeders by blocking access to animal and plant genetic resources.

SUGGESTIONS

The Committee on Legal Affairs calls on the Committee on Development, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Considers that a clear and coherent system of proprietary rights would contribute to the creation of knowledge and its dissemination to developing countries, to the benefit of local entrepreneurship, research, education and poverty alleviation;
2. Stresses that further work must be carried out in order to clarify and consolidate the legal terminology in the area of intellectual property rights on genetic resources, in particular with a view to a definition of the term 'biopiracy' based on authoritative figures;
3. Takes the view that future bilateral and multilateral agreements aiming at harmonisation, and in particular those concerning the scope of exceptions and limitations to patent rights, will require careful scrutiny from a development perspective, with a view to achieving global equity for public health in the spirit of the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement, safeguarding local knowledge and, in relation to plant breeders' rights, securing access to seeds;
4. Takes notice of the work of the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, and encourages similar measures to be taken and consistent definitions to be used at EU level;
5. Reiterates that, against the background of its recent resolution on the patenting of essential biological processes¹, excessively broad patent protection in the area of breeding can hamper innovation and progress, to the detriment of small and medium-sized breeders, by blocking access to genetic resources;
6. Calls on the international community to take into account the fact that the International Union for the Protection of New Varieties of Plants provides a *sui generis* system, already in force, for plant variety protection where patent protection is not applicable; recommends that core requirements for effective *sui generis* models are contemplated;
7. Takes the view that local knowledge of indigenous methods of water exploitation should be scientifically researched and freely disseminated, while technologies covered by patents in developing countries should facilitate innovation in access to water and sanitation.

¹ European Parliament resolution of 10 May 2012 on the patenting of essential biological processes, P7_TA(2012)0202.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	6.11.2012
Result of final vote	+: 23 -: 0 0: 0
Members present for the final vote	Raffaele Baldassarre, Luigi Berlinguer, Françoise Castex, Christian Engström, Marielle Gallo, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Antonio López-Istúriz White, Antonio Masip Hidalgo, Jiří Maštálka, Alajos Mészáros, Evelyn Regner, Francesco Enrico Speroni, Rebecca Taylor, Alexandra Thein, Rainer Wieland, Cecilia Wikström, Zbigniew Ziobro, Tadeusz Zwiefka
Substitute(s) present for the final vote	Eva Lichtenberger, Angelika Niebler, József Szájer, Axel Voss
Substitute(s) under Rule 187(2) present for the final vote	Sylvie Guillaume

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	6.12.2012
Result of final vote	+ : 20 - : 3 0 : 1
Members present for the final vote	Thijs Berman, Michael Cashman, Ricardo Cortés Lastra, Nirj Deva, Leonidas Donskis, Charles Goerens, Catherine Grèze, Eva Joly, Filip Kaczmarek, Miguel Angel Martínez Martínez, Gay Mitchell, Norbert Neuser, Bill Newton Dunn, Birgit Schnieber-Jastram, Michèle Striffler, Alf Svensson, Keith Taylor, Patrice Tirolien, Ivo Vajgl, Daniël van der Stoep, Anna Záborská, Iva Zanicchi
Substitute(s) present for the final vote	Cristian Dan Preda
Substitute(s) under Rule 187(2) present for the final vote	Helmut Scholz