



DIRECTORATE-GENERAL FOR EXTERNAL POLICIES
POLICY DEPARTMENT



**INTELLECTUAL
PROPERTY RIGHTS
ON
GENETIC RESOURCES
AND
THE FIGHT AGAINST
POVERTY**

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DIRECTORATE-GENERAL FOR EXTERNAL POLICIES OF THE UNION

DIRECTORATE B

POLICY DEPARTMENT

STUDY

INTELLECTUAL PROPERTY RIGHTS ON GENETIC RESOURCES AND THE FIGHT AGAINST POVERTY

Abstract

The developmental impact of intellectual property rights (IPRs) on genetic resources (GR) and associated traditional knowledge (TK) has been intensely discussed internationally for more than a decade. In this respect, plant GR for food and agriculture, GR for health as well as the related rights of indigenous and local communities possess particular importance for poverty reduction. The EU can play an important role in advancing regulatory action in this field that enhances the effectiveness of the fight against poverty, both domestically and at the international level. The 2010 Nagoya Protocol to the Convention on Biological Diversity that addresses “biopiracy” related to GR/TK is awaiting ratification and full and effective implementation, which will, inter alia, require capacity building especially for least developed countries. Another important contribution to combating biopiracy would be the establishment of a requirement to disclose in patent applications the source of any GR/TK used, as currently under negotiation in the World Trade Organisation and the World Intellectual Property Organisation. The rights of indigenous and local communities, especially with respect to their TK, deserve particular protection both in the EU and internationally, to be designed in consultation with these communities. IPRs on seeds and medicines should not be allowed to compromise the human rights to food and health. There is a need for advancing research and development on seeds and medicines that are targeted at low-income populations in developing countries.

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LIST OF ABBREVIATIONS

ABS	Access and benefit-sharing
ACTA	Anti-Counterfeit Trade Agreement
ATS	Antarctic Treaty System
BS	Benefit-sharing
CBD	Convention on Biological Diversity
CGEN	Genetic Patrimony Management Council
CGIAR	Consultative Group on International Agricultural Research
EPO	European Patent Office
FAO	Food and Agriculture Organisation of the United Nations
GMOs	Genetically Modified Organisms
GR	Genetic resources
ILCs	Indigenous and Local Communities
IPR	Intellectual property right
ITPGR	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually agreed terms
NGO	Non-governmental organisation
PCT	Patent Cooperation Treaty
PIC	Prior informed consent
R&D	Research and development
SMTA	Standard Material Transfer Agreement
TK	Traditional knowledge
UNCLOS	United Nations Conference on the Law of the Sea
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UPOV	International Convention for the Protection of New Varieties of Plants
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
WTO-TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

EXECUTIVE SUMMARY

From a development perspective, the utilization of genetic resources (GR) and associated traditional knowledge (TK), including through claiming intellectual property rights (IPRs), poses **two main sets of problems**. First, IPRs on GR (especially patents and plant breeders' rights) result in restrictions on access by developing countries to markets in developed countries as well as restrictions in the access to IP-protected goods (seeds, affordable medicines). The restrictions on access that emanate from IPRs aggravate the existing general lack of research and development (R&D) addressing the specific needs of the poor populations in developing countries especially in the agriculture and health sectors. The second main problem concerns the fair and equitable sharing of the benefits arising from the utilization of GR/TK. Whereas the biotechnological industry is concentrated in developed countries (including the EU), developing countries are the main providers of GR/TK. The latter have traditionally been left out of the benefits thus generated and have even had to face the aforementioned restrictions arising out of IPRs granted for related inventions/products. The fair and equitable benefit-sharing (BS) required by the 1992 Convention on Biological Diversity (CBD) has not been achieved in reality. Instead, "biopiracy" – i.e. the utilization of GR/TK originating from developing countries in defiance of BS requirements under relevant international and national law – has become a prominent, even though not quantifiable, phenomenon. These problems have particular relevance for the fight against poverty where they relate to food and agriculture as well as health.

The **2010 Nagoya Protocol to the CBD** is designed to advance fair BS and to prevent biopiracy – an important interest of developing countries. The Protocol needs to be effectively implemented and further developed. To this end, the EU and its member states should continue to work towards ratification of the Protocol so as to enable its earliest possible entry into force. This will also require domestic implementation to ensure that any GR/TK utilised in the EU have been obtained in accordance with national requirements of the provider country as provided for by the Protocol and that effective mechanisms for enforcement exist (recourse in case of disputes, access to justice). It is furthermore important to realise that the effective implementation of the Protocol puts high demands on developing countries and will thus require substantial capacity building support especially for least developed countries. Assistance (including country-specific legal advice and counsel) will also be needed to enable developing country actors, including indigenous and local communities (ILCs), to seek enforcement of relevant requirements in developed countries. The Nagoya system is likely to entail further elaboration in future international negotiations so as to address any shortcomings and advance its effective implementation.

The existing **IP system** serves the interests of users of GR/TK without helping ensure a fair and equitable BS with the providers. The main proposal on the table to mend the situation concerns the establishment of a mandatory requirement to disclose the origin of any GR and associated TK in patent applications (together with information on prior informed consent and the establishment of mutually agreed terms in accordance with the Nagoya Protocol). Such a requirement (that should also extend to applications for plant breeders' rights) has, for several years, been on the table in the context of the World Trade Organisation's Doha Round of negotiations and in discussions at the World Intellectual Property Organisation (WIPO). It should be implemented as soon as possible, and the scope for synergy with the "internationally recognised certificate of compliance" established under the Nagoya Protocol should be explored. In the absence of an international agreement, the EU could consider how such a requirement might be introduced in EU legislation in accordance with existing international law.

The **rights of ILCs** have been increasingly recognised internationally, in general and more specifically as they relate to **traditional knowledge**. As an overarching principle flowing from existing international instruments such as the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), concrete steps to protect TK should always be undertaken in consultation with representatives of ILCs. A core option in this regard concerns the elaboration of a sui generis system for the protection of TK in ongoing negotiations in WIPO for the benefit of ILCs that frequently belong to the poorest within developing countries. The EU should furthermore grant TK at least the same level of protection as GR as such when implementing the Nagoya Protocol. It should also support recognition of the rights of ILCs and specifically the need to consult with ILCs in all other relevant fora, including the World Health Organisation (WHO) and the Food and Agriculture Organisation of the United Nations (FAO), as well as in its bilateral relations. A particular potential lies in exploring how the positive experience with a TK “digital library” in India can be expanded and employed to facilitate effective TK protection and prevent misappropriation by others (e.g. through building a network of national databases).

Existing **arrangements for multilateral access and benefit-sharing in the areas of agriculture and health** – the 2002 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) and the 2011 WHO framework regarding influenza viruses – need to be fully implemented and further enhanced. The attractiveness of the ITPGR for developing countries and the resources available could be increased if ex-post payments for utilising Annex I crops once a new variety is marketed would be complemented with a mechanism that helps generate resources earlier (i.e. through a fee for receiving a “licence”/“concession” for utilising an Annex I crop for R&D). The first task with respect to the non-binding WHO framework consists in its effective implementation. While the benefits developing countries receive under the framework could be further enhanced, expanding the system to other viruses and medicines is worth exploring and could help generate resources to support access to medicines and pharmaceutical research targeted at the needs of poor populations. In the evolving discussions on the possible introduction of specialised ABS systems for other sectors of food and agriculture in the context of the FAO, care needs to be taken to ensure access to relevant products for the poor (farmers, fishers, etc.) and an appropriate focus of relevant research on products that are useful for poor populations in the fight against poverty.

For number of **GR not covered by existing arrangements** for access and benefit-sharing (ABS) the gap could be filled by the **elaboration of further multilateral mechanisms**. Ex-situ collections, GR originating from the high seas/deep seabed and those from the Antarctic Treaty area are not regulated under the Nagoya Protocol or other, specialised ABS regimes. An appropriate arrangement for ex-situ collections could be designed under the Nagoya Protocol (Article 10 on a Global Multilateral Benefit-sharing Mechanism). Efforts concerning the high seas/deep seabed and Antarctica are underway under UNCLOS and the Antarctic Treaty system. These frameworks provide the opportunity to elaborate multilateral systems that ensure sharing of GR for research and generate resources for developing countries to support (1) the protection of related biological diversity; (2) relevant research addressing the needs of developing countries (agriculture and health), and (3) access to relevant products (seeds, medicines).

Bilateral relations between the EU and other countries and regions have gained in importance as regards IPRs given the stalemate of the WTO Doha Round. Pushing developing countries, especially least developed countries, through bilateral agreements to accept far-reaching IP standards (e.g. by requesting adherence to UPOV 1991 or so-called “TRIPS plus” IP protection) regarding seeds/agriculture and health/medicines, has generally negative effects in terms of poverty reduction. Adherence to UPOV 1991 would increase pressure on developing countries to prohibit traditional seed exchange practices

by farmers. In a similar vein, the EU should not take poorer developing countries to WTO dispute settlement for alleged violations of TRIPS regarding agriculture and health. Similarly, implementation and enforcement of the 2011 Anti-Counterfeit Trade Agreement and other efforts to fight (medical) counterfeit could have negative effects especially on poor developing countries.

1. INTRODUCTION

For more than a decade, the developmental impact of intellectual property rights (IPRs), including their relationship with the use of developing countries' genetic resources (GR) and traditional knowledge (TK), has subsisted as a particularly divisive issue at the international level. The debate on IPRs gained particular momentum with the entry into force of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. This agreement aims, inter alia, at a broad recognition of patents, including in biotechnology. In parallel concerns grew over "biopiracy", i.e. the illegal use of GR and TK located mainly in developing countries. The latter were addressed, to an extent, by the 1992 Convention on Biological Diversity (CBD) that aims, inter alia, at a fair and equitable sharing of the benefits arising from the use of GR and associated TK. The 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD tries to strike a balance so that both biodiversity-rich providers (mainly developing countries) and users of GR/TK (mainly developed countries who have the technological know-how to add economic value to GR and TK) may benefit from legal certainty and transparency while contributing to the conservation and sustainable use of biodiversity.

As regards the fight against poverty, the agricultural and health sectors possess particular importance in this respect. It is widely acknowledged that a sustainable and productive agricultural sector is essential to poverty reduction and economic growth in developing countries. Approximately three quarters of the population in the world live in rural areas. Appropriate measures to raise agricultural productivity could lead to an increase of their income and food security. The arrival of biotechnology in the last quarter of century has hugely increased the possibilities of agricultural research; accordingly private and public sector investment has expanded quickly. The health sector figures prominently in debates on IPRs in particular because health is a fundamental precondition for human wellbeing, the "global poor" face considerable constraints as regards access to affordable medicines, and the pharmaceutical sector is one of the main areas of biotechnological innovation. In both areas, it is debatable whether and how IPRs on GR and associated TK help research and innovation relevant to the needs of poor peoples and poor countries.

Against this background, this study aims to analyse the development effects of IPRs on GR/TK, with a particular focus on plant GR for food and agriculture as well as for health, and its implications on the rights of indigenous and local communities. The study contains eight further sections. Section 2 provides a general introduction to and an overview of IPRs and GR as regards developing countries and the fight against poverty, identifying in more detail the issues involved. Section 3 introduces the CBD and its Nagoya Protocol, the WTO-TRIPS Agreement, and a number of other international organisations and agreements that are relevant in the context of IPRs and GR and provides information on recent developments in these fora related to developing country concerns. Section 4 discusses in more detail issues related to IPRs on GR as regards the agriculture and health sectors. Section 5 presents the results of three case studies on Brazil, India and South Africa, which are based on a literature review along with interviews. Section 6 specifically addresses the rights of indigenous and local communities and the TK held by them. Section 7 turns to the implementation of the Nagoya Protocol in the EU and beyond, focusing on some major concerns and interests of developing countries in this respect. The study

concludes with a set of policy recommendation derived from the preceding analysis (section 8). Overall the study is based on existing literature as well as a limited number of interviews with representatives of developing country governments/ stakeholders as well as relevant Commission services (see references).

2. INTELLECTUAL PROPERTY RIGHTS, GENETIC RESOURCES AND DEVELOPING COUNTRIES

Since the discovery of recombinant DNA in 1953 and the subsequent formation and development of biotechnology and the life sciences, GR of plants, animals, microorganisms and humans have become increasingly valuable raw materials for multiple economic sectors. As a result, biotechnological industries have emerged in areas such as agriculture, food production, medicine, pharmaceuticals ("biopharmaceuticals"), and cosmetics. Depending on the methodology used and the scope of the products considered, the value of the market for products based on GR has been estimated at 220-800 billion USD annually in the 2000s (Ten Kate and Laird 1999; Scott 2004; Laird and Wynberg 2005; Phillips and Onwuekwe 2007; Deke 2008).

The **most important sectors** in terms of turnover as well as development impact are agriculture and health, especially based on plant GR. As regards modern agriculture, use of GR in biotechnology and breeding of new varieties of plants in particular holds the promise of contributing to food security (e.g. through increased resilience to viruses, insects, water scarcity, herbicides, etc. and increasing yields). At the same time, genetically modified organisms (GMOs) may also have negative effects on farmers in developing countries such as increased dependence on GMO seed providers for seeds and accompanying pesticides. As regards health, pharmaceutical companies use natural compounds to create new medicines, such as cancer drugs and vaccines. Mostly, they are utilized in the form of vaccines or as laboratory-made antibodies (PhARMA 2011). This study will focus especially on the agricultural sector and, to a lesser extent, the health sector.

The utilization of GR has considerable further potential. For example, GR existing under the extreme circumstances of the deep sea (e.g. microorganisms living within hydrothermal vents ecosystem on the seabed and ocean floor) possess properties with a potentially very significant scientific and economic value ("blue revolution"; see Scott 2004; Greer and Harvey 2004; Leary 2007). Moreover, new technological developments (e.g. synthetic biology) open up new opportunities for the utilization of GR, which, however, require a thorough assessment in terms of their impacts on developing countries and beyond.

GR have, however, not only economic benefits, but also a broader multi-dimensional value. The preamble of the Convention on Biological Diversity (CBD) acknowledges the ecological, genetic, social, scientific, economic, educational, cultural, recreational and aesthetic values of biological diversity and its components (of which GR form one). From this perspective, it becomes more difficult to assess and quantify the overall value of GR (and biodiversity in general). In any event, the value of GR by far exceeds the economic value it has in the context of biotechnological applications (Alcamo et al. 2003; SCBD 2006; TEEB 2010).

The global **biotechnological industry** is concentrated in developed countries. According to OECD data, as of 2009 the US was home to 6213 biotech-active firms, with the next contenders in line being Spain (1095) and France (1067) (OECD 2011). The biotech-industry in developing countries is far less developed. Patent applications reflect this asymmetry: in 2006, the US, the EU and Japan together

accounted for about 80% of all applications for biotechnology-related patents under the Patent Cooperation Treaty (PCT) system administered by the World Intellectual Property Organisation (WIPO). Emerging countries (Brazil, India, Indonesia, Russia, China, South Africa) accounted for about 4%, and the rest of the world for the remainder (OECD 2009). In the period 2007-2009, China accounted for about half of PCT applications in biotechnology among the aforementioned emerging countries (OECD 2011). After spiking in the late 1990s, overall patenting activity in biotechnology has been sloping downwards in recent years: in the period 2003-2007, patent applications in biotechnology shrank by a total of 1.5%. This contrasts with general trends in patenting: patent applications under the PCT across all sectors have been continuously growing since 1995, with annual growth rates ranging from 2% to 16% (all data as of 2008) (WIPO 2010). As a result, the share of biotechnology patents in all patents has decreased from more than 10% in the mid-1990s to 6.5% in the period 2004-2006 (OECD 2009: 70).

Table 2.1: Share of countries in biotechnology patent applications under the Patent Cooperation Treaty (PCT) in 2006

Country / Region	%	Country / Region	%
USA	41.5	Japan	11.9
EU-27	27.4	Canada	3.2
– Germany	7.0	South Korea	3.0
– UK	4.5	Australia	2.1
– France	3.6	China	1.9
– Netherlands	2.8	India	0.9
– Denmark	1.7	Russian Federation	0.8
– Italy	1.4	Brazil	0.3
– Sweden	1.4	South Africa	0.1
– Spain	1.3	Other	6.9
– Belgium	1.3		
– other EU	2.4	TOTAL	100

Source: OECD 2009.

In contrast to the biotech-industry, biodiversity (as the pool of GR and species/ecosystems) and the associated “traditional knowledge” of indigenous and local communities (ILCs)¹, which enables or facilitates the utilization of GR, are concentrated in developing countries. While quantitative data are hard to come by and less than 10% of the world’s species are believed to have been formally identified,

¹ There is an unresolved political discussion about the use of the terms indigenous “people/peoples” versus indigenous/local “communities”. Many indigenous organisations prefer the term “indigenous peoples”, a term that is also used in some of the international legal instruments discussed in this study. For reasons of simplicity and without the intention to take sides in this debate, we use the term “indigenous and local communities” (ILCs) throughout this study except where discussing legal instruments that specifically address “indigenous peoples”.

species diversity in the tropics tends to be generally higher. In many if not most cases, traditional knowledge (TK) about the characteristics, effects and possible uses of particular plants (and other species) that is held by ILCs is crucial for efforts to utilize and exploit related GR in biotechnology and the life sciences. At the same time, the relevant communities contribute to the conservation and sustainable use of biological diversity, including GR.

Under these circumstances of contrasting distribution of the world's GR, on one side, and the industries utilizing them, on the other, in particular two sets of problems have occurred and deserve highlighting in the context of this study (see also section 4 below). The first relates to the protection of intellectual property (especially through patenting) that can result in restrictions on access by developing countries to markets in industrialised countries as well as restrictions in the access to goods protected by intellectual property rights (IPRs). The second issue relates to the (access to and) benefit-sharing from the utilization of GR with the providers of such resources, in particular developing countries.

Intellectual property (IP) refers to creations of the mind and is divided into industrial property (including patents on inventions, trademarks, industrial designs, and geographic indications) and copyright (for literary and artistic works). Table 2.2 summarises core characteristics (requirements, duration of validity, competent authority for registration) of the most important types of IPRs relating to GR: patents, plant breeders' rights (or plant variety protection rights) and geographical indications. Patents and plant breeders' rights apply in the country for which they were registered. Geographical indications are particular in that they do not necessarily require registration, are not attributed to individual holders and are valid indefinitely.

Table 2.2: Important Types of Intellectual Property Rights

Type of IPRs	Typical requirements	Duration	Responsible authority
Patents (for inventions)	Invention must be: <ul style="list-style-type: none"> • Novel • Involve an inventive step or be non-obvious (no mere discovery) • Commercially applicable 	Minimum duration according to WTO-TRIPS: 20 years	Patent offices (in the EU: European Patent Office, member states' patent offices)
Plant breeders' rights for plant varieties (or plant variety protection rights)	Plant variety must be: <ul style="list-style-type: none"> • New • Distinct from other varieties • Uniform • Stable across generations 	Minimum duration according to UPOV: 20-25 years (depending on variety)	Plant variety offices (e.g. EU Common Plant Variety Office)
Geographical indications	Geographical indications identify a good as: <ul style="list-style-type: none"> • Originating in a certain territory • Having a given quality, reputation or other characteristic essentially attributable to the geographical origin 	Unlimited	--

A first IPR-related challenge for developing countries stems from the fact that **IPRs** give the holders an exclusive right to decide on the use of IPR-protected products, including the **right to prohibit others**

from certain uses of such products. This may, for example, prevent developing countries from fostering industries that require IPR-protected products or technologies from developed countries. The production of generic drugs is a particularly relevant example. The holders of IPRs typically ask for licence fees for certain uses of an IPR-protected product, which may add considerably to the price of a product. It has been observed, for example, that royalty rates in commercial transactions usually range from 0.5% to 10% of the (net) sales of the licensed product, depending on the market volume and turnover of the specific product (South Centre 2000). The implied price increases may create problems especially for purchasers that are poor. The problem is aggravated where IPRs are expanded into new areas. For example, German farmers nowadays need to pay fees to breeders from which they purchased seed of certain IP-protected crops when re-planting part of their harvest during the subsequent year (so called re-seeding fees). The relevant regulation is based on EU law.² Some NGOs have argued that Germany has set a dangerous precedent, which could have disastrous consequences when applied in developing countries, where (poor) farmers have traditionally relied on (free) re-seeding (INKOTA n.d.)

A further problem concerns **market access** for developing country exporters to developed countries where companies in developed countries hold IPR on product originally coming from developing countries. While no in-depth cross-sectoral and quantitative study appears to exist on this issue, there are several well-known cases where related effects could be observed. One of the best-documented cases is that of the Enola bean (see, also for the following, Shashikant and Asghedom 2009; Rattray 2002). In this case, a US-based seed company purchased a bag of differently coloured beans in Mexico. Subsequently the company planted and re-planted the yellow beans over several plant generations, using traditional breeding methods. In the end, they had created a plant population which reliably produced uniformly yellow beans. Subsequently, the company obtained a US patent on the bean, now known as Enola bean, and required US bean importers to pay licence fees for imports of Mexican beans. According to some source, sales subsequently dropped over 90% among importers, causing economic damage to more than 22,000 farmers in northern Mexico who depended on sales of this bean and had cultivated and sold yellow beans long before the US company had found out about them (Goldberg 2003; Shashikant and Asghedom 2009). The US Patent Office eventually revoked the US patent in 2009 since the requirement that a patented invention must be non-obvious/novel had not been fulfilled. There are several other cases where alleged economic losses for developing country exporters led to challenges against either trademarks or patents granted to developed country firms and relating to food crops traditionally produced in developing countries.³

These challenges have culminated in **political conflicts over IPRs** along a North-South dimension.⁴ On one side, developed countries have advocated similar/uniform and strong international IP standards, as reflected in the World Trade Organisation (WTO) Agreement on Trade-related Intellectual Property Rights (TRIPS) and the International Convention for the Protection of New Varieties of Plants (UPOV Convention). Some economists and many industrialized country actors have argued that strong and uniform IP protection sets economic incentives not only for innovation, but also for technology transfer. Accordingly, strong IPRs create the proper conditions for furthering economic development in

² The relevant article is Art. 14.3 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.

³ Examples include the cases of cupuaçu and roiboos described in section 5 and the case of basmati rice. On the latter one see "India-U.S. Fight on Basmati Rice Is Mostly Settled", New York Time, 25 August 2001, <http://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-is-mostly-settled.html?pagewanted=all&src=pm>.

⁴ It should be noted that not everyone subscribes to the view that the debate on IPRs should be primarily along a North-South dimension. DG Trade for example has expressed criticism of this view, interview with Pedro Velasco Martins, DG Trade, 10 November 2011.

developing countries and attracting foreign capital: foreign corporations will have a larger incentive to transfer technology to and invest in developing countries if the risk of imitation of this technology is small (Chen and Puttitanun 2005). Developing countries, on the other side, have argued for more flexibilities in national IP rules, for example for allowing certain technologies to be excluded from patentability or reducing the reach of patents in case of national crises/emergencies. They argue, together with other economists, that too strong IP protection rather hampers economic growth and poverty reduction in developing countries and that IP standards should be adapted to the respective economic context. Weak IP standards will allow domestic firms in developing countries to prosper by copying technology. In this line of thinking, existing global IP standards are tailored towards developed countries' economic needs and do not sufficiently take care of the specific conditions of developing country economies and economies in transition (Correa 2000).

The second issue at play as regards GR and IPRs in a development context is the **fair and equal sharing of the benefits arising from the utilization of GR**. With the biotechnological industry being concentrated in industrialised countries, the main provider countries of GR and associated TK have traditionally been left out of the benefits thus generated and have even had to face the aforementioned restrictions arising out of IPRs granted for related products/inventions to companies commercializing these resources (Rosendal 2000; Raustiala and Victor 2004). The CBD in 1992 established fair and equitable benefit-sharing (BS) arising out of the utilization of GR (and associated TK) as an important international objective, recognised the sovereign rights of states over their biological resources and created related rules and obligations on appropriate access to and benefit-sharing from GR (ABS). However, the CBD and further rules developed over the years under it have so far not succeeded in settling the issue and especially in ensuring a fair and equitable BS from GR. The 2010 Nagoya Protocol to the CBD is, however, hoped to significantly improve the situation (see sections 3 and 7 below).

Of particular relevance is the problem of so-called "**biopiracy**", itself a highly politicised concept (Robinson 2011). It refers to the utilization of GR originating from developing countries (which may involve claiming IPRs) without having accessed these GR appropriately in accordance with relevant international and national law (Mgbeoji 2006).⁵ A number of cases of "biopiracy" that triggered action by environmental/developmental non-governmental organisations (NGOs) have been widely mediatised since the 1990s. A famous example is the San-Hoodia case where international protests resulted in indigenous people participating, to some extent, in the profits made from the commercialization of their knowledge (see case study on South Africa in section 5.3). The case of patent claims on parts of the Enola bean is a further example where transnational alliances of developing country actors and developed countries' NGOs succeeded in politicising a case of "biopiracy" to such an extent that patents were revoked. While analyses have highlighted the significance of "biopiracy" (e.g. Mgbeoji 2006; Mushita and Thompson 2007; Robinson 2011), no authoritative studies exist that would provide solid figures on the volume and prevalence of "biopiracy". This may also be due to the fact that it is difficult to monitor relevant activity.

"Biopiracy" usually has two main causes: lack of national regulations/enforcement in developing countries and/or lack of compliance mechanisms in developed countries. Many developing countries have failed or been unable to put into place adequate legal frameworks on ABS. More importantly, developed countries, have failed to provide for effective mechanisms that would ensure that fair and equitable BS can be enforced where private actors under their jurisdiction utilize GR without due regard

⁵ "Biopiracy" is sometimes also used to refer to any patenting of life forms which had formerly been in the public domain; this study follows the understanding of biopiracy as defined in the main text.

to applicable ABS requirements. One of the main requests by developing countries to improve the situation has been to make the granting of patents dependent on compliance with a mandatory requirement to disclose the origin of any GR/TK in patent applications. Such disclosure should include proof that the GR/TK in question have been acquired in accordance with applicable rules (prior informed consent and mutually agreed terms) (Blakeney and Mary 2005; Carr 2008). This request has been made in several international contexts. While the EU has shown willingness to accept it in some form⁶, it remains contentious and under consideration especially under the WTO and WIPO. Under the Nagoya Protocol, parties instead agreed to designate one or more “checkpoints” to collect or receive relevant information so as to monitor the uses of GR/TK (see also section 3 below).

The **EU** can be considered the second-largest player in global biotechnology next to the US. In 2004, the number of European biotech companies (2163) was even higher than that in the US (1991). However, European companies on average had a smaller size, investments in research and development (R&D) are higher in the US, and US companies are comparably more successful in transforming basic research into commercial applications (OECD 2009). Biotechnology in Europe is used mainly in agro-food applications and pharmaceuticals; its overall contribution to European Gross Value-added has been estimated in the range of 1.43-1.69% (Papatryfon et al. 2008). Within the pharmaceutical industry, biotechnology plays an important role, with the number of biopharmaceuticals on the market doubling between 1998 and 2008 (ibid.). As of 2006, the EU accounted for 34.5% of all patent applications in biotechnology at the European Patent Office (US: 39.9%) (van Beuzekom and Arundel 2006). For filings under the Patent Cooperation Treaty, the relations are similar. Within the EU, Denmark, France, Germany, the UK, the Netherlands and Sweden account for the largest part (European Commission 2007).

Against this backdrop, official EU policy on GR, IPRs and ABS has, in recent years, gone some way towards acknowledging developing country concerns, but has maintained strong IPRs as one of its major cornerstones. The EU played an active role in bringing about agreement on the 2010 Nagoya Protocol, and as of October 2011, the EU and 20 of its Member States had signed the Protocol. While supporting ABS has so far not been a central element in the EU’s development cooperation, it is likely to enjoy higher priority in the future.⁷ However, frequently environment is not one of the priority sectors of developing countries in development cooperation with the EU.⁸

The European Commission, in its communication “Trade, Growth and World Affairs” (European Commission 2011), emphasises that the intellectual property of European companies should be adequately respected by trading partners, especially in developing countries; and that these countries ought to aim at regulatory convergence with the EU standards. The communication also mentions, however, that the level of development of the countries concerned should be taken into account. In bilateral trade negotiations, EU generally seeks an approximation of the IP legislation of the partner country to EU standards.⁹ The EU has concluded several bilateral trade agreements which include chapters on IPRs, for example with Korea, Central America, Colombia and Peru. Negotiations with Singapore, India and MERCOSUR are ongoing. The EU also conducts regular IP dialogues with a number of countries, including China, Brazil, Thailand and Turkey, involving enforcement authorities.¹⁰

⁶ See also Interview with Pedro Velasco Martins, DG Trade, 10 November 2011.

⁷ Interview with Jérôme Petit, DG EuropeAid, 9 November 2011.

⁸ Interview with Merete Pedersen, EEAS, 21 November 2011.

⁹ Interview with Pedro Velasco Martins, DG Trade, 10 November 2011.

¹⁰ In these dialogues, EU partner countries have reportedly not indicated major problems with the EU IP system in the realm of biotechnology; interview with Pedro Velasco Martins, DG Trade, 10 November 2011.

Moreover, the EU also provides technical assistance on IP matters to several developing countries, such as China, the ASEAN countries and several African countries. Finally, it is noteworthy that the Commission currently is in the process of revising its communication on IPRs in its external relations.¹¹ Better enforcement of IP standards is also sought to prevent counterfeit from reaching the common market.

3. THE NAGOYA PROTOCOL IN THE INTERNATIONAL REGULATORY FRAMEWORK

A wealth of international institutions contribute to the governance of the triangle of IPRs, GR and poverty alleviation (Oberthür and Pożarowska 2011). In addition to the CBD and its 2010 Nagoya Protocol on Access and Benefit-sharing, other relevant international organisations and agreements include the WTO's TRIPS Agreement; WIPO and agreements under it; the Food and Agriculture Organisation (FAO), especially its International Treaty on Plant Genetic Resources of Food and Agriculture (ITPGR) and its Commission on Genetic Resources for Food and Agriculture; the World Health Organisation (WHO); and the UPOV Convention. Furthermore, the United Nations Convention on the Law of the Sea (UNCLOS) and the Antarctic Treaty System possess relevance for the governance of marine and Antarctic GR beyond the jurisdiction of states. The general relevance of these international institutions for the field of this study and the current state of discussions on IPRs/GR in a development context in these institutions are discussed in the following.

3.1 The Convention on Biological Diversity and its Nagoya Protocol

The **CBD** constitutes the central global framework for the governance of ABS. Deficiencies in the effective operation of its ABS regime were at the roots of the latter's further elaboration through the 2010 Nagoya Protocol. The CBD and its Nagoya Protocol regulate ABS and thereby address the problem of "biopiracy", while having lesser relevance for developing country access to markets and to IPR protected goods.

The fair and equitable sharing of the benefits arising out of the utilization of GR constitutes one of the core objectives of the CBD, which was adopted in 1992 and entered into force in 1993. The other CBD objectives are the conservation of biological diversity and the sustainable use of its components (see CBD Art. 1). Developing countries brought ABS to the Convention in order to ensure the sharing of benefits from the utilization of GR. According to Article 15 of the Convention, countries have sovereign rights over their natural resources and as a result they may determine access to GR under their jurisdiction. Access to GR is subject to prior informed consent (PIC) of the provider country and access is granted on the basis of mutually agreed terms (MAT). The system thus entails the conclusion of a contract between the provider and the user of GR. Generally, countries should share in a fair and equitable way the results of R&D and the benefits arising from the commercial and other utilization of GR with the party providing such resources. Developing countries should be enabled to participate in scientific research, especially biotechnological one, that is based on GR provided by them and they should have priority access to the results of such research and benefits. In essence, the CBD creates an ABS system that facilitates (largely private) commercial transactions based on contracts. Contracts between GR users and providers should indicate their reciprocal rights and obligations, including

¹¹ The previous version is the 2004 Strategy for the Enforcement of Intellectual Property Rights in Third Countries, OJ C129 of 26 May 2005, <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/enforcement/>.

appropriate arrangements for the sharing of the benefits (in various forms), and thus support transparency. In this way, the commercialisation of GR and the creation of an international GR market could become mutually advantageous and support conservation and sustainable use of GR (Tvedt and Young 2007; Brand et al. 2008).

The Convention furthermore strikes a delicate balance between, on the one hand, providing for and facilitating access to and transfer of relevant technology to developing provider countries in particular and, on the other hand, respecting patents and other IPRs under national and international law. Thus, access to and transfer of technology shall occur on fair and most favourable terms, while being consistent with the adequate and effective protection of IPRs (CBD, Article 16.2). Provider developing countries shall be able to employ technologies which make use of GR provided by them “on mutually agreed terms”, even if those are IPR protected (Article 16.3). Finally, countries are expected to cooperate in order to ensure that IPRs, which are recognized as being important for the implementation of the CBD, are supportive of and do not run counter to the Convention’s objectives “subject to national and international law” (Article 16.5).

The Convention also addresses TK. In particular, its Article 8(j) commits parties to respect, preserve and maintain TK of ILCs and to “encourage the equitable sharing of the benefits arising from the utilization” of such knowledge (see also section 6).

The ABS rules of the CBD were further elaborated in the non-binding 2002 Bonn Guidelines on ABS in order to assist parties in establishing national ABS systems and to clarify the roles and responsibilities of different stakeholders (including the providers and users of GR, competent national authorities and national focal points) (Chambers 2003; Tully 2003). However, neither the CBD itself nor the Bonn Guidelines succeeded in resolving, or even significantly advancing, ABS; in the absence of strong compliance incentives, implementation in both developing and developed countries remained deficient (Young 2004). This provided the major rationale for the elaboration of the Nagoya Protocol.

The **Nagoya Protocol on Access to GR and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the CBD** was adopted in October 2010 and was opened for signature from 2 February 2011 to 1 February 2012. It reconfirms and elaborates the basic ABS approach of the CBD. Accordingly, BS is to be ensured through PIC and MAT (private contracts). Possible monetary and non-monetary benefits are suggested based on the Bonn Guidelines mentioned above. The Protocol does not provide for a requirement to disclose the origin of GR in patent applications as requested by developing countries (but requires parties to designate “checkpoints”; see below). It does not only cover GR but also their derivatives, which are currently more often the source of the benefits (on the Nagoya Protocol see, also for the following, Buck and Hamilton 2011; Morgera and Tsioumani 2011; Nijar 2011a).

Core elements of the Protocol include the elaboration of international access standards and of measures to ensure compliance with national PIC and MAT requirements so as to ensure fair and equitable BS. As regards access to GR, the Protocol obliges provider countries that decide to require PIC (relevant especially for developing provider countries) to provide for legal certainty, clarity and transparency of their domestic ABS legislation and for clear rules and procedures for requiring and establishing MAT, as further detailed in Article 6 of the Protocol. For many if not most developing countries wishing to combat “biopiracy”, the Protocol thus requires the establishment or further elaboration of detailed domestic ABS legislation that is a precondition for the obligation of users to comply with PIC. Given the current lack of ABS legislation in many developing countries, this is likely to pose considerable challenges and to require substantial capacity building.

As regards compliance and in order to fight “biopiracy” in user countries, parties to the Protocol will have to implement measures securing that the GR utilized on their territory have been accessed in accordance with PIC and MAT as required by the provider country in its national legislation. They also have to provide appropriate, effective and proportionate measures to address situations of non-compliance. To support compliance, parties are also obliged to take measures to monitor the utilization of GR through the designation of one or more checkpoints (which could but do not have to be patent offices). The checkpoints will collect from users information on the source of GR, if PIC was received, if MAT were established, and /or on GR utilization. Permits issued by user countries can serve as (non-obligatory) internationally recognized certificates of compliance that contain such relevant information. Importantly, countries (especially user countries) are also obliged to “ensure that an opportunity to seek recourse is available under their legal systems (...) in cases of disputes arising from mutually agreed terms” and to take effective measures regarding access to justice and mutual recognition and enforcement of foreign judgments and arbitral awards (Article 18). In other words, provider countries must take action to enable enforcement of MAT to be provided for under the jurisdiction of user countries.

As regards TK, the Protocol establishes/reconfirms similar requirements with respect to PIC by ILCs and the establishment of MAT ensuring fair BS, including the taking of measures to address situations of non-compliance and the possibility of recourse and access to justice. The main difference, however, consists in the requirements being formulated in less binding language, being subject to domestic law of provider countries as well as the non-applicability of the monitoring system (“checkpoints”) and the internationally recognized certificate of compliance.

Since the Protocol only applies to GR transactions after its entry into force as well as only to GR under national jurisdiction, it does in particular not cover (a) previously established ex-situ GR collections (mainly in developed country genebanks) and (b) marine GR of the high seas and Antarctic GR. In this respect, it is worth noting that the Protocol envisions the establishment of a Global Multilateral Benefit-sharing Mechanism applicable to transboundary situations for which it is not possible to grant or obtain PIC. The exact need for and possible form of this mechanism remains to be determined.

The relationship with other international institutions forms another key element of the Protocol. Overall, the relevant provisions of the Protocol (esp. Art. 4) give general guidance to the future ABS-related development (and interpretation) of other relevant international institutions. Accordingly, complementary specialized ABS regimes cannot only be maintained but may also be newly created and further developed. In general, other international institutions should be supportive of and not run counter to the CBD regime to achieve mutual supportiveness.

3.2 The World Trade Organisation (WTO) and the World Intellectual Property Organisation (WIPO)

Concluded in 1994 and in force since 1995 as part of the WTO, the **WTO-TRIPS** Agreement aims to contribute, by means of IPRs, to technological innovation, technology transfer and dissemination, to the mutual advantage of producers and users of technological knowledge and social and economic welfare (TRIPS Article 7). WTO-TRIPS provides for international minimum standards of IP protection, including copyrights, trademarks, geographical indications, industrial designs, patents, layout-designs and trade secrets. In particular, it requires 20-year patent protection for any invention, product or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (TRIPS Article 27). The inventions, products and processes covered include also those based

on GR. TRIPS Article 27.3(b) specifically addresses GR allowing governments to exclude from patenting plants, animals and “essentially” biological processes. However, micro-organisms, and non-biological and microbiological processes have to be eligible for patents¹². WTO-TRIPS does not refer to ownership of GR and to benefits arising from their utilisation. It has been found to be in tension or even conflict with the CBD: while the latter aims at fair and equitable BS between providers and users of GR, WTO-TRIPS favours benefit appropriation by the users of GR (patent protection for 20 years) and is supported by the powerful WTO dispute-settlement mechanism (Rosendal 2006).

The **World Intellectual Property Organisation (WIPO)** and its agreements form another important element of the international legal framework on IPRs (referred to in WTO-TRIPS). Established in 1967, WIPO aims “to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organizations” (WIPO Convention, Article 3). The WIPO administers 24 international treaties related to intellectual property, including, with particular relevance for IPRs on GR, the Patent Cooperation Treaty (PCT), and the Patent Law Treaty (PLT). Developing countries have requested the inclusion of mandatory disclosure requirements in one of these instruments (as well as in a draft “Substantive Patent Law Treaty (SPLT)” that is under negotiation). Related discussions also take place in the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC), established in 2000¹³. In 2009, the WIPO General Assembly mandated the Committee to complete negotiations on new international legal instrument(s) effectively protecting GR, TK and traditional cultural expressions.

Developing countries have for a long time requested, in both the WTO and WIPO, to establish mandatory requirements on disclosing the origin of GR in the course of patent proceedings. More specifically, they have proposed that the disclosure of the source and origin of GR and TK used in an invention as well as evidence of PIC from competent authorities in the provider country and of fair and equitable BS be required for the granting of any patent (Medaglia 2010). Since 2008, the EU has in principle accepted the incorporation of a disclosure of origin requirement into WTO-TRIPS in exchange for enhanced protection of “geographical indications”.¹⁴ Such information could be disclosed and communicated by means of an international certificate of origin. Establishing a related requirement would be a major step towards the effective implementation of global ABS rules under the CBD. Furthermore, developing countries have an interest in establishing, especially under WIPO, a sui generis system of IPRs for TK, since the criteria of the existing systems of IP protection under the WTO/WIPO (novelty, inventive step, capability of industrial application) (and UPOV; see below) do not allow protecting such knowledge. For instance, TK is not considered “novel” in the sense of existing IP protection legislation. Moreover, TK is frequently “owned” by communities that are not organised in a legal form that would allow them to apply for IPRs, since IPRs are always granted to an individual or an established legal entity.

¹² According to the WTO interpretation of the Article 27.3(b), see http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm.

¹³ Other WIPO bodies discussing GR and TK issues include the WIPO General Assembly; the Standing Committee on the Law of Patents; the Working Group on Reform of the Patent Cooperation Treaty; the WIPO Working Group on Biotechnology and, in relation to the WIPO Development Agenda, the Provisional Committee for the Development Agenda (PCDA) (Medaglia 2009).

¹⁴ See also interview with Pedro Velasco Martins, DG Trade, 10 November 2011.

New developments. In the aftermath of the Nagoya Protocol, several developing countries¹⁵ 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. In order to make WTO-TRIPS and the CBD more mutually supportive, the authors of the proposal draw on the Nagoya Protocol (especially provisions on designation of effective checkpoints to collect or receive relevant information regarding the utilization of GR) and the discussions in the TRIPS Council on mandatory disclosure requirements. Accordingly, where the subject matter of a patent application involves utilization of GR and/or associated TK, parties would have to require applicants (1) to disclose the provider country; (2) to disclose the source in the country providing such resources; and (3) to provide a copy of an internationally recognized certificate of compliance (or equivalent information). Fulfilment of these requirements would be a condition for the processing of patent applications (WTO 2011). Developing countries thus brought their long-standing request for a mandatory disclosure requirement in line with the Nagoya Protocol by drawing on the internationally recognized certificate of compliance established in the Protocol (see also section 3.1). The EU may wish to continue and strengthen its support for a mandatory disclosure requirement in the context of WTO-TRIPS.

In **WIPO**, negotiations on new instrument(s) on GR, TK and traditional cultural expressions are set to intensify towards a 2013 deadline. The WIPO Intergovernmental Committee was originally scheduled to complete its work on these items by 2011. Due to slow progress (about which many developing countries were disappointed), however, the WIPO General Assembly renewed the Committee's mandate for another two years in September/October 2011. Accordingly, the Committee will "during the next budgetary biennium (2012/2013), and without prejudice to the work pursued in other fora, expedite its work on text-based negotiations with the objective of reaching agreement on a text(s) of an international legal instrument(s) which will ensure the effective protection of GRs, TK" and traditional cultural expressions. A meeting scheduled for February 2012 is to address GR and the 2012 WIPO General Assembly is to consider the draft text of the new instrument(s) envisaged and decide on convening a Diplomatic Conference for their adoption (WIPO 2011a).

In June 2011, the Group of Like-minded Developing Countries¹⁶ informally proposed drafts on the three components under negotiation (GR, TK, traditional cultural expressions). This initiative was positively received, including by the EU (who will still have to fully assess these proposals). Developing countries are particularly interested in intensifying the work on GR as the so far least developed component. In this respect, the proposals in particular suggest: (1) mandatory disclosure of GR origin in patent applications; and (2) linking the new instrument(s) envisaged under WIPO and the CBD regime through supporting the implementation of the CBD and its Nagoya Protocol. Developing countries expect the WIPO instrument(s) to complement the Nagoya regime with an obligatory disclosure requirement for IPR applications. The draft proposals were forwarded to the next meeting to be held in February 2012 (ICTSD 2011). The EU may wish to consider to what extent the new proposals presented by the like-minded developing countries can provide the basis for compromise in the further negotiations, also in view of the Nagoya Protocol's guidance that other international institutions should be supportive of it.

¹⁵ Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group.

¹⁶ Algeria, Angola, Bangladesh, Colombia, Egypt, India, Indonesia, Malaysia, Myanmar, Namibia, Pakistan, Peru, South Africa, Tanzania, Thailand, and Zimbabwe.

3.3 Food and Agriculture: The UPOV Convention and the Food and Agriculture Organisation (FAO)

Adopted in 1961 and in force since 1968, the International Convention for the Protection of New Varieties of Plants (**the UPOV Convention**) established a specific IP system for new plant varieties with the aim to stimulate breeding. The Convention was revised three times; in 1972, 1978 and 1991. It provides for IP protection in the form of so called “plant breeders’ rights” when a plant variety developed by a breeder is new, distinct, uniform and stable. The breeders’ rights are granted for a minimum of 20 (25) years (Article 19). There are two important exceptions to breeders’ rights, one compulsory and one optional. First, breeders’ rights do generally not apply to acts done for experimental purposes and for the purpose of breeding other varieties (compulsory “breeders’ exception”). Second, parties may permit farmers to use their own harvest of a protected variety for propagating purposes, on their own holdings, i.e. for replanting/re-sowing (optional “farmers’ exception”) (Medaglia 2010).

The UPOV Convention qualifies as a sui generis system in accordance with the WTO-TRIPS Agreement. The latter requires IPR protection for new plant varieties either by means of patent protection or a sui generis system. Therefore countries that do not provide patent protection for plant varieties are encouraged to join the UPOV Convention, which tends to reflect developed country concerns. It might be in the interest of developing countries to elaborate own national sui generis systems for plant variety protection (including for instance provisions related to TK, like in India; see section 5.1) rather than to join UPOV.

As of mid-2011, the UPOV Convention had 70 parties, not many of which from the developing world. In parallel with WTO-TRIPS and WIPO, developing countries have also called for mandatory disclosure requirements in the granting of breeder’s rights, and for keeping and extending exemptions from plant breeders’ rights (“farmers’ rights”) (that have become weakened in consecutive versions of the UPOV Convention). The farmer’s exception is especially important for developing countries as it allows farmers to save seeds deriving from new varieties and re-sow them for usual (food) purposes thereby enhancing food security, which is in line with traditional practices in the developing world. At the same time, this exception remains limited and optional, and can be restricted under national law (on the example of Germany, see section 4.1).

Established in 1945, the **Food and Agriculture Organisation of the United Nations** (FAO) is to promote welfare by inter alia raising levels of nutrition and standards of living, securing production and distribution of food and agricultural products as well as ensuring freedom from hunger (FAO Constitution, Preamble). In relation to the subject of this study, two elements of the FAO are particularly relevant. First, the **International Treaty on Plant Genetic Resources for Food and Agriculture** (ITPGR) adopted in 2001 and in force since June 2004 aims at the conservation and sustainable use of plant GR for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD and for sustainable agriculture and food security (ITPGR, Article 1.1). At the core of the treaty is the Multilateral System (MLS) of Facilitated Access to and Benefit-sharing from plant GR that applies to genetic material of crops and forages crucial for global food security included in Annex 1 of the Treaty. When using Annex 1 crops in developing new varieties (i.e. developed after the entry into force of the ITPGR in 2004), such varieties have to be freely available for research purposes or the user of the Annex 1 crop needs to pay a percentage of commercial benefits into a Benefit-sharing Fund financing farmers/projects, especially in developing countries. A Standard Material Transfer Agreement (SMTA) sets detailed conditions for ABS and defines the levels of BS within the MLS.

Whereas the ITPGR is generally heralded as a major success in the international management of GR, few resources have yet become available to the Benefit-sharing Fund, not least because of the long time it usually takes from the initiation to the commercialisation of a new variety (given that the ITPGR entered into force in 2004). In order to advance projects devoted to the conservation of plant GR for food and agriculture in developing countries, new ways to raise resources for the Benefit-sharing Fund may be considered, including through an amendment of the STMA. One possibility to be explored relates to the establishment of a mechanism of upfront payments for a "license" or "concession" for the utilisation of Annex I crops for R&D.

New developments: The second major relevant element of the FAO is its **Commission on Genetic Resources for Food and Agriculture** (FAO Commission). The Commission negotiated and adopted the ITPGR. Since then, it has also engaged in discussions on animal GR for food and agriculture and aquatic GR, forestry GR, GR of microorganisms and invertebrates of relevance for food and agriculture. After the adoption of the Nagoya Protocol, the Commission took further action on GR in July 2011. It established an Ad Hoc Technical Working Group on Access and Benefit-sharing to identify any particular sectors of GR for food and agriculture that may require distinctive solutions. The Working Group will also analyze "the need for, and modalities of, possible instruments addressing access and benefit-sharing for GRFA, taking into account the full range of options, including those presented in the Nagoya Protocol" (FAO 2011). The Commission will discuss the above measures at its next meeting in 2013. The demand for sectoral mechanisms may increase in light of the expanding use of IPRs with respect to GR for food and agriculture and the central importance of food and agriculture as a whole for world food security. The FAO Commission intensified its work on animal GR and is moving towards forest GR, aquatic GR, microorganism and invertebrates (which all are sectors of GR for food and agriculture in addition to the plant GR covered by the ITPGR). Many countries expressed that they saw a leading role of the Commission in developing any specialized ABS regimes relevant for food and agriculture (ENB 2011).

The main developing country concerns would appear to relate to ensuring appropriate BS in any new sectoral mechanisms/instruments under the FAO, preventing any additional barriers for achieving food security in developing countries as well as ensuring consistency with and enhancing synergy with the CBD and its Nagoya Protocol. These policy objectives should be in line with established policy objectives of the EU.

3.4 The World Health Organisation (WHO)

Since 2007 ABS from GR such as pathogens has been discussed within the WHO. The WHO was established in 1948 with the objective of "the attainment by all peoples of the highest possible level of health" (WHO Constitution, Article 1). The WHO Global Influenza Surveillance Network serves to share viruses to enable an effective international response to the risk emanating from such viruses. The main WHO legislation of relevance to pathogen sharing is the International Health Regulations (2005) covering the issue of information/communication and cooperation on the global level on public health emergencies. The main discussions related to GR within the WHO, conducted by the Intergovernmental Meeting on Pandemic Influenza Preparedness (IGM-PIP), have over the past years focused on developing an ABS system related to influenza viruses. Negotiations on such a system were not least triggered by Indonesia's decision in 2007 to withdraw from WHO's laboratories Indonesian samples of avian influenza viruses after discovering that such samples had been developed into vaccines, patented by the pharmaceutical industry and sold at high price (unaffordable for developing countries) without knowledge, consent and compensation of Indonesia's government (Irwin 2010).

The following quote of a Thailand representative summarises the concerns of developing countries (cited in: Fidler 2007): “[w]e are sending our virus [samples] to the rich countries to produce antivirals and vaccines. And when the pandemic occurs, they survive and we die. (...) We are not opposed to the sharing of information and virus [samples], but on the condition that every country will have equal opportunity to get access to vaccine and antivirals if such a pandemic occurs.” Hence, the main concerns of developed countries within relevant WHO discussions are the patents preventing the use of products, processes, and technologies necessary to develop vaccines, their dependence in these respects on developed countries, and lack of compensation to developing countries (Lawson 2009).

New developments: The 64th Session of the World Health Assembly of the WHO in May 2011 adopted the non-binding *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*. The objective of the framework is “to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system (WHO GISRS), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing, (i) the sharing of H5N1 and other influenza viruses with human pandemic potential and (ii) access to vaccines and sharing of other benefits” (WHO 2011). Priority is to be given to developing countries, particularly affected countries that do not have domestic capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals.

The framework is based on two types of the Standard Material Transfer Agreements (SMTAs). The SMTA 1 covers virus sharing within the WHO’s influenza surveillance network and establishes that the provider and recipient of samples should not apply for IPRs over the material received from the network. SMTA 2 addresses virus sharing outside the WHO network. Whereas developing countries had requested compensation for virus sharing in the form of non-exclusive licenses to their industries, countries (and, as non-members of the WHO, the pharmaceutical industry) agreed that the pharmaceutical industry should, starting from 2012, cover half of the running costs of the Global Influenza Surveillance Network and should provide 10% of vaccines and anti-virals for use in developing countries in exchange for the access to biological material granted. The Framework will be reviewed by 2016 with the aim that the World Health Assembly readopts it in 2017 (ICTSD 2011; Fidler and Gostin 2011).

One of the most immediate tasks will now be to ensure the full and effective implementation of the non-binding Framework. In a next step, towards the 2016 review, scope for enhancing BS, including through further enhanced access of developing countries in particular need to vaccines and anti-virals could be explored (Fidler and Gostin 2011).

3.5 The UN Convention on the Law of the Sea (UNCLOS) and the Antarctic Treaty System

Marine GR placed on the seabed and ocean floor beyond national jurisdiction constitute promising objects of R&D. For example, microorganisms living within ecosystems of hydrothermal vents on the seabed and ocean floor have adapted to extreme conditions and may have enormous significance for biotechnology (Scott 2004; Greer and Harvey 2004; Leary 2007). Similarly, bioprospecting and other research activities on Antarctic flora and fauna are of growing scientific and commercial interest (Lohan and Johnston 2003; 2005).

GR in areas outside national jurisdiction may be regulated under the United Nations Convention on the Law of the Sea (UNCLOS) and the Antarctic Treaty System (ATS). As the CBD only covers GR under

national jurisdiction, it does not apply to such resources¹⁷. **UNCLOS** of 1982, as amended by the Implementing Agreement of 1994, establishes a comprehensive legal order for the seas and oceans. Relevant discussions on marine GR under the UN General Assembly take place within the UN Open-ended Informal Consultative Process on Oceans and the Law of the Sea, launched in 1999, and the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction which was established in 2004. The **ATS** consists of the 1959 Antarctic Treaty, the 1972 Convention for the Conservation of Antarctic Seals, the 1980 Convention on the Conservation of Antarctic Marine Living Resources, and the 1991 Madrid Protocol on Environmental Protection to the Antarctic Treaty. There are 28 Consultative Parties to the Treaty that are allowed to participate in decision-making, and 20 Non-Consultative Parties (as of 2011) that may attend meetings but cannot participate in decision-making. The Antarctic Treaty established a joint and all-encompassing governance regime for Antarctica by the contracting parties. GR and related ABS have also been discussed under the Antarctic Treaty System, so far without a firm result.

Countries are divided on whether the issue of marine and Antarctic GR and related ABS requires further regulation (La Fayette 2009). At present, the common heritage principle implies free access to GR beyond national jurisdiction. In practice such an access is possible for those who possess advanced technologies to explore and exploit such resources, in particular developed countries. Not surprisingly, developing countries have argued for the establishment of a BS mechanism for the use of marine GR in areas beyond national jurisdiction and Antarctic GR that might be able to generate much needed resources. There are good arguments for sharing the benefits from the use of such resources as they belong to the common heritage of humankind, and thus all humankind should benefit from their use.

New developments: The Ad Hoc Open-ended Informal Working Group on marine biological diversity beyond areas of national jurisdiction in June 2011 recommended that the UN General Assembly initiate a new process on biodiversity beyond national jurisdiction (under UNCLOS). Such a process should effectively address the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction “including through the implementation of existing instruments and the possible development of a multilateral agreement under the United Nations Convention on the Law of the Sea” (UNGA 2011). The process should address conservation, sustainable use, equitable BS, capacity-building and transfer of marine technology. The recommendation of the Working Group is, as of the time of writing, under consideration by the UN General Assembly. Contentious issues include in particular whether to elaborate a new comprehensive regime in the form of an implementing agreement to UNCLOS (the EU, G-77/China, Mexico) or not (Japan, Russian Federation, Iceland, Canada and, most opposed, the US) (ENB 2011).

If and when adopted, important issues will arise as to the design of a BS mechanism covering marine GR. In this respect, the EU could build on the common ground with developing countries in order to arrive at appropriate compromise solutions, possibly building on the experience of the International Treaty on Plant Genetic Resources for Food and Agriculture that has been indicated as a potential model for BS arrangements for marine GR.

¹⁷ The CBD may also apply to activities undertaken in areas outside national jurisdiction by actors that are subject to national jurisdiction however GR in marine areas beyond national jurisdiction and Antarctica are generally not covered by the CBD (Korn et al. 2003).

4. SECTOR-SPECIFIC DISCUSSIONS: AGRICULTURE AND HEALTH

This section discusses the impact of IPRs on developing countries in two specific sectors, namely agriculture and health. These sectors are of particular relevance for two reasons. First, they are of central importance for sustainable development and combating poverty. Many of the world's poor people live in rural areas and work in agriculture, and adequate health care, including access to medicinal products, is among the most fundamental requirements for human well-being. Second, GR are most frequently used in the development of new crops or new health products, including medicinal products, but also cosmetics or dietary supplements. Thus, the issues of "biopiracy" and BS are of particular relevance in these two sectors. Given the scope of the discussion, the section cannot discuss the subject exhaustively but only provide an overview of this discussion's main lines on the basis of a literature review.

4.1 Agriculture

Agriculture is of huge relevance in many developing countries as a source of food and income, in particular for the poor. At least 1.5 billion people in the world depend on small-scale farming for their livelihoods (de Schutter 2009). Agriculture is thus a very important factor in enhancing world food security, and it is one of the most important elements in implementing the right to food. The right to food is recognised in Article 25 of the Universal Declaration of Human Rights and Article 11 of the International Covenant on Economic, Social and Cultural Rights. In both documents, the right to food is a part of the right of everyone to an adequate standard of living for him/her and his/her family.

In the agricultural sector, IPRs over GR have increased in number and scope over the past 20-30 years. Until the second half of the 20th century, IPRs were not relevant to or were not granted in the agricultural sector (CIPR 2002:58). Today, the most important types of IPRs in agriculture are plant breeders' rights, patents and geographic indications. IPRs in agriculture are mostly based on the rationale that they provide an incentive for (private sector) R&D in this sector. Enhanced R&D is considered to be essential to satisfy present, and in particular, future world food needs; agricultural research is generally considered a sector where R&D investments produce disproportionately high societal benefits. The discussion on whether that is true, and whether IPR in agriculture are generally beneficial for developing countries, is part of the general controversy on IPR and their impact on developing countries. However, in the agricultural sector the debate carries particular weight, because IP policies are likely to be one of the factors influencing food security.

Generally, there is little conclusive, cross-country empirical evidence on the impact of IPRs in developing countries. Methodologically, the impact of IPRs on e.g. innovation or trade volumes is hard to measure, as IPRs are more often than not only one factor influencing complex economic processes. However, with a degree of caution some observations can be made on some of the main arguments in the debate on the impact of agricultural IPRs on developing countries.

A first important aspect of this debate is who reaps the **immediate economic benefits of IPRs** on GR for food and agriculture. As shown above (Section 2), most of the patents granted in the world apply in developed countries and are held by developed country actors. While these figures do not specifically relate to agriculture, it may be reasonably assumed that the broad trends are similar in the agricultural

sector.¹⁸ For PVP, the five offices with the highest numbers of applications filed were in China, Japan, EU, Ukraine and the US (UPOV 2010)¹⁹, indicating that these are particularly important agricultural markets. In each of these countries applications came predominantly from residents. In light of this distribution of IPR holders, developing countries are not benefiting from IPRs in the form of royalties or license fees for agricultural products to any significant extent. This is a sobering picture, given that IP protected products are based on today's agricultural biodiversity, which is in turn the result of farmers' breeding efforts all over the world for long periods of time and the free exchange of seeds between them (CGRFA 2009: 14f). By contrast, geographical indications such as Havana cigars or Mexican tequila currently hold some promise for developing countries, depending on an adequate position of developing countries exporters in the value chain and proper regulatory frameworks.²⁰

A second aspect is whether IPRs foster (private sector) **agricultural R&D**, to the benefit of developing countries. Generally, the corporate sector has taken interest in agricultural research relatively late,²¹ but is nowadays investing significant sums of money. There are significant differences in agricultural R&D spending between developed and developing countries. For example, only 11% of global public agricultural research expenditures were in low-income countries in 2000. Differences in private sector spending were even bigger: 96% of global private agricultural R&D funds were spent in developed countries (Beintema and Stads 2008). Private agricultural R&D mainly focuses on crops with high commercial value (Binenbaum et al. 2003:310), which are not necessarily those cultivated or consumed by the poor in developing countries. Thus, even if IPRs indeed induced more private sector spending for agricultural R&D, this would not automatically translate into benefits for developing countries. Moreover, there is no conclusive evidence that IPRs are, in general, a decisive factor in influencing the amount of agricultural R&D spending²² (Lesser et al. 1999:7f). Conversely, the proliferation of IPRs in some cases has hampered agricultural R&D, as breeders could not freely use existing innovations in research (UNCTAD 2006). However, this is currently more of an issue in developed than in developing countries, as many relevant technologies are not IP protected in developing countries (Binenbaum et al. 2003). Altogether, then, IPRs do not appear to be the best instrument for fostering pro-poor agricultural R&D. By contrast, targeted public R&D funding may be quite effective in this regard. For example, the institutes of the publicly funded Consultative Group on International Agricultural Research (CGIAR) play a significant role in agricultural research in developing countries.²³ The CGIAR indicates on its website

¹⁸ This assumption can be based on the market shares of large agricultural companies and their countries of origin. Moreover, Chan (2006) notes that nine agricultural biotech firms are the ones to obtain most patents worldwide; with the exception of Novartis (CH) all of them are based in the US.

¹⁹ It should be noted that in the US both patent applications on plant varieties and PVP are counted by UPOV. In Ukraine, there is a high number of applications, but the registration number is considerably lower.

²⁰ See Reviron 2009; Larson 2007. Pedro Velasco Martins, DG Trade, also mentioned geographical indications as one type of IPRs which may be beneficial for developing countries.

²¹ Malla et al. (2004) note for the US, for example, that private agricultural research funding has increased significantly since the 1980s/90s.

²² However, Lesser et al. (1999: 7f) also note that particularly in developing countries, effects of IPRs on R&D investments are likely to be specific to the crops and the structure of national agricultural systems, making any general statements somewhat difficult.

²³ CGIAR is a consortium of 15 agricultural research centres, mostly in developing countries. Each of them specialises in a certain topic or crop, and a general focus on crop improvement. Eleven of the CGIAR institutes entertain ex situ collections of plant GR which have become part of the ITPGR Multilateral System. However, the CGIAR also has recently been criticised by NGOs for cooperation with agricultural corporations and becoming less responsive to developing countries needs, see Devinder Sharam, Agricultural Research: CGIAR turns to outsourcing, 9 May 2004, http://www.inmotionmagazine.com/global/devsh_cgiar.html.

that “estimates of the benefits from CGIAR research since 1989 range from nearly US\$14 billion to more than \$120 billion”;²⁴ this contrasts with total research expenditures of \$7.1 billion since 1960.

A third issue concerning IPRs on GR in the agricultural sector is whether IPRs limit the **access of farmers to seed**. This is an issue, in particular, for small holders in developing countries. In developing countries, farmers’ seed systems, involving on-farm seed multiplication and informal diffusion of seed from farmer to farmer, are the most important source of crop seeds for farmers (Louwaars et al. 2005:28f). Obviously, these systems provide cheap access to seed. Undermining these systems is thus likely to have far-reaching negative consequences for farmers in developing countries, who are in their majority poor; the current Special Rapporteur for the Right to Food has therefore argued that introducing legislation or other measures which create obstacles to the reliance of farmers on informal seed systems may violate the right to food (de Schutter 2009). So far, however, IPRs do not appear to impose significant restrictions on small farmers’ traditional seed exchange practices in developing countries; the situation is thus different from developed countries where farmers have in recent years faced an increasing number of law suits for alleged violations of IPR laws. Most developing countries as of today either recognise the rights of small farmers to save and exchange seed (see for example the case study on India), or there is no relevant IP legislation (yet) forbidding such practices. The 1991 version of the UPOV Convention, which contains rules on plant breeders’ rights and drastically limits the possibility for states to set forth, at the national level, exceptions from plant breeders’ rights in favour of farmers’ right to re-use and exchange harvested seed, so far has only been signed by a handful of developing countries. Concerning economic access restrictions resulting from IPRs, i.e. seed becoming more expensive with IP protection, a study by the World Bank concludes that there is little evidence of “excessively high prices for agricultural inputs” as a result of IPRs (Lesser et al. 1999: 9); again, however, effects may vary by crop and country.

A fourth aspect of IPRs in agriculture and their impact on developing countries is to what extent IPRs **restrict access to developed country markets** for developing countries’ exporters. As the case of the Enola bean described in Section 2 and other cases show, this can be an issue. However, trade data indicate that currently the trade in staple foods from developing to developed countries is limited, both regarding total amounts and the number of crops traded (Binenbaum et al. 2003). Thus, in overall quantitative terms the impact of IPR on developing countries’ access to developed countries markets is unlikely to be huge currently.

Finally, there is debate on the impact of IPRs on the **concentration on agricultural markets**, and, of market concentration on food security, in particular in developing countries. Critics of IPRs argue that IPRs in agriculture lead to further concentration in agricultural markets as they benefit a few, large market players (Hendrickson et al 2008: 16). Indeed, global agricultural markets are today characterised by a high degree of concentration. This applies to both horizontal concentration, i.e. concerning certain sectors of agricultural markets, and vertical concentration, i.e. along the production chain of agricultural commodities (FAO 2003). For example, in 2004, the six major companies by reported sales accounted for roughly 77% of the global agro-chemicals market in the seed market, the four biggest companies accounted for about 30% of the market share, with, however, much higher degrees of concentration in some markets and crops (UNCTAD 2006). It is also true that the major players in agricultural markets holds a disproportionate share in IPRs – for example in the US five corporations hold 41% of agricultural biotechnology patents granted from 1982 to 2001 (UNCTAD 2006). However, a causal connection between IPRs and this market concentration is somewhat difficult to establish. Market concentration in

²⁴ See <http://www.cgiar.org/impact/index.html>.

today's agricultural markets is primarily a result of an intense period of mergers and acquisitions during the 1990s. IPRs may have been one factor in influencing the corporate decisions behind such mergers and acquisitions, but are unlikely to be the only one.

4.2 Health

The **human right to health** is well established in relevant international instruments, including a right to access to affordable medical treatments and medicine. The Universal Declaration of Human Rights in its Article 25 stipulated that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care”. The WHO Constitution, furthermore, establishes in its preamble that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being [...]”. Also, the UN’s International Covenant on Economic, Social and Cultural Rights of 1966 proclaims that “[t]he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. As of November 2011, 160 countries are members to the Covenant, including all EU member states. On this Covenant, the UN Committee on Economic, Social and Cultural Rights has elaborated that the right to health encompasses a broader perspective than mere access to health care, including also access to affordable treatments (Matthews 2009).

In parallel to the general concerns highlighted in section 2, developing countries have two main, related concerns with respect to IPRs, GR and the fight against poverty as regards health. First, IPRs should not hinder access to affordable medicines for their populations, especially where such IPRs rely on GR that originate from developing countries. Second, appropriate BS from the pharmaceutical/medicinal utilization and commercialization of GR found on their territories should be ensured (e.g. through free/preferential access to pharmaceutical products developed from such GR).

There is a clear tension between the human right to health, including access to affordable medicines, and **IPRs on pharmaceutical products**. The WTO-TRIPS Agreement specifies that patents must be granted in all fields of technology, clearly including pharmaceutical products. As with other products, patents on pharmaceutical products make them more expensive and limit access to them especially for the poor. IPRs are thus a double-edged sword in the health sector: while IPRs can induce technology transfer to developing countries and thus support access to medicines, they also negatively affect the affordability of treatment and, thus, the human right to health (e.g. Naghavi 2007; Park and Lippoldt 2008; Baker 2009). In the words of the UN Economic and Social Council: “in adopting intellectual property regimes, States and other actors must give particular attention at the national and international levels to the adequate protection of human rights of disadvantaged and marginalized individuals and groups” (ECOSOC 2011).

Different opinions exist in the literature on whether WTO rules provide sufficient flexibility to accommodate the human right to health (Musungu 2006; Abbott 2006). The WTO’s Doha Public Health Declaration has acknowledged the human right to health so that an acute norm conflict between WTO-TRIPS and the global human rights regime does not necessarily exist. Furthermore, strong collisions between IPR protection and the human right to health led NGOs and developing countries to campaign against rules that had made it difficult for developing countries to restrict patents in cases of public health crises in 1999/2001. That is, many NGOs and Southern activists contended that the WTO-TRIPS Agreement did not provide enough leeway to protect public health, but wrongly prioritized IPRs over public health. As a result, the 2002 WTO Public Health Declaration clarified that the TRIPS Agreement allowed for restrictions of patents in cases of public health crises and extended the transition period for least developed countries to fully implement TRIPS until 2016.

IPRs do not only limit access to affordable medicines in developing countries by making such products more expensive. They have also been found to restrict the ability of developing countries to produce and export generic medicines, including to other developing countries depending on affordable supplies. For example, there have been reports of shipments of generic medicines being seized while on transit through the Schengen area on the basis of IPRs (Arkininstall et al. 2011). Legal efforts to increase trade measures against medical counterfeit have been intense in international negotiations in recent years. For example, the Anti-Counterfeit Trade Agreement (ACTA), concluded in 2011, provides for customs measures against counterfeit medicine. Under the WHO, there are currently two taskforces: the working group on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC) and the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Developing countries fear that such measures might be used to clamp down on generic medicines, thus posing a problem for access to medicines. A recent report by OXFAM mentions how the fight against counterfeit drugs is used to impose stricter regulations on generic medicines, potentially hindering access (OXFAM 2011). Another recent study concludes that “ACTA proposes to require a broad range of TRIPS-plus measures on intellectual property enforcement that will predictably lead to increased burdens on the cross-border trade of medicines to and from developing countries” (Flynn and Madhani 2011).²⁵

GR contribute significantly to pharmaceutical R&D and thus form part of these general problems regarding IPRs and access to medicines. While reliable figures are hard to come by, according to one source 25% of drugs in developed countries and up to 75% of drugs in developing countries are based on naturally occurring chemicals (Perrings et al. 2009). However, some authors warn not to overemphasise the contribution and importance of GR to pharmaceutical R&D, since often the costs of bioprospecting outweigh the costs of chemically synthesizing an analogous product (Firn 2003). At the moment, bioprospecting is often regarded an expensive gamble that might or might not yield results. Where medicinal products developed on the basis of GR and TK are patented, this hinders the development and export of relevant medicines in developing provider countries. Moreover, IPR protection frequently contributes to medicines developed on the basis of GR and TK from developing countries – somewhat ironically – often remaining unaffordable for poor populations in those developing countries (see also below on the case of virus vaccines). Enforcement of trade disciplines in developed countries may also under these circumstances significantly impede South-South trade in cheaper generic medicines. These negative effects are currently not balanced by appropriate BS arrangements.

At the same time, developed countries and the pharmaceutical industry have warned that crucial new medicines may not be developed timely, if developing countries were to restrict access to valuable GR in this respect. More important from a development policy perspective, there is a lack of incentives for spurring R&D of medicines that are of particular relevance for developing countries and the parts of their populations that lack purchasing power (e.g. Baker 2009).

Traditional and alternative medicines are a particular concern. In Africa, about 80% of the population depend upon such medicines for meeting their health-care needs. Traditional and alternative medicines have the advantage that they require little to no industrial processing and that knowledge on their use is often wide-spread. Patents have rarely been used in this context, not least because such medicines often fail to fulfil basic formal criteria for patentability (Hsiao 2007). With a global annual market size of

²⁵ The European Parliament has also regarded the relationship between the ACTA provisions and the human right to health as problematic European Parliament (2011). ‘Anti-Counterfeiting Trade Agreement (ACTA) Written questions by the European Parliament.’ From <http://trade.ec.europa.eu/doclib/html/147852.htm>.

an estimated US-\$ 60 billion (as of 2002), the WHO fears, however, that benefits from traditional and alternative medicine are “being appropriated, adapted and patented by scientists and industry, with little or no compensation to its original custodians, and without their informed consent” (WHO 2002). Still, there have been no prominent cases in which patents inhibited access to traditional and alternative medicines (i.e. no cases that would be comparable to the cases of biopiracy referred to in sections 2 and 5).

A particularly prominent discussion in recent years in this respect concerns ABS regarding **influenza viruses**. The case of the 2006/2007 Avian Flu is instructive: in early 2007, the Indonesian government refused to supply influenza viruses to WHO laboratories on the basis of insufficient BS mechanisms under WHO regulations. Indonesia expected that pharmaceutical companies would commercialize a vaccine, without sufficiently letting Indonesia participate in the profits and even selling the vaccine to Indonesia at unaffordable prices (Velasquez 2011). Additionally, the Indonesian government was worried that patents on components of the Indonesian virus could be granted without PIC and MAT (Irwin 2010).

In response to these concerns, the World Health Assembly of the WHO adopted the *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* in May 2011, which is further discussed in section 3.4.

The utilisation of other viruses and GR for health purposes would appear to fall under the Convention on Biological Diversity and its Nagoya Protocol (Vezzani 2010). The extent to which a fair and equitable BS can be achieved/ensured in this sector, including access to affordable medicines, thus currently depends on the full and effective implementation and further development of the Nagoya Protocol in general.

5. CASE STUDIES: INDIA, BRAZIL, SOUTH AFRICA

This section provides an overview on the use of GR and TK as well as the regulatory framework on ABS and intellectual property in three different countries: India, Brazil and South Africa. For each country, some examples in which actors from the developed world used the GR of the respective country are described. The three countries were selected, because they are among the 17 so called mega-diverse countries of the world,²⁶ which together host most of the world’s biodiversity, as measured by the total number of species and the number of endemic species in a country. Besides that, they are all emerging countries, have put ABS legislation in place some time ago and have been leading developing country voices in international debates and negotiations on IPRs (e.g. in the health sector) and ABS. All three countries are also early signatories of the Nagoya Protocol.

5.1 India

India is one of the eight primary centres of origin of cultivated plants and a centre of crop diversity with around 45,500 plant species, 375 closely related wild varieties and 6,500 varieties used in indigenous healthcare (Government of India 2008). Traditional beliefs play an important role in the conservation of many of these species and India has over 19,000 community established ‘sacred groves’ for the protection of medicinal and wild plants about which TK and beliefs are kept.

²⁶ The list of 17 countries was developed originally in a 1997 report by Conservation International entitled “*Megadiversity: Earth's biologically wealthiest nations*”.

India is home to over 700 indigenous groups - known as scheduled tribes - accounting for around 8.2% of the country's population (Government of India 2011). ILCs have few legal rights over natural resources with around 95% of total forest area being nationalised (Mitra and Gupta, 2009: 198; Pant 2009: 12). India's Scheduled Tribe Recognition of Forest Rights Act (2006) seeks to grant community rights to TK of forest biodiversity and to intellectual property and TK related to this biodiversity. However, where communities seek to establish their rights over land or its resources, the processes for according legal ownership can be overly bureaucratic and at odds with customary practices (Vedavathy 2009).

5.1.1 Regulatory framework on ABS

The Protection of Plant Varieties and Farmers' Rights Act (2001) provides for the right of farmers to share in the benefits arising from the use of plant genetic resources. Under this Act, plant breeders are required to pay compensation into a 'Gene Fund' for the use of traditional germplasm. However, the key legislative framework for the conservation of biological diversity and ABS in India is enshrined in the Biological Diversity Act (2002). The 2002 Act recognises that India is rich in TK related to GR and is responsible for regulating access to TK and GR. Suman Sahai of Gene Campaign noted however, that the Act focuses mainly on the protection of GR rather than TK as well as on access to biological resources rather than the sharing of benefits from their use.²⁷ To obtain access to TK or GR, PIC is required from the National Biodiversity Authority (for foreign nationals) or from the State Biodiversity Board (for Indian nationals). Both the National Biodiversity Authority and the State Biodiversity Board must consult with local Biodiversity Management Committees before access is granted, although there is no legal obligation to follow the latter's recommendations. These local committees are required to document TK in the form of People's Biodiversity Registers. They can also demand fees from persons collecting bioresources for commercial purposes (Section 41(3)) which are paid into local biodiversity funds.

However, interviewees noted that a number of issues exist with the Indian system of access to biological resources and associated knowledge. Awareness about the implications of India's three tier system on operationalising the ABS provisions of the National Biodiversity Act is not yet widespread,²⁸ and several states have yet to even establish Biodiversity Management Committees.²⁹ Furthermore, slow progress in establishing State Biodiversity Boards³⁰ has left access to biological resources open to misuse by Indian nationals who could use local knowledge without sufficiently compensating local farmers and other owners of resources (Robinson 2011). Jebra Muchahary of the Indian Confederation of Indigenous and Tribal Peoples (ICITP) noted that resources may be extracted without obtaining PIC as many holders of biological resources and related knowledge are ignorant of their rights, and eligibility for BS.³¹ Distribution of benefits is also complicated by the increasing tendency in India towards ex-situ development of GR in government or private sector facilities away from the original source (Robinson 2011).

²⁷ Interview with Suman Sahai, 7 November 2011.

²⁸ Interviews with Jebra Ram Muchahary, 10 November 2011, and with R.S. Rana, 3 November 2011.

²⁹ The National Biodiversity Authority website (visited 16 November 2011) shows 4 of the 22 states to have established several hundred Biodiversity Management Committees. However, 6 have yet to establish a single one.

³⁰ From 2003 onwards, State Biodiversity Boards were being set up in India. However, by February 2009, eight States had still not established their State Biodiversity Board (Pattanaik 2009).

³¹ Interview with Jebra Ram Muchahary, 10 November 2011.

The National Biodiversity Authority is obliged to ensure that the terms and conditions for access to biological resources secure 'equitable sharing of benefits' arising from their use between applicants, local bodies and benefits claimers.³² However, the term equitable is left undefined. Also, although informal guidelines exist (see Rana 2010 for outline), the National Authority has yet to publish a 'benefit-sharing formula' as required by the National Biodiversity Act 2002. This lack of clarity may not only slow down the process of BS, but may also deter private companies from investing in R&D if the total costs of compensation are unknown (Demanague 2005). Even where PIC is sought, the centralised structures for regulating ABS may lead to long delays in the distribution of benefits (Dutfield 2000; Nellithanam 2007) as illustrated in Box 5.1.

Box 5.1: Source: Intellectual Property Rights, Trade and Biodiversity

In Southern India, an agreement between the Tropical Botanic Garden Research Institute (TBGRI) in Kerala, the Arya Vaidya Pharmacy and the Kani tribal group was complicated and delayed due to the State government's failure to recognise the territorial and resource rights of the local people concerned. The Kani do not have a legal title for the land they occupy (which has also prevented them from harvesting the plant themselves), making equitable BS difficult. An exclusive seven-year-license to manufacture and sell a product based on extracts of the sub-species 'Jeevani' was granted to the TBGRI who agreed to sharing the license fee and royalty payments with the Kani. This amounts to a de facto recognition of the Kani's IPRs over the resource. However, the Kani are dependent on the State government's consent to transfer the funds to the trust established for the benefit of the Kani. The government was slow to proceed, likely due to the lack of recognition for the Kani's basic rights, and the TBGRI had to wait for more than three years until it could transfer the funds.

Source: Dutfield 2000.

5.1.2 IPRs and genetic resources

In the past, India's approach to IP has been similar to that of countries such as Taiwan and Korea, emphasising the value of imitation and reverse engineering with weak IP protection (CIPR 2002). Historically, India also has a high level of informal seed exchange between farmers, and until the late 1980s, the public (rather than the private) sector was the primary supplier of seeds (Demanague 2005). The Indian Patents Act 1970 did not permit patents on seeds or pharmaceuticals. This more relaxed regime led to India becoming known as the 'pharmacy of the developing world', providing generic drugs at a fraction of the price of branded products (ABIA 2009; MSF 2010). This background may explain a general lack of awareness of IP beyond the higher levels of authority³³ as well as a general apprehension about the likely monopolisation of seed business by the multinational seed companies under the cover of IPRs.³⁴

Nevertheless, after the entry into force of WTO-TRIPS in 1995, India was obliged to strengthen IP protection for the R&D of pharmaceuticals and plant varieties by 2005. Most WTO members with no system for plant variety protection in place adopted the UPOV 1991 Convention to comply with WTO-TRIPS. However, India opted for a *sui generis* regime in the form of the 2001 Protection of Plant Varieties and Farmers' Rights Act. This act is novel in IP protection in that it explicitly takes farmers as well as the

³² National Biodiversity Act, 2002 (Section 21 (1)).

³³ Interview with Jebra Ram Muchahary, 10 November 2011.

³⁴ Interview with R.S. Rana, 3 November 2011.

public and private sector into account. In practice, however, the law does not distribute rights to all three groups on an equal basis: A particular novelty of the Indian plant variety act is that it maintains a number of farmers' privileges which allow them to save, use, sow, re-sow, exchange, and share seeds and even to sell their seeds in unbranded form ('brown bag' sales). Farmers are additionally provided protection in the case of innocent infringement where they are not aware of the existence of breeder rights (Brahmi et al. 2004).

However, most of the rights accorded by the plant variety act belong to the Indian government³⁵, the largest formal supplier of seeds, which has led to pressure to revise the Act to reduce government monopoly and increase control of the informal market for seeds. The Indian government thus announced in 2002 that it would accede to UPOV 1978 (although not the stricter 1991 version). At present, however, it has yet to do so. According to Suman Sahai of the NGO Gene Campaign, despite the fact that India has met its WTO-TRIPS obligations, external pressure, including from the EU, continues for India to enact even stricter so-called 'TRIPs plus' standards for IP protection.³⁶ Further pressure comes from the seeds industry which seeks increased IP protection under the Indian Seeds Bill (2004). The Seeds Bill undermines the plant variety act on several terms, notably regarding the rights of farmers to sell seed. Furthermore, the Seeds Bill allows for registration, commercialisation and export of seed without *a priori* establishing legal ownership. This freedom could lead to the commercialisation of GRs within the public domain with no liability for BS (Bala Ravi 2009: 4).

In a further discrepancy, a 2005 amendment of the 1970 Patents Act – known as the Patents (Amendment) Act – contains several key safeguards not mentioned by UPOV and the Indian Seeds Bill. The amendment includes a prohibition on the patenting of insignificant or minor improvements of known medicines (MSF 2010). The Patents (Amendment) Act further stipulates several grounds for opposition to a patent which take indigenous rights into account. These include failure to disclose the source and geographical origin of biological material used and the use of oral or other TK which is seen to constitute prior art. Nevertheless, in practice, full information is not readily provided in patent applications, although the CBD requirement for PIC submitted by Biodiversity Management Committees and State Biodiversity Boards is checked by the National Biodiversity Authority, whose prior approval is essential before seeking IPRs.³⁷ Thus, although the Patents Act, combined with the Biological Diversity Act, seeks to provide several safeguards for TK associated with GR, these mechanisms are still developing and there remains a lot of scope for improving their effectiveness.³⁸

Currently, there is a high number of patent applications pending in the Indian Patent Office.³⁹ Of these, a number are multiple applications relating to the same drug (ABIA 2009: 128).⁴⁰

³⁵ The government's high market share in seed supply and the historically hostile approach to foreign companies (foreign direct investment in the seed industry was not permitted until 1991) has deterred private investment and driven private sector focus towards the development of hybrid plant varieties.

³⁶ Interview with Suman Sahai, 7 November 2011.

³⁷ Interview with R.S. Rana, 3 November 2011.

³⁸ Interview with R.S. Rana, 3 November 2011.

³⁹ As of 30 June 2010, 78,792 patent applications were pending with the Indian Patent Office of which 6,322 were for pharmaceuticals, according to Commerce and Industry Minister Anand Sharma (IIPTA 2010); see also Figure 5.1.

⁴⁰ There are further reasons for the high number of patent applications pending. Publication of patent applications was made mandatory following the amendment of the Patents Act in 2002. Initially, a lack of digital documentation available for publication meant that no change was visible. However, a digitisation drive between 2006-09 led to a surge in the publication of patents granted between 2007-09. The low number of patents examined and granted in 2009-10 may be explained by staffing issues: 55 patent examiners left and 47 examiners were promoted to other posts (Government of India 2010: 6).

Figure 5.1: Trend in Patent Applications to the Indian Patent Office (2003-2010)

Year	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10
Filed	12613	17466	24505	28940	35218	36812	34287
Examined	10709	14813	11569	14119	11751	10296	6069
Granted	2469	1911	4320	7539	15316	16061	6168

Source: Government of India 2010.

The measures India has taken to strengthen its IP regime have been accompanied by considerable growth in the number of non-resident patent applications as shown in Figure 5.2.

Figure 5.2: Patent Applications to the Indian Patent Office by Residents and Non-Residents (2000-2008)

Applicant Type	2000	2001	2002	2003	2004	2005	2006	2007	2008
Resident	2.179	2.371	2.693	3.425	4.014	4.521	5.314	n.a.	n.a.
Non resident	6.324	8.221	8.772	9.188	13.452	19.984	23.626	n.a.	n.a.
Total	8.503	10.592	11.465	12.613	17.466	24.505	28.940	35.218	36.812

Source: WIPO Statistics Database, January 2011.

India has been an active voice against biopiracy of GR and TK related to their use. This has been bolstered by innovative efforts such as the systematic documentation of TK related to medicinal plants and related practices in a Traditional Knowledge Digital Library. The Digital Library has been made available to patent offices in other countries who may search to see if a patent application is based on prior art. Without documentation of TK, it is unlikely that patent applications for traditional uses of biological resources such as neem and turmeric could have been overturned. As such, the Digital Library is essential for the Indian government's ability to preserve national ownership of biological resources. Nevertheless, the Library is not without its critics. In one interview, it was noted that despite non-disclosure agreements between the Indian government and patent offices, the absence of legislation governing the use of the Digital Library and providing for penalties in case of abuse leaves it vulnerable to abuse.⁴¹

India has fought several high profile and costly legal battles to overturn patents based on traditional use of GR found in India, such as a patent granted for turmeric by the US patent office (Brody 2010). Following these experiences the development of the Digital Library proved to be a key tool for establishing prior art of GR and their use. For example, in 1994, the European Patent Office (EPO) granted a patent to the US Department of Agriculture and the firm WR Grace for the fungicidal properties of the neem plant. In 2005, however, a civil society consortium presented a challenge.

⁴¹ Interview Suman Sahai, 7 November 2011.

Following oral testimony and evidence of the public knowledge of neem use by Indian farmers as documented in the Digital Library, the EPO overturned the 1994 decision (Sheridan 2005).

5.2 Brazil

Brazil has 70% of the world's catalogued animal and plant species. It is estimated that Brazil hosts between 15-20% of the world's biological diversity, and the greatest number of endemic species on a global scale.⁴² In Brazil, there are more than 200 indigenous peoples, with a population of 600,000 or 0.2% of the Brazilian population, and 180 languages; thus Brazil is also a culturally megadiverse country (Santilli 2009a: 190). One thousand *Quilombola* communities (*Quilombolas* being communities of Afro-descendants, or villages of run-away slaves) have been officially identified with a population estimated at around 2 million people.⁴³ Other traditional communities include artisan fisherfolk, nut gatherers and rubber tappers, adding up to approximately 4.5 million people, according to the Ministry for the Environment. These communities and villages hold considerable knowledge of flora and fauna species, especially regarding traditional management of these natural resources. There is also agricultural diversity, with for example the indigenous people of Kaiabi using more than 140 plant varieties of 30 different species and the traditional community of the *seringueiros* using 17 varieties of mandioca, 14 of banana and nine of beans (Santilli 2006: 1). Despite this variety on the local level, on a national scale Brazil is highly dependent on the import of plant GR for food uses (Santilli 2009b: 24).

According to a 2003 report by a Brazilian parliamentary commission⁴⁴, Brazil's legal and institutional systems were inadequate to control biopiracy, mainly because of the ambiguity of the legislation.⁴⁵ Since even when co-operation agreements were in compliance, the benefits to Brazil were in several cases found to be insignificant and thus unacceptable, it was proposed that the government create new legislation on the export of wild animals and genetic material. According to the 4th national report to the CBD in October 2010, biopiracy continues to be a serious problem in Brazil.⁴⁶

5.2.1 Regulatory framework on ABS

Brazil was one of the first mega-diverse countries to enact national legislation on ABS, in the form of the Provisional Measure (PM) 2.186-16⁴⁷ in 2001. Brazil also is a party to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)⁴⁸ and accessed UPOV 1978. It is a signatory, but not yet a party to the Nagoya Protocol. With both ministries in the field of agriculture (the Ministry for Agriculture and the Ministry for Agrarian Reform and Development) and the Ministry for the Environment having stakes concerning the implementation of the Protocol,⁴⁹ it is expected that Brazil's

⁴² See <http://www.cbd.int/countries/profile.shtml?country=br>.

⁴³ See <http://www.palmares.gov.br>.

⁴⁴ See http://www.camara.gov.br/Internet/comissao/index/cpi/rel_fin_cpitrafi_01_pdf.pdf.

⁴⁵ The ambiguity of the legislation and the resulting difficulties for implementation were also highlighted by Fernanda Alvares da Silva (interview on 14 December 2011).

⁴⁶ See <http://www.cbd.int/doc/world/br/br-nr-04-en.pdf>.

⁴⁷ Provisional Measures are issued by the President of Brazil, coming into force as laws upon publication. They may later be approved, amended or rejected by the national Congress. Provisional Measure 2186-16/2001 was first published in June 2000 and has never been voted on by the Congress. However, it became a legally binding instrument due to a constitutional amendment.

⁴⁸ According to Santilli (2009c: 20) the multilateral system of the ITPGR is generally seen as a positive step, but it must be made sure that its GR are not privatized, since due to the ambiguous treaty language merely cosmetic changes could lead to the granting of a patent.

⁴⁹ Interview with Juliana Santilli, 10 November 2011.

national Congress will ratify the Protocol in due course.⁵⁰ Many people in Brazil do see the provisions of the Protocol as positive steps in the direction of fair and equitable sharing of benefits regarding GR and there is an expectation especially towards user countries to ratify the Protocol and to adopt measures to effectively protect GR and TK.⁵¹ According to one interviewee⁵², this could bring a change in the international framework that has so far favoured the holders of IPRs. Since the CBD and the Nagoya Protocol are much weaker than WTO-TRIPS⁵³ or TRIPS plus standards, there still remains a feeling of imbalance regarding the enforcement and the effectiveness of sanctions.

The first steps to implement PM 2.186-16 were taken in April 2002 with the creation of the Department of Genetic Heritage, a division of the Ministry of the Environment, and the first meeting of the Genetic Patrimony Management Council (CGEN) which has rule-making and deliberative functions. The CGEN is responsible for authorising access to GR for commercial research or to TK, while the Brazilian Institute of Environment and Natural Resources is responsible for authorizing access to GR for the purpose of scientific research with no potential for commercial use.

The CGEN is formed by 19 ministries and federal agencies under the coordination of the Ministry of the Environment. Since 2003, stakeholders such as biotechnology companies, researchers in scientific institutions or indigenous and traditional communities have attended the monthly meetings, with the right to speak but no to vote. In 2007, a decree stipulated that the Management Council may invite experts or representatives of various sectors of society involved with the subject matter (Santilli 2009a: 188).

BOX 5.2: The Krahô case

The Federal University of Sao Paulo in 1999 accessed plants used in medicinal rituals and traditional practices by several ethnic groups of the Krahô peoples in the State of Tocantins. Out of 400 species collected, 138 were identified as having potential neurological functions, and 11 of them already had been tendered for pharmacological and phytochemical studies. The lack of representation of TK holders led to a breakdown in the negotiations aimed at the drafting of a bilateral BS contract. During the process, two associations said they represented the Krahô peoples (the Vyty Cati and the Kapéy). However, only one of them – the Vyty Cati - had initially been consulted. The Kapéy did not participate from the beginning in the PIC procedure nor agree to the use of the collected genetic material based on their uses and customs. As a result, in 2002 the Kapéy conditioned any further discussions on the prior payment of an indemnification of 5 million *reals* (approx. 2 million Euro) for moral damages, plus an up-front prospecting fee of 20 million *reals* (approx. 8,3 million Euro). Following new negotiations, an agreement to replace the 25 million *reals* with a health clinic and a vehicle to be used on the Krahô peoples' territory was reached. Access to TK that had already occurred was validated by the prior consent of the villages represented by the Kapéy, who also agreed to the continuation of the research. However, the procedure was suspended, and the contract on use and BS was not concluded. The reason for this can be found in the already destroyed mutual trust and enduring strong criticism from the public.

Sources: Kishi 2009; Santilli 2009a.

⁵⁰ According to Fernanda Alvares da Silva (interview on 14 December 2011), a draft law shall be published during the next days.

⁵¹ Interview with Fernanda Alvares da Silva, 14 December 2011. She added that the biotechnology sector in Brazil is preoccupied that the implementation of the Nagoya Protocol could even increase the stimulus to concentrate the research activities from the side of the developed countries.

⁵² Interview with Juliana Santilli, 10 November 2011.

⁵³ Before the ratification of TRIPS no patents were allowed in Brazil on food products and pharmaceutical products.

PM 2.186-16/2001 provides for two main instruments: authorization of access to GR and TK, and the BS contract. Access to GR⁵⁴ can generally only be granted following the prior consent of the indigenous peoples (when access occurs in indigenous territories or involves TK), of an environmental agency (when access occurs in a protected area) or of the owner of private land. When access takes place in waters under Brazilian jurisdiction, on the continental shelf or in the exclusive economic zone, the prior consent of the maritime authority must be obtained, or of the National Defence Council if it involves an 'area that is indispensable to national security'. Foreign institutions aiming to access GR must necessarily be associated with a Brazilian institution (ICTSD 2010a: 2). By now, PIC is conditioned on prior independent anthropological studies in order to ensure due representation of knowledge holders (Kleba 2009: 123). The anthropological expert opinion does not substitute consent, but it assists indemnification of the peoples who share the same TK and enhances the knowledge level of the provider communities about the project content and its consequences (Kishi 2009: 314f).

BOX 5.3: The Cupuaçu case

Patents have already been granted on literally all well-known Amazonian and Andean medicinal plants, including Andiroba (*Carapa guianensis* Aubl.), Copaiba (*Copaifera* sp), Cat's Claw (*Uncaria tomentosa*), Maca (*Lepidium meyenii*), Sangre de Drago (*Croton lechleri*), Quebra Pedras (*Phyllanthus niruri*), and Wormseed (*Chenopodium ambrosioides*). Almost all of these patents were registered by companies or people from developed countries. In 2002 the NGO Amazonlink discovered the existence of several worldwide patent applications on oils and chocolate made from the Cupuaçu tree. It also found that the name of the fruit had been registered as a trademark in the EU, US and Japan by Japan's Asahi Foods and its allied US company, Cupuaçu International. Cupuaçu (*Theobroma grandiflorum*) is a rainforest tree that belongs to the cocoa family. Indigenous peoples as well as local communities along the Amazon have cultivated Cupuaçu as a primary food source for generations. In earlier times, Cupuaçu seeds were traded along the Rio Negro and Upper Orinoco rivers where indigenous people drink Cupuaçu juice after it has been blessed by a shaman to facilitate difficult births. The "beans" are utilized by the indigenous Tikuna people for abdominal pains. Cupuaçu-chocolate has been produced in Brazil since 1983 and is known as 'Cupulate'. Upon discovery of the Cupuaçu trademark, Amazonlink launched a worldwide campaign and submitted a challenge against the Japanese trademark Cupuaçu at the Japanese Patent Office. In Germany, a group of NGOs filed an objection against the patent request on Cupuaçu oils and chocolate at the European Patent Office (EPO). In 2004, the Japanese Patent Office in Tokyo decided to cancel the trademark Cupuaçu. It also rejected a patent request by Asahi Foods for the production of Cupuaçu chocolate (Cupulate). In 2005, the EPO rejected the patent request and informed Asahi Foods about the cancellation of the trademark Cupuaçu.

Sources: <http://www.amazonlink.org/biopiracy/cupuacu.htm>.

When there is a prospect for commercial use of the resources accessed, BS contracts must be signed between the providers and the users of the GR/TK, and these contracts must be approved by the CGEN to assure they are in accordance with the law (Article 16). These contracts are to provide for benefits such as profit sharing, payment of royalties, access to and transfer of technology, no-cost licensing of products and processes and training (Article 25). The CGEN, however, does not go further in the

⁵⁴ CGEN published an official 'technical orientation' to make it clear that access is different from the collecting of biological material, access being 'the activity carried out with GR with the objective of isolating, identifying or using information of genetic origin or molecules and substances arising from the metabolism of living beings and of extracts obtained from such organisms'.

examination of the BS contracts between private persons, for example if it is fair and equitable.⁵⁵ As of March 2009, CGEN had registered 22 contracts,⁵⁶ most of them relating to bioprospecting at the initial stage, conducted mainly by national public institutions (ICTSD 2010a: 2). Many contracts stipulate that benefits will be shared only if economic exploitation occurs as estimating the potential beforehand often is very difficult. Although a formal economic assessment of the BS contracts in Brazil has not been made, the general feeling is that almost no sharing of benefits has resulted from these contracts.⁵⁷ Until 2009, none of the BS contracts concluded between users of GR or TK and farmers on the basis of PM 2.186-16/2001 resulted in concrete benefits for the farmers and the protection of biodiversity (Santilli 2009b: 54).

Generally, hopes for joining biotechnological development with fair treatment for TK holders have faced some disenchantment (Kleba 2009: 119). Companies and scientists are discouraged from accessing GR and TK because of the high transactions costs, the legal uncertainties, the risks of public blame and the time-consuming procedure. Some argue that this system induces biopiracy and the whole process must be urgently amended.

The focus on bilateral contracts is seen as one of the law's most serious flaws as often knowledge on the characteristics, properties and uses of biological resources are held, produced and/or shared by various traditional peoples (Santilli 2009a: 190; Kishi 2009; Kleba 2009: 120ff.; ICTSD 2010a: 2f). The need for a bilateral contract could and did often create a competition between the various traditional peoples or local communities commonly holding the knowledge.⁵⁸ This situation was exemplified by the Krahô case (see Box 5.2), where bioprospecting failed because some indigenous peoples that claimed holding TK on the GR concerned were not represented in the agreement for access. While this is a problem for TK related to wild GR, it is an even bigger problem concerning agrobiodiversity, where there often has been an even stronger exchange of TK and it is nearly impossible to find out who exactly is the holder of this TK.⁵⁹

The federal government prepared a new draft law in which contracts with providers of GR are no longer mentioned. Accordingly, when users of GR are based in Brazil there would be an obligation to contribute to a public fund of BS based on a fixed percentage rate of benefits deriving from commercial sale or licensed patents. Contracts only would remain in cases where users of GR are foreign institutions, and the BS would be negotiated with CGEN and directed to the public fund. The fund would finance the conservation and sustainable use of biodiversity and ILCs would be able to apply for measures for *in situ* and on farm protection of biodiversity (ICTSD 2010a: 2/3f). However, as there is no agreement between the Ministry for Agriculture, the Ministry for Science and Technology and the Ministry for the Environment on who is going to be in charge of granting access to GR and to TK the adoption of this draft law is still uncertain.⁶⁰

⁵⁵ Interview with Fernanda Alvares da Silva, 14 December 2011.

⁵⁶ There is some confusion about numbers, as the 4th national report of Brazil to the CBD mentions 25 contracts that had been agreed to and signed and only one BS contract that had been completed and approved by CGEN.

⁵⁷ Interview with Juliana Santilli, 10 November 2011.

⁵⁸ Interview with Juliana Santilli, 10 November 2011

⁵⁹ Interview with Juliana Santilli, 10 November 2011

⁶⁰ Interview with Juliana Santilli, 10 November 2011

5.2.2 Legal status of indigenous communities and recognition of their rights

The Brazilian Constitution (Article 231) recognizes the social organisation, customs, languages, beliefs and traditions of indigenous peoples as well as of the *Quilombola* communities; they have the right to the exclusive use of the natural resources located in their traditional lands. The indigenous populations, their communities and organisations have standing to sue to defend their rights and interests (Article 232 of the Constitution). The Public Prosecution has an important role in safeguarding these rights. According to Article 129/III and V of the Constitution the Public Prosecution is to institute civil investigations and public civil suits to protect public and social property, the environment and other diffuse and collective interests, and to defend in court the rights and interests of the indigenous populations. This is important as the rights regarding TK⁶¹ are considered as collective rights or diffuse interests in Brazil by the prevailing opinion (Kishi 2009: 317f).

ILCs that create, develop, detain or conserve TK associated to the genetic patrimony according to Article 9 of PM 2.186-16/2001 have the right to have the origin of the accessed TK indicated in every single publication, utilization, exploration and divulgation. In addition, the communities can impede non-authorized third parties to use, test, research or explore TK and to divulgate, transmit or re-transmit data or information that integrate or constitute TK. Last but not least, they can require BS in case of the direct or indirect economic exploitation of TK by third parties. Communities must be clearly informed in an accessible language about the research activities (purpose, methodology, duration, geographical area, knowledge to be accessed, budget and potential impacts), and the rights and responsibilities of each party. This includes the right to refuse the access to their knowledge PIC procedures (ICTSD 2010: 4).

BOX 5.4: The breu branco case

In 2000, Natura, a Brazilian cosmetics company, founded the EKOS Line, which “draws from the wealth of Brazil's biodiversity and is inspired by traditional uses of plants ingredients.” In 2001, Natura staff collected information on the Ver-o-Peso market in Belem on a range of useful plants. Species incorporated into Natura Products included *breu branco*, a resin produced from insect-damaged trees, used traditionally as incense and in art work and handicraft, and extracted from the forests of Iratapuru. Natura did initially not enter into an ABS agreement, although the company gave the Ver-o-Peso market association (Ver-as-Ervas) acknowledgment in its materials, and an oral agreement was reached. As the Brazilian legislation on ABS evolved and awareness grew on the importance of compensating TK holders for the use of their knowledge, the women of Ver-as-Ervas requested assistance from the competent authority in order to claim benefits. The CGEN decided that access to TK had indeed taken place. An agreement with Natura was formalized in 2006. The herb and perfume traders were recognized as providers of TK involving breu branco. In October 2006, Natura signed a BS contract with the Ver-as-Ervas association. The contract provided for up-front payments, as well as a percentage of net profits, when the fragrance ingredients were highlighted on the label or present in the recipe used. The benefits were to be used for biodiversity and conservation projects, as well as cultural projects, with no direct monetary advantages accruing to any member of the association. Through this process, Natura built its internal capacity to deal with PIC associated with TK, and developed ways to engage with local groups to achieve truly informed consent, including explaining the Brazilian ABS legislation through theatrical performances, and hiring economists and lawyers selected by communities to work on their behalf. Sources: Kleba 2009: 124-125; Laird 2008: 81-82.

⁶¹ Associated TK is defined in Article 7/IV PM 2.186-16 as the information about knowledge or individual or collective practice, associated to GR, of a native Brazilian or local community.

5.2.3 IPR and genetic resources

The legal link between ABS and the Brazilian patent system is Art. 31 PM 2.186-16⁶². The implementation of Article 31 PM 2.186-16 began in late 2006.⁶³ The Brazilian Patent Office adjusted the form and the internal procedures for patent applications. Since then, every patent applicant has to declare, at the time of the patent application, whether or not the underlying invention is based on access to GR or TK and whether access was in compliance with the relevant legal rules.⁶⁴ The number and date of the relevant authorization must also be provided.

Moreover, according to the National Plant Varieties Protection Act 9.456 of 25 April 1997 (based on UPOV 1978) it is possible to apply for plant variety protection (no patents are allowed on plant varieties). This law foresees some exceptions (Article 10), *inter alia* a (small) farmers' privilege (Santilli 2009c: 31). There is strong pressure from agribusiness to adapt the national legal system to UPOV 1991 which might bring stronger restrictions concerning farmers' rights and might allow patents on plant varieties.⁶⁵ Currently, the Brazilian Agricultural Research Corporation (Embrapa) holds 32% of the plant variety rights, followed by the company Monsoy with 13,39% and two national cooperations (Coodetec and Copersucar) with 7.30% and 5.04% respectively.⁶⁶

5.3 South Africa

Covering 2% of the world's surface, South Africa is home to approximately 10% of global plant species, 65% percent of which are endemic to South Africa. A "biodiversity hotspot," the Cape Floristic region is the smallest and richest of the world's six floral kingdoms (DEA 2009). Plant resources have traditionally played an important role for indigenous communities and the country is rich in medicinal plant knowledge (Crouch 2008). Indigenous plants are used by 60-70% of South Africans for health care or cultural practices, making use of approximately 3,000 different species (Coetzee 1999; Reinten 2002).

South Africa's rich plant diversity contributes to innovations and commercial success in pharmaceuticals, cosmetics, ornamental products, cut flowers, crops, and more. Indigenous plants such as rooibos and honeybush for tea, aloes, buchu, and devil's claw as medicinal products, and cut flowers are all exported in large volumes and are sources of jobs and revenue (Reinten 2002; Coetzee 1999; Wynberg et al. 2009). Nevertheless, foreign industries have previously profited from unconstrained access to the country's genetic resources and providers of resources and traditional knowledge have not benefited equitably (Wynberg and Taylor 2009; Crouch 2008; Coetzee 1999).

⁶² Article 31 reads "... grants of industrial property rights made by the competent bodies to a process or product obtained from sample components of genetic heritage is contingent on the observance of this Provisional Act, and the applicant must inform the origin of genetic material and associated traditional knowledge, where appropriate."

⁶³ A study carried out in 2006 showed that until that date fewer than 10% of the patent applications filed at the Brazilian patent office identified the origin of GR/TK, and no patent application filed had an access authorization attached (Santilli 2009a: 194).

⁶⁴ Interview with Fernanda Alvares da Silva, 14 December 2011.

⁶⁵ Interview with Juliana Santilli, 10 November 2011.

⁶⁶ Information of the National Plant Variety Protection Service of the Ministry of Agriculture, Livestock and Supply in 2009 according to interview with Juliana Santilli, 10 November 2011.

5.3.1 Regulatory framework on ABS

South Africa is a party to the CBD and early signatory of the Nagoya Protocol. The primary framework for ABS in South Africa is the National Environmental Management: Biodiversity Act No. 10 of 2004 (Biodiversity Act) and implementing Bioprospecting, Access and Benefit Sharing Regulations (Regulations), adopted in February 2008. The Biodiversity Act meets South Africa's domestic obligations under the CBD and much of the Nagoya Protocol (DEA 2009; DAFF 2011).

Under the Biodiversity Act, permits are required for commercialization and export of indigenous biological resources. Notice must be given to authorities before bioprospecting begins. Once a patent application has been filed, a project is considered as having entered the stage of commercialization, and hence requiring a permit. Issuing authorities must ensure that permitted activities will not deplete resources and exports must be in the public interest. Where access to resources is provided or indigenous communities have contributed knowledge, applicants must enter into a BS agreement that is approved as fair and equitable. Applicants must enter into a material transfer agreement where stakeholders provide access to resources. Permits may only be issued to either a juristic person incorporated in South Africa, a citizen or a permanent resident, or, alternatively, must be applied for jointly with a qualifying juristic or natural person, thus helping to further ensure that benefits are retained domestically.

BOX 5.5: Hoodia Hoodwinking

The San of South Africa have traditionally used the Hoodia succulent plant as an appetite suppressant and thirst quencher during long hunting trips. In 1995, the South African Council for Scientific and Industrial Research (CSIR) obtained a patent for the use of Hoodia's active constituents responsible for appetite suppression. In 1998, CSIR licensed the extract to a British pharmaceutical company, Phytopharm, who in turn licensed it to Pfizer Pharmaceuticals. Until 2001, the San had no knowledge of CSIR's ventures, which were performed without consultation or BS. In fact, CSIR told Phytopharm that the San, numbering 100,000 at the time, no longer existed. After CSIR's actions were revealed, the San threatened legal action. The dispute was eventually settled through a memorandum of understanding recognizing the San as custodians of traditional knowledge and CSIR's role in isolating the active ingredient. In 2003, a benefit-sharing agreement between the San and CSIR was produced and a trust fund created. Pfizer discontinued clinical development in 2003 and returned the rights to Phytopharm. While the CSIR patent focused on the Hoodia extract, it did not cover raw Hoodia, resulting in a frenzy of unregulated collection of the species, where the San received no benefits and natural populations were threatened. As of 2010, only US\$ 100,000 had been received by the San Hoodia Trust, although non-monetary benefits, such as research, collaboration, and training, were also provided. Here, as with other ABS cases, stakeholders must grapple with how to equitably distribute the money and to whom.

Sources: Wynberg 2010; Robinson 2010; Wynberg et al. 2009; Wynberg 2008; King et al. 2004; Teljeur 2003; Interview with Rachel Wynberg, 17 November 2011.

Many problems, however, are associated with the Biodiversity Act, in particular from hurried drafting that is perceived as having created a lack of clarity regarding interpretation, scope and requirements. "Although the aims of the Biodiversity Act are laudable, unfortunately, the provisions of the Biodiversity Act are problematic in that the legislation is poorly drafted," comments Joanne van Harmelen, a patent attorney with Spoor & Fisher in Cape Town. "As a result there has been much resistance to the enactment of the legislation and much confusion caused by it." Permit applicants often have difficulty identifying knowledge holders, especially as traditional knowledge is often widely held by numerous communities, thus stakeholders may be overlooked or companies may choose to develop a BS agreement with only one community. At the drafting stage, there are problems in estimating future benefits and for communities without resources to help create fair and equitable agreements. Further, it can be difficult to identify which resources should be covered when using complex value chains.⁶⁷ Other problems noted with the Biodiversity Act include enforcement, insufficient government resources and lacking awareness among stakeholders (DFAA 2011a; Teljeur 2003; Kameri-Mbote 2005; Mahop 2010). "Our main concerns are around access to information, consultation, the issues around intellectual property rights, issues around permits, loopholes being created, lack of capacity by government... we just put access and benefit sharing legislation on the table, on the ground it has a very different impact," stated Mariam Mayet of the African Centre for Biosafety.⁶⁸ "It's a complex legal system in a nutshell, it's not easy to implement, and we're not sure if it's having the benefits we had hoped it might have," says Rachel Wynberg of the Environmental Evaluation Unit. Only two permits under the Biodiversity Act have been approved since 2008 when the Regulations went into effect, which, according to Wynberg, may be "an indicator of how complicated the system is." Plans to review the Biodiversity Act and the Regulations are currently underway.

5.3.2 IPRs and genetic resources

South Africa has an advanced intellectual property regime and is a party to, *inter alia*, TRIPS and UPOV 1978. The country's plant variety protection system, adopted prior to TRIPS, is aligned with UPOV 1978 and in 1996 was amended to follow UPOV 1991, which South Africa is a signatory to but has not yet ratified (Wynberg 2006; Kameri-Mbote 2005; DAFF 2011a). Plant variety protection is governed by the Plant Breeders' Rights Act 15 of 1976. Plant breeders' rights can only be acquired by South African citizens or by persons domiciled or juristic persons having a registered office in South Africa or another UPOV country. The Plant Breeders' Rights Act contains a "farmers' privilege" whereby farmers may reuse protected seed and harvested material obtained on their own land for their own propagation purposes without infringement of plant breeders' rights. Exceptions are also made for research, propagation of different varieties and private or non-commercial purposes.

⁶⁷ Interview with Rachel Wynberg, 17 November 2011.

⁶⁸ Interview with Mariam Mayet, 18 November 2011.

BOX 5.6: Patenting Pelargonium

Pelargonium has long been used by traditional communities in South Africa for therapeutic treatments. In 1897, an Englishman, Charles Henry Stevens, was diagnosed with tuberculosis and travelled to South Africa where he recovered after receiving treatments utilizing Pelargonium. Upon return to England, Stevens began selling a “consumption cure” based on the plant. In the early 1900s, a Swiss doctor and German researchers separately began testing the plants’ healing properties. In 2002, a German company began filing for Pelargonium-related patents, three of which were later assigned to Schwabe, a German pharmaceutical company. By February 2009, five international Pelargonium-related patents had been filed. Two were granted by the European Patent Office (EPO) and one by the German Patent Office. Several NGOs launched a campaign against “biopiracy” of Pelargonium in 2008 and challenged the patents. In 2010, the EPO withdrew Schwabe’s patent, finding that development of the drug was not a “discovery” as required under patent law. In April 2010, it published a written decision, followed by Schwabe’s announcement that it would not further pursue its Pelargonium-related patents. Nevertheless, the issue remains alive as local groups now dispute reportedly monopolistic harvest and collection permits issued to Parceval Ltd., a primary supplier of Pelargonium to Schwabe.

Sources: ACB 2011; Mahop 2010; Mayet 2010; ACB 2010; Wynberg 2010; Berckmoes 2008; interview with Mariam Mayet, 18 November 2011.

The Patents Act No. 57 of 1978 prohibits patenting of plants and animals, although patents are allowed for microbiological processes or products, following TRIPS. In 2005, the Patent Act was amended to require patent applicants to disclose where an invention uses indigenous biological resources, genetic resources or traditional knowledge, in which case the applicant must submit proof of right to use the resource or knowledge. Proof can be in the form of a permit, BS agreement or material transfer agreement under the Biodiversity Act or through PIC, or any other proof meeting the responsible authority’s satisfaction. While the Patent Act’s requirements may be simpler than those in the Biodiversity Act, some feel they lack teeth in practice. South Africa does not have a patent examination office and thus no authorities are systematically inspecting and analyzing adequacy and links to resources and knowledge.⁶⁹

Ownership of IPRs in South Africa varies depending upon product and sector. Foreign companies are considered to play a role in patents governing pharmaceuticals and biotechnology. In order to facilitate technology transfer and gain funding, South African universities and research institutions cooperate with partners locally and abroad and license technology, in which case there may be co-ownership or, depending on the project, even full ownership overseas.⁷⁰ Agricultural IRPs in South Africa are perceived as having strong foreign dominance. The majority of protected plant varieties in South Africa are ornamental crops (DAFF 2011a; Kameri-Mbote 2005). Others include fruit, vegetables, agricultural and pastoral crops. In 2011, statistics indicated that 60% of plant breeders’ rights granted in South Africa belonged to foreigners, largely based in the US, Germany, France and the Netherlands (DAFF 2011a; DAFF 2011b; Kameri-Mbote 2005).

⁶⁹ Interviews with Rachel Wynberg, 17 November 2011 and Joanne van Harmelen, 18 November 2011.

⁷⁰ Interview with Joanne van Harmelen, 18 November 2011.

Unsurprisingly, the impact of patents in South Africa is complex. A 2009 study examining devil's claw, hoodia and rooibos showed that patents for these products did not necessarily restrict value adding in South Africa and at times played a positive role in stimulating industry development and local economies. Restricted market access and dominant markets and players had a greater negative impact than patents alone (Wynberg et al 2009). The study emphasizes the foundational contributions of traditional knowledge in these cases.

BOX 5.7: Rooibos Rights

The plant rooibos is indigenous to South Africa and was traditionally used by the Khoi and San as an herbal tea and remedy. Currently, the industry provides jobs for over 5,000 people and generates US \$70 million annually. Despite its success, rooibos has not been free of conflict. In 1993, a trademark for the term "rooibos" was filed with the US Patent and Trademark Office and later sold to the company Burke International. The trademark created difficulties for cooperative farmers trying to export to the US and was challenged in court, where it was determined that "rooibos" is a generic description of the plant variety. Burke eventually voluntarily surrendered the trademark. This incident in part prompted the Minister of Trade to, in 2008, submit a bill to introduce geographical indications in South Africa. Outside of South Africa, geographical indications for the name "rooibos" could give local producers and processors greater control, such as with a Protected Denomination of Origin in the EU, a large importer.

Sources: Robinson 2010; WIPO 2010; ICTSD 2010; Wynberg et al. 2009.

While there have been positive changes to South Africa's IP and ABS framework that help to recognize and protect local and indigenous contributions, there is a desire for further improvement, particularly within the requirements of the Biodiversity Act. In addition to better protecting stakeholders, legal clarification may encourage investment in domestic research and community harvested resources. Tensions remain between promoting economic investment and protecting community rights and resources in South Africa.

6. RIGHTS OF INDIGENOUS AND LOCAL COMMUNITIES AND TRADITIONAL KNOWLEDGE

ILCs are the primary holders of TK and have thus also played a significant role in developing and preserving TK. Today, an estimated 300 million indigenous people live in 70 countries (OCHCR n.d.), with different traditions, religions, customs and beliefs. They often are among the poorest. While there is no internationally recognised definition, the WIPO Intergovernmental Committee has, in 2008, defined TK as "knowledge resulting from intellectual activity in a traditional context, including the know how, skills, innovations, practices and learning that form part of TK systems, and knowledge embodying traditional lifestyles of ILCs, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources" (WIPO 2008).

TK is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, forestry and environmental management in general. A typical example of TK relating to GR would be knowledge held by traditional healers on the use of plants for curing certain diseases. Other examples

relate to agricultural practices, development of plant species and animal breeds. In many if not most cases, the value and use of GR seem to be linked to TK, although this is rarely officially acknowledged (CBD 2009).

Over the last few years, the rights of ILCs in general, and relating to TK specifically, have progressively been recognised at the international level. However, there are still difficulties in finding ways of protecting TK against misappropriation that are in line with indigenous customs and beliefs. The following section first describes the current international legal framework on the rights of ILCs. Second, it summarises ongoing debates on the protection of TK, including an overview of some positions by indigenous organisations on intellectual property and TK. Upfront, it is important to point out that, since the status of indigenous peoples varies across countries, the issue of their rights is controversial on the international stage. Consequently, to the extent that such rights are recognised internationally, this recognition is frequently subject to and thus limited by the domestic law of the country they live in.

6.1 Indigenous Rights in the International Legal Order

Rights of ILCs are a relatively recent phenomenon in international law, but have become increasingly recognised. Until today, the only legally binding international convention relating to indigenous rights is the 1989 Convention No. 169 of the International Labour Organisation on Indigenous and Tribal Peoples. As of November 2011, only 22 countries have ratified it, including Denmark, the Netherlands and Spain as the only EU member states. ILO Convention 169 is primarily concerned with employment and social security related rights. However, it recognises, in Art. 13ff., the rights of indigenous peoples over their land, including the right to participate in natural resource management and use.

The most important non-binding instrument is the 2007 **UN Declaration on the Rights of Indigenous Peoples (UNDRIP)**,⁷¹ which resulted from work of the UN Commission on Human Rights and the UN Economic and Social Council and was adopted by the UN General Assembly.⁷² It is significant in particular as it is the first international document addressing indigenous rights in a comprehensive manner. It recognises indigenous rights to the full enjoyment of all human rights and fundamental freedoms. Importantly, this does not apply only to the individual members of indigenous communities, but also to the communities as collective (Art. 1 UNDRIP).

The Declaration recognizes and stresses the fundamental importance of indigenous peoples' right to self-determination. It highlights that respect for indigenous knowledge, cultures and traditional practices contribute to sustainable and equitable development and proper management of the environment. UNDRIP recognises the right of indigenous peoples to their lands, territories and resources (Article 26) as well as the right to conserve the environment and the productive capacity of their lands or territories and resources (Article 29). The Declaration also confirms the right of indigenous peoples to maintain, control, protect and develop their cultural heritage, TK and traditional cultural expressions. It furthermore recognises the right of indigenous peoples to the manifestations of their sciences, technologies and cultures, including inter alia human and genetic resources, seeds, medicines, and knowledge of the properties of fauna and flora. Indigenous peoples have the right to maintain, control, protect and develop their IP over such cultural heritage, TK, and traditional cultural expressions (Article 31). The indigenous peoples also have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals

⁷¹ Online at http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf.

⁷² As have been several relevant Resolutions of the General Assembly, e.g. Resolution A/RES/59/174 of 2005.

(Article 24). States should consult and cooperate in good faith with the indigenous peoples through their own representative institutions in order to obtain their free and informed consent prior to the approval of any project affecting their lands or territories and other resources (Article 32).

As a binding international treaty, the **CBD** contains, in its Article 8(j), an obligation for states to protect TK held by ILCs.⁷³ Art. 8(j) CBD addresses “knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity” and thus a subset of the broader issue of TK. It is a recognition of the fact that, during the last decades, TK has been exploited to identify useful GR and add value to them, becoming a base for new products developed mainly by industrialised country actors. Such R&D related to TK often took place without the involvement, consent and compensation of TK holders. Art. 8(j) therefore obliges Parties to the CBD not only to respect and preserve TK, but also to “encourage the equitable sharing of the benefits arising from the utilization” of such knowledge.

To the extent that TK is associated with GR, the CBD rules governing TK have been further developed in the 2010 **Nagoya Protocol** to the CBD (see also section 3.1) The Protocol requires Parties to take measures in order to share benefits from the utilization of TK with the ILCs holding such TK (Article 5.5). Such benefit-sharing shall be based on MAT. The Protocol also requires parties to take measures with the aim that TK is accessed with PIC (or approval/involvement of ILCs) and MAT (Article 7), which is especially relevant for providers. At the same time, parties have to take measures providing that TK utilized within their jurisdiction has been accessed in accordance with PIC and that MAT have been established, in accordance with domestic legislation of the provider country where ILCs are placed (Article 16.1), which is especially relevant for users. Parties have to address non-compliance with such measures. However, 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 recognized certificate of compliance does not cover TK associated with GR, which limits possibilities of tracing biopiracy related to such TK.

6.2 IPRs and TK

Thus efforts are being made at the international level, through the CBD and the Nagoya Protocol, to prevent the access to TK without the consent of or sharing the benefits with its indigenous holders. At the same time and in the light of a lack of enforcement of the CBD’s ABS provisions so far, there are also ongoing discussions on how TK could be better protected through other instruments.

There are practical and **legal difficulties with protecting TK** held by ILCs in developing countries through conventional IPRs. One problem is that conventional IP systems are based on the idea of one individual or legal person being the inventor. However, in the case of TK, no such individual “owner” exists. Moreover, obtaining IPRs such as patents or plant breeders’ rights is expensive and requires a type of expert knowledge that ILCs seldom have. Most importantly, the concept of individual IPRs is rejected by many indigenous organisations when it comes to the protection of their TK.

⁷³ According to Article 8(j) of the CBD, “Each Contracting Party shall, as far as possible and as appropriate: (...) (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices.”

Indigenous organisations have repeatedly pointed out that property rights attributed to an individual holder are in contradiction with their beliefs and values. According to a 2004 statement by 15 indigenous organisations directed at the UN Permanent Forum on Indigenous Issues⁷⁴, “Western property law, and in particular, intellectual property rights, are contradictory to the customary laws of Indigenous peoples to safeguard and protect our traditional knowledge” (IPCB 2004).

Indigenous organisations have demanded that instead of “Western” IPRs, legal models to protect their TK and GR which are more in line with their beliefs should be developed, with them being actively involved in the development of such models. According to a declaration by several indigenous tribes in New Zealand, such models should be based on the following principles: recognition of collective (as well as individual) ownership and origin, retroactive coverage of historical as well as contemporary works, protection against debasement of culturally significant items, co-operative rather than competitive framework, and multi-generational coverage span. The primary beneficiaries of such rights should be “the direct descendants of the traditional guardians of that knowledge” (Tribes of Mataatua 1993).

This topic has been taken up by international organisations, notably **WIPO** (see also section 3.2). In 1998, WIPO was mandated to start the work on IPRs related to TK beyond folklore. The topic is discussed in the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) where indigenous groups are present as observers. Basically, discussions have revolved around two types of protection for TK: defensive protection of TK, i.e. measures which ensure that IPRs over TK are not given to parties other than the original TK holders, and positive protection of TK, i.e. the creation of positive rights that empower TK holders to protect and promote their TK. Measures for defensive protection are those also discussed in the context of enforcing the ABS rules under the CBD and its Nagoya Protocol, such as disclosure of origin in patent applications. Concerning models for the positive protection of TK, the discussion on appropriate models is still under way. A 2003 overview compiled by WIPO lists as models for protecting TK different measures, such as regulations on the Protection of Varieties of Chinese Traditional Medicine, the US patent office database of official insignia of native American tribes, or community intellectual rights in the Philippines (WIPO 2003).

As mentioned in section 3.2, the WIPO Intergovernmental Committee was given a mandate to initiate work on negotiating an international instrument to protect, inter alia, TK in 2009. Currently, WIPO is working on developing draft articles on the protection of TK (see section 3.2).⁷⁵ In addition to a definition of TK and its utilisation, criteria for TK protection (mainly that TK is associated with ILCs), identification of the beneficiaries of the protection/holders of TK, the draft currently under negotiation (WIPO 2011b) in particular addresses the scope and time of the protection. The proposed scope of TK protection includes exclusive/collective rights to: control/exploit/utilise TK, authorise or deny access and use of TK, fairly and equitably share the benefits arising from the use of TK based on free, prior and informed consent and MAT. Options for protection include a right to prevent the granting of IPRs involving the use of TK without the mandatory disclosure of TK holders, the country of origin, and evidence of compliance with PIC and BS requirements. The draft proposes provisions on sanctions and remedies in cases of infringement of the required TK protection and a possibility to establish competent

⁷⁴ Comprised of 16 independent experts nominated by governments and indigenous organisations, the UN Permanent Forum on Indigenous Issues is an advisory body to the UN Economic and Social Council with a mandate to discuss indigenous issues related to economic and social development, culture, the environment, education, health and human rights.

⁷⁵ Latest version available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_19/wipo_grtkf_ic_19_5.pdf.

(regional, national, local) authorities supporting TK holders. It further contains provisions for a global BS mechanism to address TK occurring in transboundary situations for which it is not possible to grant or obtain PIC. The draft refers to the consistency with other international instruments, especially the Nagoya Protocol.

Indigenous groups have been strongly critical of the WIPO process, as they feel they have no real influence in it.⁷⁶

7. IMPLEMENTATION OF THE NAGOYA PROTOCOL

The main elements of the Nagoya Protocol have been summarised in section 3.1. A full assessment of the issues involved in the implementation of the Protocol is beyond the scope of this study (several studies at the level of the EU and individual member states are ongoing at the time of writing). Instead, this section focuses on some major concerns and interests of developing countries as regards the implementation of the Protocol in the EU and beyond, including at the international level (see also for the following Nijar 2011b).

First of all, the Nagoya Protocol is designed to address an important interest of developing countries regarding the implementation of the CBD, namely achieving a fair and equitable BS with respect to GR. As such, the increasing number of developing country signatories to the Protocol (as of October 2011, 41 out of 66 signatories, including Brazil, India, Indonesia, Mexico, Peru, and South Africa) testifies the importance developing countries attach to the Protocol. A first interest of developing countries is thus the ratification and entry into force of the Protocol. In this respect, the EU and its member states have declared that they will work towards ratification and should continue to do so to enable the earliest possible entry into force of the Protocol.

Furthermore, it is worth highlighting again that the effective overall implementation of the Protocol and thus its success in establishing an effectively functioning ABS system and in preventing misappropriation of GR and associated TK ("biopiracy") crucially depends on congruent **action both in developing and developed countries**. As pointed out in section 3.1, the Protocol requires the establishment or further elaboration/adaptation of detailed domestic ABS legislation in developing countries as a precondition for the obligation of user countries (mainly developed countries such as the EU and its member states) to comply with PIC requirements. According to Article 6 of the Protocol, provider countries that require PIC for access to GR are obliged to create a "user-friendly" system for access ensuring legal certainty, clarity and transparency of domestic legislation; fair and non-arbitrary rules and procedures on access; information on how to apply for PIC; clear and transparent written decisions by a competent national authority, in a cost-effective manner and within a reasonable time; the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, and its notification to the international ABS Clearing-House; setting out criteria/processes for obtaining PIC, including approval/involvement of ILCs for access to GR; establishment of clear rules and procedures for requiring and establishing MAT. Also, the Protocol requires the establishment of relevant institutional infrastructure, including national focal points, competent national authorities, and checkpoints.

⁷⁶ See ICTSD (2011), Govts Divided over Disclosure at WIPO Talks on Genetic Resources, Traditional Knowledge, Intellectual Property Programme, Vol 15:18, 18th May 2011, <http://ictsd.org/i/news/bridgesweekly/106911/>

It is worth noting that many developing countries currently do not have ABS legislation or relevant institutions. As of 18 July 2007, 72 out of the 190 Parties to the CBD (both developed and developing countries) had established national focal points for ABS and 15 had established competent national authorities for ABS. The database on the CBD website still counts less than 40 developing countries with relevant measures in place.⁷⁷ Ensuring the above access standards and institutional infrastructure will thus be challenging for many developing countries, especially for least developed countries. They are likely to require substantial financial support as well as support for the building of human, legal and institutional capacities from developed countries and/or international institutions.⁷⁸

ABS so far has not been a core topic of EU development cooperation;⁷⁹ the EU may thus consider to extend its involvement in **ABS related capacity building in developing countries** taking into account key areas identified in Article 22.4 of the Protocol (capacity to implement and comply with the Protocol; to negotiate MAT; to establish domestic legislation; to develop research capabilities) as well as measures specified in Article 22.5 (for instance bio-prospecting or technology transfer).

Concerning **compliance**, developing countries are particularly interested in the EU and its member states establishing effective measures ensuring that GR have been acquired in accordance with PIC and MAT in compliance with provider countries' national ABS legislation. Such measures by developed user countries are required in order to prevent misappropriation ("**biopiracy**"). In accordance with Articles 15-18 of the Protocol, the EU and its member states are required, among other things, to: (1) provide for appropriate, effective and proportionate measures to address non-compliance (e.g. sanctions); (2) implement measures to monitor utilization of GR including designation of effective checkpoints collecting/receiving from users information on PIC, the source of GR, MAT establishment, and utilization of GR; (3) ensure an opportunity to seek recourse in case of disputes related to MAT and to provide access to justice and mechanism for mutual recognition and enforcement of foreign judgements and arbitral awards.

Developing countries have long demanded a mandatory **disclosure of origin of GR and TK in patent applications** as an effective means to ensure applicants lay open where and under what conditions they acquired the resources, and thus to allow to check whether they were acquired legally, in accordance with PIC and MAT. Such a requirement might be added to the 1998 Biotechnology Directive, which, in its preamble, specifies the possibility of disclosure of origin in biotech patent applications. Internationally, such a disclosure requirement could be introduced by means of an amendment of the WTO-TRIPS Agreement or in an appropriate agreement under WIPO. In this context, it would also make particular sense to consider establishing patent offices as obligatory **checkpoints** (as demanded by the developing countries). The Nagoya Protocol itself leaves the choice of which institutions be designated as checkpoints to individual parties. Designating patent offices as obligatory checkpoints in combination with a disclosure requirement would entail an obligation of users of GR to provide to these offices specified information when applying for patents.

Providing for **recourse in case of disputes** and for **access to justice** is also likely to require adaptations of domestic legal systems in the EU. In addition, mechanisms need to be established to support such recourse and access to justice by developing countries, especially least developed countries. The lack of legal mechanisms is only one barrier for developing country actors enforcing compliance by GR users in

⁷⁷ With a wide divergence of the nature of these measures; see <http://www.cbd.int/abs/measures>.

⁷⁸ Interview with V. Koutsouris, DG ENV, 24 November 2011, who pointed to a lack of capacity especially in Africa and the Pacific region.

⁷⁹ Interview with J. Petit, DG DevCO, 9 November 2011.

the EU (and other developed countries). At least as important is a lack of transparency, information and resources that makes it difficult for developing country actors, including ILCs, to effectively utilise the opportunities for recourse and access to justice, especially where domestic legal systems vary from one country to the other. Under the circumstances, there is a **high demand for legal and institutional capacity building and assistance**, including providing developing country actors with country-specific legal advice and counsel.⁸⁰

Focusing on the fight against poverty, the concerns of **ILCs** in developing countries deserve particular attention. They are often among the poorest, and could benefit significantly from effective BS. To this end, the EU may wish to consider going beyond the (rather hortatory) literal legal requirements of the Nagoya Protocol and provide for protection of relevant TK held by ILCs at the same level as GR themselves.

A particular concern of developing countries related to the inclusion of “derivatives” in the Nagoya Protocol. Article 2 of the Protocol suggests that the Protocol and the obligations it contains apply to GR as well as to their derivatives such as biochemical components. Such derivatives currently are more often used than pure GR, and consequently, more likely to generate benefits. Developing countries would be concerned if developed countries tried to (re)interpret the Protocol so as to avoid its application to derivatives and benefits arising from their use.

Other concerns of developing countries relate in particular to the **future international development of the Protocol**. It can be expected that the Protocol’s ABS system is going to be further clarified and complemented through follow-up decision-making by the parties to the CBD/the Nagoya Protocol. In this process, further progress may be achieved in addressing developing country concerns and enhancing the effectiveness of the Protocol. Developing countries have highlighted a number of relevant concerns, including the following (see Nijar 2011b):

- The Nagoya Protocol does not apply to the so-called ex-situ collections which are stored generally in developed countries’ gene-banks, but consist of GR originally mainly from developing countries. These collections were typically created before the entry into force of the CBD and the Protocol, and consequently benefits from their use need not be shared. A system for sharing of benefits from GR in ex-situ collections could be achieved under the Protocol. In particular, the ex-situ collections may be covered by the **Multilateral Benefit-Sharing Mechanisms** to be elaborated in accordance with Article 10 of the Protocol.
- It is in the interest of developing countries to determine more precisely (through future decisions of the Conference of the Parties to the CBD / Meeting of the Parties to the Nagoya Protocol) the measures to be implemented with respect to compliance in user countries (as addressed above).
- Even after the adoption of the WHO ABS framework on influenza viruses, developing countries remain concerned about access to affordable treatments by those in need, especially developing countries (also in view of the limited scope of the WHO framework). In this context, it is pointed out that if patents are granted for vaccines, they become a barrier for expeditious access. In these cases, patents impede BS as well as access to and transfer of technologies related to vaccines production.
- Other important issues for developing countries include: making the currently optional internationally recognised certificate of compliance an obligatory requirement for transfers of GR,

⁸⁰ Interview with V. Koutsouris, DG ENV, 24 November 2011, who pointed out that access to justice in the EU constitutes a major problem for developing countries.

including the granting of related patents; the development of mechanisms to ensure monitoring of TK associated with GR as “biopiracy” often relates to TK; and the clarification of the status of publicly available TK.

8. RECOMMENDATIONS

The preceding sections have, from the perspective of developing countries and the fight against poverty, analysed the relationship between intellectual property rights (IPRs), genetic resources (GR) and traditional knowledge (TK) and how it has been addressed in various international fora. In the following, a set of policy recommendation for the EU is derived from the preceding analysis.

Implementation of the Nagoya Protocol. The EU and its member states should continue to work towards ratification of the Nagoya Protocol so as to enable its earliest possible entry into force. To this end, it will be necessary for the EU to establish clear requirements and accompanying compliance measures to ensure that any GR and TK utilised in the EU are acquired in accordance with PIC and MAT as required by provider countries’ national ABS legislation. Providing for recourse in case of disputes and for access to justice is also likely to require adaptations of domestic legal systems in the EU. As important as effective domestic implementation is substantial capacity building support for developing countries, especially least developed countries, so as to enable them to benefit from the implementation of the Protocol in developed countries. Capacity building and assistance, including country-specific legal advice and counsel, is also needed in order to enable developing country actors, not least indigenous and local communities, to effectively utilise the opportunities for recourse to dispute settlement and access to justice in developed countries to enable them to enforce their PIC and MAT requirements. The EU should also remain open to a further elaboration of the Nagoya system in future international negotiations, including the consideration of common BS standards.

Reforming the IP system. The main item on the agenda as regards the IP system is to establish a clear mandatory requirement to disclose the origin of any GR and associated TK in patent applications (together with information on PIC, MAT and BS in accordance with the Nagoya Protocol). Such a requirement (that should also extend to plant breeders’ rights) should be established internationally in the WTO-TRIPS Agreement and/or under WIPO. It should not be allowed to be held hostage and be further delayed by the deadlock in the WTO Doha Round negotiations. The EU could also consider how such a requirement might be introduced in EU legislation in the absence of an international agreement, in accordance with existing international law. It would also make sense to further explore in cooperation with developing countries how synergy between such a mandatory disclosure requirement and the “internationally recognised certificate of compliance” under the Nagoya Protocol can be created and maximised. Furthermore, it could be further investigated whether and to what extent the existing system of compulsory licensing as regards medicinal products under the WTO could be expanded (e.g. by broadening it to more products and/or softening the requirements for its use). Finally, the EU could take an active part in elaborating a sui generis system for the protection of TK under WIPO, in close consultation with representatives of indigenous and local communities, in order to ensure an effective protection of such TK for the benefit of ILCs that frequently belong to the poorest.

Rights of Indigenous and Local Communities and Traditional Knowledge. As an overarching principle flowing from existing international instruments on the rights of ILCs, the EU should always undertake any particular steps in this area in consultation with representatives of ILCs (and should thus advocate such consultation also in the relevant international bodies). This also holds for the elaboration of a sui generis system for the protection of TK, as just mentioned. The EU should furthermore grant TK

at least the same level of protection as GR as such when implementing the Nagoya Protocol. It should also support recognition of the rights of ILCs and specifically the need to consult with ILCs in all other relevant fora (including the WHO, the FAO, the UNCLOS process, etc.) as well as in its bilateral relations (see below). A particular potential lies in exploring how the positive experience with a TK “digital library” in India can be expanded and employed to facilitate effective TK protection and prevent misappropriation by others (e.g. through building a network of national databases).

Agriculture and Health. Existing arrangements for organising international access and benefit-sharing in these areas – the ITPGR and the WHO framework regarding influenza viruses – should be fully implemented and further enhanced. In the case of the ITPGR, its attractiveness especially for developing countries and the resources available could be increased if payments for Annex I crops would not only be made ex post (i.e. once a new variety is marketed) but also ex ante (for receiving a “licence” for utilising an Annex I crop). The first task with respect to the soft-law WHO framework consists in its effective implementation. While the terms of BS for the benefit of developing countries could be further improved, an expansion of the system to other viruses and medicines is worth exploring in particular to support pharmaceutical research on medicines for poor populations and access to affordable medicines. It may eventually also be necessary to transpose current arrangements in a binding form. In the evolving discussions on the possible introduction of specialised ABS systems for other sectors of food and agriculture in the context of the FAO, the EU should in particular honour the right to food and the objective of food security by ensuring access to relevant products for the poor (farmers, fishers, etc.) and an appropriate focus of relevant research on products that are useful for poor populations in the fight against poverty.

Elaboration of further benefit-sharing mechanisms. Efforts are underway to elaborate appropriate ABS regimes for cases in which ownership of the GR is unclear (and a mandatory disclosure requirement regarding GR in patent applications will thus not help much), as is the case for ex-situ collections, GR originating from the high seas/deep seabed or the Antarctic Treaty area. An appropriate arrangement for ex-situ collections could be designed under the Nagoya Protocol (Article 10 on a Global Multilateral Benefit-sharing Mechanism). The high seas/deep seabed and Antarctica may be addressed under UNCLOS and the Antarctic Treaty system. These frameworks provide the opportunity to elaborate multilateral systems that ensure sharing of GR for research and generate resources for developing countries to support (1) the protection of related biological diversity; (2) relevant research in the interest of developing countries (agriculture and health), and (3) access to relevant products (seeds, medicines).

Relations with other countries. Bilateral relations between the EU and other countries and regions have gained in importance as regards IPR given the stalemate of the WTO Doha Round. The EU should not push developing countries, especially least developed countries, through bilateral agreements to accept far-reaching IP standards (e.g. by requesting adherence to UPOV 1991 or so-called “TRIPS plus” IP protection) regarding seeds/agriculture and health/medicines. Adherence to UPOV 1991 would require developing countries to prevent or inhibit farmers from exchanging seeds, with potential negative implication for the right to food. In a similar vein, the EU should not take poorer developing countries to WTO dispute settlement for alleged violations of TRIPS (in particular regarding agriculture and health). Similarly, implementation and enforcement of the 2011 Anti-Counterfeit Trade Agreement and other efforts to fight (medical) counterfeit could have negative effects especially on poor developing countries. Bilateral agreements and cooperation concerning R&D, finally, provide the opportunity for the EU to put emphasis on research addressing in particular the needs of the poorest as regards food and agriculture as well as health.

In accordance with its institutional role, the **European Parliament** can especially contribute to realising the aforementioned recommendations through targeted requests/recommendations to the Commission and calls on/recommendations to the Council of Ministers and the member states, as appropriate (e.g. through one or several Resolutions). Such requests and recommendations appear appropriate as regards the EU's policies in ongoing multilateral negotiations (in the WTO, WIPO, the WHO and the FAO as well as under the CBD and its Nagoya Protocol, UNCLOS and the Antarctic Treaty) but also as regards bilateral agreements and related "executive" follow-up decisions (e.g. WTO dispute settlement). While no significant legislative initiatives appear to be currently ongoing in the fields investigated, concrete legislative proposals are required for the ratification of the Nagoya Protocol and, possibly, ACTA which both require the consent of the Parliament, as well as for the domestic implementation of the Nagoya Protocol. The Parliament has the opportunity to request the Commission to include particular elements into forthcoming legislative proposals and to present particular legislative proposals (and may subsequently follow-up in the normal legislative procedure). The European Parliament may also use its budgetary powers in support of its views, especially as regards actions with direct financial implications (e.g. capacity building and assistance). It could moreover play a particularly important role concerning the EU dialogue with ILCs, by inviting ILC representatives to dialogues at the European level.

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