ICTSD Project on Genetic Resources



Biodiversity Related Intellectual Property Provisions in Free Trade Agreements

By David Vivas-Eugui
María Julia Oliva

ICTSD
International Centre for Trade and Sustainable Development

Issue Paper No. 4

Biodiversity Related Intellectual Property Provisions in Free Trade Agreements

By David Vivas-Eugui
María Julia Oliva[1]

ICTSD

International Centre for Trade and Sustainable Development

Issue Paper No. 4

Published by

International Centre for Trade and Sustainable Development (ICTSD)
International Environment House 2
7 Chemin de Balexert, 1219 Geneva, Switzerland
Tel: +41 22 917 8492 Fax: +41 22 917 8093
E-mail: ictsd@ictsd.org Internet: www.ictsd.org

Chief Executive: Ricardo Meléndez-Ortiz
Core Team: Christophe Bellmann
Marie Wilke

Acknowledgments

ICTSD wishes to express its gratitude to the German Government and the German Development Institute (GTZ) whose valuable support made this project possible.

We further wish to thank Alexander Werth and the participants of the joint ICTSD-GTZ Central America and Andean Community dialogues on "Medidas Relacionadas con la Biodiversidad y el Sistema de Propiedad Intelectual" held in Heredia, Costa Rica on November 17-19, 2010 and in Lima, Peru on March 10-12 2010 respectively.

ICTSD welcomes feedback and comments on this document. These can be forwarded directly to Marie Wilke at mwilke@istc.ch.

Citation: DavidVivas-Eygui, Maria-Julia (2010), *Biodiversity Related Intellectual Property Provisions in Free Trade Agreements*, ICTSD Project on Genetic Resources, Natural Resources, International Trade and Sustainable Development, Issue Paper No.4, (International Centre for Trade and Sustainable Development, Geneva, 2010)

ISSN 1816-6970

TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS

CAFTA	Central America Free Trade Agreement
CARIFORUM	Forum of Caribbean States
CBD	Convention on Biological Diversity
EFTA	European Free Trade Association
EPA	Economic Partnership Agreement
EU	European Union
IP	Intellectual property
FTA	Free Trade Agreement
MAT	Mutually Agreed Terms
NAFTA	North American Free Trade Agreement
PCT	Patent Cooperation Treaty
PIC	Prior informed consent
SECO	Swiss Secretariat for Economic Affairs
SFIIP	Swiss Federal Institute of Intellectual Property
TRIPS	WTO Agreement on Trade Related Intellectual Property Rights
UPOV	International Convention for the Protection of New Varieties of Plants
US	United States of America
USTR	United States Trade Representative
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

FOREWORD

Loss of biological diversity – understood as our biosphere's total endowment of living organisms, their genetic variation and functions and the ecosystems of which they are a part of – stands, alongside climate change, as one of the most pressing and daunting global challenges of our time. The increasingly rapid and massive rates of deterioration and loss of environmental resources and functions have brought an acute awareness of the urgent need for effective policies and mechanisms to ensure these valuable resources are used sustainably; this is an imperative beyond moral and ethical concerns that cannot be further postponed as societies become clearer about biodiversity's critical role in human well-being, global economic development and poverty reduction.

Diversity in nature is the key to the natural regulation of global climate and the equilibrium in the gaseous composition of our atmosphere. This diversity is the essence of healthy soils; it allows for natural regeneration and recycling of nutrients, and the maintenance of a biological balance between destructive and useful plants and organisms. It enables the existence of waterways, watersheds and aquifers and allows marine life and environments to thrive. Furthermore, diversity in natural resources forms the cornerstone of strategic and pivotal industries in critical areas of economic activity for the provision of food, health, energy and fuels, clothing, and shelter. In addition, biodiversity has proven to be critical in advancements on waste treatment, environmental services and the venturing into the new frontiers of nanotechnology, and geoengineering.

Diversity of living organisms is dwindling at a much faster pace than generally realized. Not only species are disappearing, we now know for certain that their genetic richness and functions are also dramatically affected by changes in ecosystems. Even though alterations to our natural stock through either innate biophysical causes (such as natural processes and disasters) or human activity has been a characteristic of the world throughout its existence, destruction and change now occurs on a much greater magnitude and scale, and in exceptional ways. Propelled by an explosion in economic activity, ever-increasing demand and global integration of economies, impacts on diversity of living organisms are also more rapid and of major reach across ecosystems and regions.

In order to better grasp the enormity of the problem and our passion for it at ICTSD, allow me to quote one of the pioneers of our understanding of the diversity of life, Professor E.O. Wilson from Harvard University, when he states: "Almost all current biodiversity analysts agree that the extinction of species is proceeding at one hundred to 10,000 times the pre-human rate, while the rate of origin of new species is decreasing. […] Each species is the repository of an immense amount of genetic information. The number of genes range from about 1,000 in bacteria and 10,000 in some fungi to 400,000 or more in many flowering plants and a few animals. A typical mammal such as the house mouse *(Mus musculus)* has about 100,000 genes. This full complement is found in each of its myriad cells, organized from four strings of DNA, each of which comprises about a billion nucleotide pairs…"

Concluded at the earth summit in 1992, the United Nations Convention on Biological Diversity (CBD) acknowledges this important reality when underlining the "intrinsic ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic value" of biodiversity. Unlike former and other multilateral environmental agreements, it addresses global biodiversity as a whole rather than limiting itself to certain ecosystems, species, or forms of biological diversity.

Premised on a global strategy for sustainable development, the CBD recognizes the sovereign rights of States over their natural resources and pursues three objectives: 1) the conservation of biological diversity, 2) the sustainable use of its components and 3) the fair and equitable

sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge.

The realization of these objectives has faced immense challenges. The third objective in particular - fair and equitable sharing of benefits arising out of the use of genetic resources - has proven difficult to implement in an effective manner, as the use of genetic resources is increasingly linked with international trade. Users of genetic resources, such as individuals and firms that develop innovative applications based on such resources, often are located outside the country of origin of these resources. In addition, only relatively recently have countries, mostly developing ones, started to implement domestic rules that provide for access and benefit sharing. In contrast, many developed countries – where pharmaceutical, biotechnological and agricultural companies, have their headquarters – have not put in place corresponding regulations in order to ensure benefit sharing.

In this context, well known cases of misappropriation of genetic resources and associated traditional knowledge during the past two decades have crystallized the tensions between CBD objectives of promoting the fair and equitable sharing of benefits and the types of incentives established by trade and intellectual property rules, in particular those of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). While measures such as the disclosure of origin requirement, certificates of compliance and geographical indications related to trade in genetic resources and associated traditional knowledge have been introduced in domestic legislations in recent years to prevent such misappropriation, they still raise critical questions for all the actors involved.

Against this backdrop, following protracted negotiations and a critical political underwriting of all UN members at the 2002 Johannesburg Summit on Sustainable Development, the CBD Conference of the Parties (COP) mandated, in 2004, the Working Group on access and benefit sharing (ABS) to negotiate an international regime (IR) on ABS. The aim of the IR is focused on adopting an instrument(s) to effectively implement the objectives of the convention and its relevant provisions (Article 15 on access to genetic resources and Article 8(j) on traditional knowledge). In 2008, the COP instructed the Working Group to finalize the negotiation of the IR before its tenth meeting, in 2010, in Japan.

The negotiations of the IR took place amid an extraordinarily complex global landscape where a profusion of fora – such as the WTO, the World Intellectual Property Organization (WIPO), the Food and Agricultural Organization (FAO) and the Union for International Protection of New Varieties of Plants (UPOV) – address issues relating to the sustainable use of genetic resources according to their respective mandates. While countries reaffirm the need to ensure consistency between deliberations and outcomes in these different fora, they tend to disagree on how such consistency is to be achieved.

Additionally, an increasing number of North-South free trade agreements have included TRIPS-plus" provisions that reach beyond the standard established by TRIPS They are characterized by broader scope, more requirements and affect flexibility in national implementation. Additionally, differences across bilateral free trade agreements (FTAs) with major trading partners such as the US and the EC in measures related to patentable subject matter and patentability criteria generate ambiguity regarding its scope of application and related impact.

Over the last few years, however, an increasing number of FTAs have incorporated biodiversity related provisions into these bilateral trade agreements in addition to traditional IP provisions, seeking a more balanced and sustainable approach.

In this context, this issue paper – published by ICTSD's project on Genetic Resources – builds on ICTSD's previous publications in the area of intellectual property and FTAs and in the context of the current negotiations on an international regime for access and benefit-sharing of genetic resources. The paper aims to contribute to this discussion by providing an in depth overview on the inclusion of biodiversity and related intellectual property provisions in North-South free trade agreements. The paper provides a comprehensive overview of how biodiversity and intellectual property have been addressed in multiple bilateral trade agreements. It then discusses the possible impact of these provisions for regional and domestic efforts on implementing the objectives of the CBD and establishing relevant mechanisms under its third objective on access and benefit sharing.

This paper provides novel analysis on this critical issue that increasingly gains importance as more FTAs include relevant biodiversity and intellectual property provisions and regional as well as international processes see themselves influenced by this parallel process.

Since its establishment in 1996, the International Centre for Trade and Sustainable Development (ICTSD) has been working on these issues from various angles and perspectives, following and participating in the process that brought upon the system in place today: from Rio to Johannesburg, from Bonn to Geneva. As a non-partisan actor, it has generated sound and novel analysis on viable and sustainable policy options and convened exchange between a wide range of stakeholders from developing and developed countries alike.

In 2009, the German Development Agency (GTZ) and ICTSD undertook a collaborative initiative to create regional platforms for interactive and generative dialogue among key actors. The collaboration focused on problem-solving and consensus-building in regards to biodiversity issues with a high priority in development and environmental policies in Central and South America. As part of this project, in coordination with local partners, ICTSD and GTZ jointly organized two regional dialogues in Costa Rica and Peru bringing together international experts to explore concerns, knowledge gaps and priority areas for action at the political and technical level on the interface between intellectual property rights and the sustainable use of biological resources.

Almost two decades after the conclusion of the CBD a number of countries have made critical advances in design and implementation of domestic mechanisms that address these concerns. To bring their view to the international level and to analyze their experiences will be critical for the successful conclusion of multilateral processes. As we now move towards the Tenth Conference of the Parties (COP 10) to the CBD in Nagoya in October 2010, there is indeed an urgent need for deepening efforts to provide sound analysis on pressing systemic challenges and flaws, domestic and regional experiences, needs and abilities, and potential political and technical solutions.

We hope that you will find this paper a stimulating and useful contribution to the ongoing debate at the CBD on an international regime for access and benefit sharing of genetic resources as well as discussions on biodiversity and traditional knowledge at other relevant trade and intellectual property fora such as the WTO and WIPO.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

EXECUTIVE SUMMARY

This paper addresses the relationship between intellectual property and biodiversity in the context of bilateral trade agreements between developed and developing countries. It identifies the ways in which intellectual property rules can either enhance or diminish efforts to meet the three objectives of the Convention on Biological Diversity (CBD): to conserve biodiversity, sustainably use biological resources, and share the benefits resulting from their use. This is discussed in the context of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and its provisions, which have entered into the text of bilateral trade agreements.

Specifically, in bilateral agreements between the United States and developing countries, intellectual property (IP) provisions – commonly described as "TRIPS plus" – are characterized by broader scope, more onerous requirements and less flexibility for national implementation. Additionally, differences across the 17 US bilateral free trade agreements (FTAs) in measures related to patentable subject matter and patentability criteria generate ambiguity in regards to the validity and enforceability of the TRIPS Agreement rules. However, the US FTAs with both Colombia and Peru have reshaped the way in which biodiversity is addressed in US FTAs by incorporating an "understanding regarding biodiversity and traditional knowledge". An examination of the text of the US-Colombia and the US-Peru agreements and its implications for policies related conservation of biological diversity reveals that the provisions allow for policy space on biodiversity conservation and provide an opportunity to promote recognition and co-operation. However, questions remain on the legal value and possible enforcement of the clauses related to biodiversity.

In the past twenty years, Canada has strengthened its bilateral trade negotiations agenda in an effort to not only regain a level playing field in certain key markets but also to promote sustainable development objectives. Canada has negotiated environmental co-operation agreements in parallel with its trade agreements in order to promote mutual support between trade and environmental policies. Specifically, Canada has established general provisions that affirm the importance of the CBD and of working jointly to achieve its objectives in FTAs with Peru and Colombia. Additionally, included in the FTAs is an agreement to establish an information system that would prevent illegal access to genetic resources and traditional knowledge. Although Canada has set a significant precedent, it should be noted that the CBD is not included in the list of agreements whose obligations prevail in case of conflict and it is unclear whether the biodiversity provisions have implications for the application or interpretation of the intellectual property rules in the FTAs.

The European Union is a key player in both the context of biodiversity conservation and the protection of intellectual property. For this reason, the EU has played a relatively cautious role in the debate on the relationship between intellectual property and biodiversity, recognizing the importance of the objectives of the CBD, but not enthusiastically supporting measures that could restrict the granting of patents. Only in 2007 did the EU address the relationship between biodiversity and intellectual property in specific sections of an agreement with the Forum of Caribbean States (CARIFORUM). Although relatively basic, the agreement could lead to co-operation on promoting preservation of biodiversity and traditional knowledge through the establishment of geographical indications.

More recently, the EU finalized trade negotiations with Peru and Colombia in May 2010. In the negotiations, Colombia and Peru proposed provisions for traditional knowledge and biodiversity in the chapter on intellectual property that were considered too ambitious by the EU, which put forth proposals that reflected CBD language but aimed to reduce the scope and content

of obligations and avoid compliance measures. However, the EU was open to more concrete provisions on issues related to co-operation. The final outcome of the EU agreements with Colombia and Peru goes beyond any previous provisions on biodiversity in EU FTAs or Economic Partnership Agreements (EPAs), incorporating a section on "protection of biodiversity and traditional knowledge". In addition, geographical indications were addressed in a section that contains a set of fairly comprehensive obligations.

In the European Free Trade Association's (EFTA) FTA with Colombia, a section on "measures related to biodiversity" is included in the chapter on intellectual property. Due to a history of progressive legislation on intellectual property and biodiversity, Switzerland and Norway accepted the Colombian proposal with the new section on biodiversity, which includes provisions that reaffirm the objectives and main principles of the CBD. Most notably, the measures related to biodiversity in the EFTA-Colombia FTA have a strong bearing on patent law, affecting national granting and examination of patents.

Overall, this assessment of the evolution of the link between intellectual property and biodiversity in bilateral trade agreements reveals that progress has been made towards a more balanced and sustainable approach in recent years. Although the risks posed by developed countries' proposals for raising levels of intellectual property protection remain, the proactive participation of developing countries has resulted in the incorporation of biodiversity into a series of intellectual property measures included in bilateral trade agreements. Based on the developments in bilateral trade agreements summarized in this paper, it appears there is an emerging trend in which developing countries consolidate their positions through a coherent strategy and careful co-ordination in different forums. Respective clauses in cluedd in FTAs are thus likely to impact international and national biodiversity policy making processes.

1. INTRODUCTION

Bilateral Free Trade Agreements (FTAs) increasingly contain comprehensive provisions on intellectual property (IP) rules. Their potential impact on policies related to the conservation and sustainable use of biodiversity is often cited as a cautionary tale about the risks of FTA negotiations for developing countries. That is because many intellectual property provisions in bilateral trade agreements reproduce or even accelerate a problem common at the international level: various international rules on intellectual property allow and even promote the IP protection of biodiversity and traditional knowledge under patents and other intellectual property rights but do so without ensuring compliance with obligations established by the Convention on Biological Diversity (CBD).

Furthermore, bilateral trade agreements have restricted many of the existing flexibilities in international intellectual property rules, thus limiting the available options for establishing policies geared towards protecting biodiversity. For example, rules that require the adoption of specific systems for the protection of plant varieties end up closing policy spaces within the multilateral rules of intellectual property.

However, recent bilateral trade agreements show that provisions linked to intellectual property could also be used to advance goals linked to the conservation of biodiversity. The US-Peru, US-Colombia, Canada-Peru and Canada-Colombia free trade agreements, as well as the Economic Partnership Agreement (EPA) between the European Union and CARIFORUM countries, all present interesting advancements from a sustainable development perspective. These agreements do not represent an about-face in the positions and strategies of developed countries. Nevertheless, by addressing biodiversity-related issues, even in a limited and non-binding manner, these agreements reveal the promise that a positive agenda focusing on biodiversity and intellectual property can hold in the context of bilateral trade negotiations.

Recent agreements signed by the European Free Trade Association (EFTA) and Colombia and the one between the European Union (EU) with both Colombia and Peru, feature more concrete steps towards addressing intellectual property and biodiversity issues in a manner that is more in line with the objectives of the Convention on Biological Diversity (CBD). Specifically, the EFTA-Colombia agreement, in what was an unprecedented move, contains a section in the intellectual property chapter on “measures related to biodiversity”, as well as the express recognition of basic principles, such as sovereign rights over genetic resources and the need for equitable sharing of benefits derived from using these resources. These provisions are the result of specific requests made by Colombia during the negotiations. Similarly, the EU FTA with both Colombia and Peru addresses many of these issues, albeit through less precise obligations.

This paper aims to describe the evolution of the relationship between intellectual property and biodiversity in the context of bilateral trade agreements between developed and developing countries, through a brief analysis of various agreements, provisions and strategies. This note will also consider the potential impact of these developments on future FTAs, as well as on ongoing negotiations in the context of the CBD and the World Trade Organization (WTO).

2. THE LINK BETWEEN INTELLECTUAL PROPERTY AND BIODIVERSITY

The link between intellectual property and biodiversity potentially creates both opportunities and obstacles for the conservation and sustainable use of biological resources. On the one hand, obtaining intellectual property rights on products derived from biodiversity could be seen as a way to recognise and secure the economic value of biological resources and their associated traditional knowledge. Biodiversity is recognized as a source of innovation and inspiration in many industrial sectors, including agriculture, biotechnology, food, cosmetics and pharmaceuticals. A growing consumer interest in "green products" is also increasing the search for novel natural ingredients. In these instances, intellectual property ensures protection for a companies' research and development efforts, and investments. Therefore, it is seen as an important driver of commercial interest in biodiversity.

On the other hand, the exclusive rights derived from the protection of intellectual property can be difficult to reconcile with the sovereign rights of states over their biological resources, as well as with the collective rights of indigenous peoples over their resources and knowledge. This is particularly true considering the continuous lack of recognition of the need for compulsory disclosure requirements. Patents for inventions based on biodiversity and traditional knowledge need to disclose the origin of these resources and it has to be proven that the actors involved complied with both prior informed consent (PIC) and equitable benefit sharing requirements under the CBD. Indeed, biodiversity-rich countries have long expressed concerns about the lack of response from the intellectual property system to stop acts of misappropriation of biodiversity and traditional knowledge – also known as "biopiracy"[2] – as well as to provide adequate intellectual property protection to traditional knowledge holders.

These concerns have been supported by several high profile cases of misappropriation of biodiversity and traditional knowledge in the past twenty years. These cases involve intellectual property rights on biological and genetic resources, as well as associated traditional knowledge. The prominent examples include a plant patent on the *ayahuasca* vine, sacred to the indigenous people of the Amazon; and the *enola bean*, a variety of Mexican yellow bean. In these cases, not only were the novelty and inventive step questioned, but it was also clear that the CBD requirements of prior informed consent, mutually agreed terms (MAT), and benefit sharing were not fulfilled.

Thus from the perspective of biodiversity-rich countries, the debate on patents and biodiversity in the framework of international intellectual property rules should aim to generate a regulatory environment that supports the legitimate access to genetic resources, their derivatives and their associated traditional knowledge, and that ensures equitable sharing of the resulting benefits. In particular, biodiversity-rich countries have sought specific measures in the intellectual property system to improve the manner in which it links to biodiversity. Proposed measures aim to provide transparency in the access and use of biological resources and traditional knowledge; allow determination of any third-party rights; facilitate and improve patent examination especially in relation to the inventive step; shift the burden of proof from providers to users; ensure benefit sharing, and support the enforcement of national and international environmental law. These measures have been addressed in the context of three particular issues: the patentability of living organisms, disclosure requirements in patent applications relating to biodiversity, and the protection of traditional knowledge.

The patentability of living organisms

In the TRIPS negotiations, developed and developing countries adopted contrasting positions on whether living organisms – genes, microorganisms or plants, for example – should be patentable.

Developing country concerns ranged from ethical and moral considerations to criticisms over patents granted for discoveries and the lack of recognition of the specificities of innovation in agriculture. Article 27.3 (b) of the TRIPS Agreement reflects a compromise, in which the exclusion of plants and animals other than microorganisms from patentable subject matter is allowed – but not required. At the same time, the TRIPS Agreement also expressly anticipates the revision of Article 27.3 (b) – a revision that is still pending.

Moreover, Article 27.3 (b) leaves Parties the choice of protecting plant varieties by patents or other *sui generis* system. This provision is significant because it allows countries to choose systems that recognise the specificities of agricultural innovation, which requires broad access to plant varieties and germplasm, as well as farmers' rights and practices. In addition, Article 27.3 (b) contains no restriction as to which *sui generis* system should be adopted or developed, given that the needs and circumstances related to agricultural biodiversity and food security policies varies greatly among countries.

Disclosure requirements for patent applications

Disclosure requirements have been proposed as a way to prevent biopiracy — the appropriation of biological resources or associated traditional knowledge through patents and other intellectual property rights without adequate consent or compensation. One of the main objectives of the CBD is the fair and equitable sharing of benefits from biodiversity. To advance this objective, the CBD recognises the sovereign rights of states over their genetic resources and requires that access to these resources be based on prior informed consent and mutually agreed terms.

International intellectual property rules, however, do not contemplate or support compliance with these requirements in the context of patent applications related to biodiversity and associated knowledge. Patents have been granted on traditional knowledge, including in the case of the use of the Indian *neem* tree as an insecticide or the use of the South African *hoodia* plant for appetite control. The vast majority of developing countries, as well as several developed countries, support the introduction of disclosure requirements to ensure that, in these cases, patent examiners have adequate information on the origin of resources and about compliance with any applicable rule on prior informed consent and benefit sharing.

In these situations, disclosure requirements would indeed shift the burden of proof of legitimate use or access to the applicant, and also allow countries to take any necessary measures if the use or access was in fact unlawful. Moreover, disclosure requirements would also facilitate and improve patent examinations. As a result, disclosure requirements have been proposed in a variety of forums, and are currently under negotiation both in the framework of the TRIPS Agreement and of the CBD.

The protection of traditional knowledge

There is increasing recognition of the importance of traditional knowledge associated with the conservation and sustainable use of biodiversity. This recognition, however, is not yet reflected in the current instruments or policies. Effective protection of the knowledge of indigenous peoples and other local communities will necessitate a change in policies and instruments. For example, there are no adequate instruments for defensive (to prevent unauthorised appropriation of knowledge) or offensive (to ensure that holders of such knowledge reap its benefits) purposes. Several possible approaches to overcome this gap have been suggested, including the possibility of international rules to prevent misappropriation of traditional knowledge.[3] Such rules could clarify the definition and scope of the misappropriation, leaving domestic law the flexibility to determine ways to prevent misappropriation, as well as how to empower communities to exercise their rights.

The opportunities and limitations of intellectual property rights in relation to traditional

knowledge are currently under discussion at the multilateral level. The Working Group on Article 8 (j) of CBD, for example, included references to intellectual property in its recommendations on a code of ethics in the treatment of traditional knowledge. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore at the World Intellectual Property Organization (WIPO) has undertaken negotiations aimed at achieving an international legal instrument(s) to ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions. As will be discussed further, this is an issue that is also increasingly emerging at the regional and bilateral levels.

3. TRIPS–PLUS AND BIODIVERSITY IN US FTAS

The United States was one of the pioneers in the use of bilateral trade agreements to increase levels of protection for intellectual property rights. The bilateral trade negotiations undertaken by the United States in the 1980s, for example, became the foundation – politically and substantively – for the TRIPS Agreement. The entry into force of the TRIPS Agreement then led the United States to intensify its efforts and expand its bilateral strategy. On the one hand, it has used the report on the Special Section 301 to suspend trade benefits of countries which are identified as not adequately protecting intellectual property rights. On the other hand, the United States has significantly increased bilateral trade negotiations, in which they put forth intellectual property protection as one of the main points required in exchange for greater access to the US market.

The objective of the US strategy is clear: to consolidate the advantages of US companies in the field of patents and other intellectual property rights, and to address perceived deficiencies in multilateral rules. In particular, US proposals on intellectual property in the bilateral trade negotiations have focused on overcoming the "shortcomings" of the TRIPS Agreement. The resulting provisions have thus been described as "TRIPS-plus" – characterised by broader scope, more onerous requirements and less flexibility for national implementation. Bilateral intellectual property provisions are also a way to promote the rapid integration of US trading partners into other multilateral intellectual property regimes. Several FTAs include requirements to sign, ratify or adhere to rules of existing multilateral instruments. As noted by the Commission on Intellectual Property Rights established by the UK government, the complex international architecture of intellectual property, which includes rules at the multilateral, regional and bilateral levels, impose unprecedented limits on the ability for countries to identify and establish their own policies.

All bilateral trade agreements signed by the United States – there are now 17 agreements in force and even more in the process of ratification and implementation – contain TRIPS-plus standards on issues related to the protection of biodiversity. In particular, these agreements address the expansion of patentable subject-matter, the definition of certain patentability criteria, the facilitation of patents related to living organisms and the adoption of a specific system for plant variety protection. The following paragraphs elaborate upon the relevant provisions in US FTAs. However, as will be discussed below, recent agreements, including the FTA with Peru, also show a possible evolution of the US position on biodiversity.

Patentable subject matter

The TRIPS Agreement establishes the obligation to grant patents for any inventions, whether products or processes, in all fields of technology provided that they meet the patentability criteria. However, the TRIPS Agreement also recognises that member countries may establish certain exceptions to patentability, including plants and animals (other than microorganisms), and biological processes for the production of plants or animals (Article 27.3 (b)). Several US FTAs refer to the exceptions to patentability provided for in the TRIPS Agreement, stating that nothing in the intellectual property chapter be construed to preclude use of these exceptions (for example, the agreements between the United States and Central American countries, or the US-Colombia agreement).

Other agreements, however, do not make references, or make only partial references, to the TRIPS Agreement exceptions. The agreement with Jordan, for example, mentions the exceptions for public order and morality but not those related to plants and animals. The agreement with Chile does not address the subject of exceptions to patentability. The agreement with Oman alludes to the possibility of excluding animals from patentability, but says nothing about plants.

In principle, such omissions do not affect the validity and enforceability of the rules

of the TRIPS Agreement. Nevertheless, these differences generate a certain level of ambiguity. This ambiguity is further heightened by rules in other agreements – such as those with Korea and Morocco. In those agreements, the only accepted exceptions to patentability are those based on "public order" or linked to diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals – thus establishing an obligation to grant patents on plants and animals.

It is also important to note that, even in those agreements with a reference to Article 27.3 (b) of the TRIPS Agreement, there are other provisions aimed at limiting the flexibility for countries to establish such exceptions in their legislation. This is the case specifically in the agreements with Latin American countries, all of which include a clause requiring "best efforts" or "reasonable efforts" to establish patent protection for plants. In addition, parties that do grant patent protection for plants or animals at the date or after the date of entry into force of these agreements are then obliged to maintain such protection. It is still unclear which should be the extent of those efforts or obligations in practice. One could argue that introducing a parliamentarian debate on the matter or presenting a bill to expand the scope of the patentable subject matter should be considered reasonable even if the parliament does not approve or consider those proposals relevant or a priority.

Furthermore in the case of the US- Morocco FTA, parties commit themselves to make "*patents available for plants and animals. In addition, patents shall be available for any new uses or methods of using a known product, including new uses of known product for the treatment of human and animals*". This is clearly the highest standard on life forms patentable subject matter accepted by a developing country as it not only covers patents for plant and animals (even individually) but also new uses and methods. This latter type of patent has been heavily criticised, as patents should be granted to inventions and not to "new uses" of existing inventions, which allows "*evergreening*".[4] Countries accepting this expansive option must be warned that they may be obliged to grant patents even over plants and animals that might be originated in their own country, unless effective measures are put in place to avoid this type of situation.

Patentability criteria

Certain agreements signed by the United States, including those with CAFTA and Peru, establish that parties will concede that the claimed invention is industrially applicable – one of the criteria for patentability – if it has a specific, substantial and credible utility. This clause refers to differences in the requirements established by various countries for the grant of a patent. The US legal system requires that usefulness be a criterion of patentability, while other countries – including the Andean and Central American countries – require the invention to be industrially applicable.

Although the difference between the criteria of "utility" and "industrial" application does not seem significant, the adoption of utility as a criterion of patentability does have implications, including for issues related to protection of biodiversity. The difference is relevant, for example, in regards to patents linked to methods or procedures for biotechnology-related research. These methods, while not industrially applicable, can be useful, and thus patentable if that patentability criterion is used.

Deposit of microorganisms for the purpose of facilitating patent procedures

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms was signed in 1977 as a means of facilitating compliance with the requirement of "disclosure" in the procedure for obtaining a patent. Normally, a written description of the invention is required to obtain a patent. Since such a description is difficult in cases where the invention involves a microorganism, the Budapest Treaty allows the deposit of microorganisms to be considered sufficient disclosure in these cases, and also provides international authorities with which this deposit may be made.

The TRIPS Agreement does not refer to the Budapest Treaty, but the majority of bilateral trade agreements signed by the United States include the obligation to ratify or comply with this Treaty. As the term "microorganism" is interpreted broadly, encompassing any biological material whose deposit is necessary for purposes of disclosure – particularly in the food and pharmaceutical sectors – these rules can also be interpreted as tactics for facilitating and promoting patents on plants and animals. In addition, the Budapest Treaty has been criticised for facilitating and concealing "biopiracy", as the authorities of deposit are not authorised to grant information on specific patent applications, nor about which microorganisms are in the system. On the other hand, the Budapest Treaty is considered to be an important example of how inclusions of additional disclosure requirements, here with regards to "biological material", do not affect patentability criteria, but rather complement and facilitate the description of the invention.

Adoption of the International Convention for the Protection of New Varieties of Plants

Under the TRIPS Agreement, member countries must provide for the protection of plant varieties either by patents, or by an effective *sui generis* system or by any combination thereof. This flexibility to choose or develop a system of plant variety protection tailored to national needs is significant from a sustainable development perspective. In the context of agriculture, the need to balance breeders' rights with measures to ensure broad access to seeds and plant varieties is fundamental to avoid jeopardising continued innovation as well as food security.

Nevertheless, intellectual property rules in US FTAs invariably limit this flexibility, requiring parties to ratify the latest version of the International Convention for the Protection of New Varieties of Plants (UPOV Convention), which was adopted in 1991. The UPOV Convention provides a *sui generis* form of intellectual property protection for plant varieties, but has been criticised for responding primarily to the needs of commercial breeding. The characteristics of the varieties developed and used by small farmers in developing countries, therefore, are not necessarily taken into account.

In addition, the 1991 version of the UPOV Convention has raised concerns not only for its increasing level of protection, but also for recognising greater rights for breeders (whether through plant variety protection or patent rights) at the expense of farmers' rights – including the right to save seeds and exchange them freely. Finally, the position of the UPOV Convention on disclosure of origin is also worrisome, particularly as there have been cases of biopiracy through breeders' rights.[5] This position is that disclosure of origin cannot be accepted as an additional requirement for protection, since the conditions for plant variety protection under the UPOV Convention have already been established and cannot be increased.[6]

Understandings regarding biodiversity and traditional knowledge

An important reshaping of the way in which biodiversity is addressed in bilateral trade negotiations took place in the context of the US FTAs with Peru and Colombia.[7] Each of these agreements incorporates an "understanding regarding biodiversity and traditional knowledge". These documents are particularly relevant given US concerns on the link between biodiversity and intellectual property. The United States is notably absent from the more than 190 states that are Parties to the CBD. The US signed the CBD in 1993 but expressed concern about the inadequate protection of intellectual property and lack of an appropriate mechanism for financial assistance. The United States has not gone through the ratification process[8] and biodiversity remains a contentious issue in its foreign policy.

Considering this context, it is thus clear that Peru and Colombia, not the US ,have taken firm positions on biodiversity in bilateral agreements, demanding that advancing the protection of biodiversity be one of the priorities of the trade rules being negotiated. These countries recognised that, unless such an approach was taken, not only would policy space on biodiversity

conservation be compromised, but a chance to promote recognition and co-operation on these issues would also be lost.[9] The text of these understandings – the same in the Peru and Colombia FTAs – takes a noteworthy step towards such recognition, though questions remain on the legal value and possible enforcement of these clauses. Table I box below presents a brief analysis of the text of the understandings:

Table 1: Analysis of selected provisions on biodiversity and traditional knowledge in US FTAs

Provisions	Comments
The Parties recognise the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development.	The recognition of the importance of biodiversity and traditional knowledge is not insignificant, given the position taken on these issues by the United States in other agreements and forums. Moreover, this clause not only recognises the intrinsic value of biodiversity, but also mentions its link with sustainable development, following the approach of the CBD.
The Parties recognise the importance of the following: 1) obtaining informed consent from the appropriate authority prior to accessing genetic resources under the control of such authority; 2) equitably sharing the benefits arising from the use of traditional knowledge and genetic resources; and 3) promoting quality patent examination to ensure the conditions of patentability are satisfied.	This clause is noteworthy as it relates to the basic principles of access and benefit sharing established by the CBD. According to the CBD, access to genetic resources takes place subject to prior informed consent and based on mutually agreed upon terms, including with respect to equitable benefit sharing. Furthermore, this clause refers to one of the major concerns of countries rich in biodiversity, which is the low quality of patent examination in the United States. The US has allowed patents linked to traditional knowledge to be granted, for example, even when they did not meet the novelty or inventive step criteria. While the Parties do not agree to abide by these principles, their recognition has value in itself in the context of the sensitivity of the US position on these issues.
The Parties recognise that access to genetic resources or traditional knowledge, as well as the equitable sharing of benefits that may result from use of those resources or that knowledge, can be adequately addressed through contracts that reflect mutually agreed terms between users and providers.	This reference to the use of contracts in relation to access and benefit sharing has been criticised repeatedly. Particularly with regard to Peru, there are questions as to whether this is a step backward, a change in its position in favour of disclosure of origin requirements. Nevertheless, as indicated by Ruiz, the contractual approach has already been established in both the CBD and national legislation in Andean countries.[10] Furthermore, the contractual approach is not favoured over others - except of course by specifically mentioning it.

Table 1: *Continued*

Provisions	Comments
Each Party shall endeavour to seek ways to share information that may have a bearing on the patentability of inventions based on traditional knowledge or genetic resources by providing: (a) publicly accessible databases that contain relevant information; and (b) an opportunity to cite, in writing, to the appropriate examining authority prior art that may have a bearing on patentability.	One of the main concerns of Peru, Colombia and other biodiversity-rich countries is avoiding the use of patents for the misappropriation of genetic resources and traditional knowledge. This last clause of the understandings promotes the exchange of information to allow better patent examination and avoid patents that do not meet all the necessary criteria. Although it does not establish any obligations for the Parties, the importance of the clause is – again – in the recognition of these mechanisms and strategies. It also establishes the possibility of future collaboration for development and implementation.

The legal nature of these understandings is not yet clearly defined. Some commentators consider that the understandings do not establish any obligation for the parties, but can only be used for the interpretation of the obligations in the agreement itself. Another perspective is that the parties could press for compliance with these understandings, though such a requirement would be difficult given how general the provisions are. Nevertheless, this debate does not detract from the value that these understandings have as precedents, or from the possibility that more specific clauses will be included in future.

4. BIODIVERSITY IN ENVIRONMENTAL CO-OPERATION AGREEMENTS SIGNED BY CANADA

Canada has strengthened its bilateral free trade negotiations agenda, particularly within the Americas, as part of its broader trade strategy. It is clear that Canada is attempting to regain a level playing field in certain key markets that have signed or are in the process of negotiating agreements with other competitors. In addition to the North America Free Trade Agreement (NAFTA, which entered into force in January 1994), Canada has implemented FTAs with Israel (January 1997), Chile (July 1997), Costa Rica (November 2002), the European Free Trade Association (EFTA, July 2009) and Peru (August 2009). In 2009, Canada signed agreements with Colombia and Jordan.

Canada's strategy for its bilateral trade negotiations is explained not only in terms of economic advantages, but also as a tool for sustainable development. Canada considers trade agreements to be contributors toward greater prosperity and, when supplemented with other policies, creators of opportunities for advancing social and environmental objectives. Canada has thus negotiated environmental co-operation agreements in parallel with its FTAs, in order to promote mutual support between trade and environmental policies. These environmental co-operation agreements aim to promote greater environmental protection, as well as a more effective enforcement of environmental laws and regulations. They also provide for increasing environmental co-operation, transparency and public participation.

While the general approach in environmental co-operation agreements has remained more or less constant, the Canadian agreements with Peru and Colombia contain important developments in relation to biodiversity. In their general provisions, these agreements affirm the importance of the CBD and of working jointly to achieve its objectives. Moreover, Article 5 deals specifically with biodiversity. In addition to reiterating their commitment to the principles of the CBD, these countries also agree to co-operate on biodiversity matters and – most interestingly – establish an information exchange system to prevent illegal access to genetic resources and traditional knowledge and to advance the equitable sharing of benefits derived from the use of genetic resources and associated traditional knowledge.

These new clauses in Canadian environmental co-operation agreements set significant precedents, and reaffirm the positive outcomes possible as a result of pro-active strategies on biodiversity, such as those adopted by Peru and Colombia. However, it should be noted that the CBD is not mentioned in the Canadian FTAs themselves – it is not included in the list of agreements whose obligations prevail in case of conflict. In addition, it is not clear that the provisions on biodiversity in the environmental co-operation agreement will have any implications for the application or interpretation of the intellectual property rules in the FTAs.

5. LATEST ECONOMIC PARTNERSHIP AND FREE TRADE AGREEMENTS WITH THE EUROPEAN UNION

The European Union is a key player both in the context of the conservation of biodiversity and the protection of intellectual property. All the countries in the European Union are Parties to the CBD and have implemented a range of policies for the conservation and sustainable use of biodiversity. European countries have also actively contributed to the development of the Bonn Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising from their Utilisation, as well as to the CBD negotiations on an International Regime on ABS.[11]

On the other hand, Europe is the cradle of the intellectual property system and remains among the main *demandeurs* for greater levels of intellectual property protection in the context of trade agreements. Intellectual property provisions in the Economic Partnership Agreements (EPAs) pursued by the European Union began as relatively general references intended to advance the development and adoption of higher standards of intellectual property protection. The trend, however, has now turned towards specific chapters with more precise rules in the various categories of intellectual property rights.[12] In terms of biodiversity, the most relevant intellectual property provisions in these "new generation" agreements address patents, plant breeders' rights, geographical indications and enforcement.

In the debate on the relationship between intellectual property and biodiversity, the EU has played a rather cautious role. It has always recognised the importance of the objectives of the CBD, but has not been too enthusiastic in supporting measures that could affect the granting of patents related to biotechnology. EPAs did not even address the relationship between biodiversity and intellectual property until the 2007 agreement with the Forum of Caribbean States (CARIFORUM), part of the Group of African, Caribbean and Pacific States. The issue has continued to come up, including in the recently concluded agreements with Peru and Colombia.

EU-CARIFORUM EPA

In the EU-CARIFORUM EPA, the relationship between intellectual property and biodiversity is addressed in the sections on intellectual property and on co-operation. The intellectual property section includes Article 150, entitled "Genetic Resources, Traditional Knowledge and Folklore". Although this article addresses the issue more comprehensively than the side letters of US FTAs, it remains relatively basic. The text focuses primarily on the topic of traditional knowledge. There seems to be a long way left to go before the range of concerns arising from the relationship of biodiversity and intellectual property are comprehensively addressed. Table II below presents analysis and comments on the main intellectual property provisions dealing with biodiversity in the EU- CARIFORUM EPA.

Table 2: Analysis of biodiversity related provision in the EU CARIFORUM EPA

Provisions	Comments
Subject to their domestic legislation, the EC Party and the Signatory CARIFORUM States 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…	This provision recognises the need to preserve and maintain traditional knowledge, as called for by Article 8 (j) of CBD. It addresses the protection of traditional lifestyles and the biodiversity that supports them, one of the major concerns of indigenous and local communities. This provision does not deal with intellectual property protection *per se*, but it could prove relevant for the purposes of technical and financial co-operation on intellectual property issues.
. . . And promote their wider application with the involvement and approval of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.	This provision addresses the promotion of the wider application of traditional knowledge, with the approval and involvement of the holders of such knowledge and with equitable sharing of the resulting benefits. These principles are also recognised in Article 8 (j) of CBD. One possible approach towards compensating the use of traditional knowledge involves the "paid public domain" system that has been incorporated into some copyright laws.
The EC Party and the Signatory CARIFORUM States recognise the importance of taking appropriate measures, subject to national legislation, to preserve traditional knowledge and agree to continue working towards the development of internationally agreed *sui generis* models for the legal protection of traditional knowledge.	This is a hortatory provision, aimed at improving co-operation towards developing appropriate measures for the protection of traditional knowledge, including *sui generis* approaches developed at the multilateral level.
The EC Party and the Signatory CARIFORUM States agree that the patent provisions of this subsection and the Convention on Biological Diversity shall be implemented in a mutually supportive way.	This provision reflects existing obligations under Article 16 of the CBD. The added value, however, is the inclusion of these principles in this subsection, which would make them relevant for interpretation in cases of potential conflict.
The EC Party and the Signatory CARIFORUM States may require, as part of the administrative requirements for a patent application concerning an invention that uses biological material as a necessary aspect of the invention, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention.	This is the only provision in the EU-CARIFORUM EPA with specific measures aimed at creating synergies between biodiversity and intellectual property protection. It is, however, of a non-binding nature, and it does not mention the consequences of non-compliance. This provision may be linked to the preamble to the European Biotechnology Directive, which provides for voluntary disclosure of the geographical origin of biological material.[13] But the word "source", rather than "origin", gives it wider connotation and includes both geographical origin as the origin and / or supplier.

Table 2: *Continued*

Provisions	Comments
The EC Party and the Signatory CARIFORUM States agree to regularly exchange views and information on relevant multilateral discussions . . .	This rule seeks to promote transparency and dialogue on multilateral issues in relevant forums, including WIPO and the WTO. It is striking that there is no mention of the Conference of Parties to the CBD as one of the relevant forums.
Following the conclusion of the relevant multilateral discussions . . . the EC Party and the Signatory CARIFORUM States, at the request of the EC Party or a Signatory CARIFORUM State, agree to review this Article within the Joint CARIFORUM-EC Council, in light of the results of such multilateral discussions.	This rule is what is considered a clause of *"rendez-vous"*, or gathering, which also could be interpreted a clause for renegotiation if the conditions are modified multilaterally.

Among the issues on which co-operation is foreseen, the agreement between the EU and CARIFORUM mentions the identification of products that could benefit from the protection of geographical indications (GIs). And the European Union also commits itself to paying particular attention toward promoting and preserving traditional knowledge and biodiversity through the establishment of geographical indications.

EU Peru and Colombia FTAs: negotiations and outcomes

The negotiations between the EU and Peru and Colombia to achieve an FTA began in February 2009 and were finalised in March 2010. The text of the agreement was finally signed in May 2010. The new agreement will enter into force as early as 2011.

Intellectual property issues were agreed upon only in the final round, with issues linked to geographical indications and biodiversity proving to be particularly complex. Colombia and Peru, however, treated biodiversity and traditional knowledge as a critical issue in the chapter on intellectual property. A joint text on these issues was presented at the beginning of the negotiation process.

The main provisions of the text proposed by Colombia and Peru focused on:

- reaffirming States' sovereign rights over genetic resources, as well as CBD principles and obligations under the CBD regarding the fair and equitable sharing of benefits derived from the use of these resources;

- recognising the contribution of indigenous and local communities to the conservation and sustainable use of biodiversity, and more generally the role of traditional knowledge in cultural and economic development;

- stating that intellectual property rights should be granted on the basis of the recognition of CBD principles and relevant national legislation on biodiversity and traditional knowledge;

- incorporating a mechanism for disclosure of origin or legal provenance, proof of prior informed consent and evidence of benefit sharing agreements;

- including a mandate to develop a national and effective system for the *sui generis* protection of traditional knowledge; and

- incorporating compliance measures and co-operation provisions to improve the quality of patent examination and relevant exchange of information.

These proposals were considered too ambitious by European negotiators. The European

position seemed to recognise the need for a mutually supportive relationship between intellectual property rules and the conservation of biodiversity, while rejecting the specific measures put forth by Colombia and Peru. In this regard, European negotiators have adopted a relatively "defensive" approach, putting forth proposals that reflect CBD language, but do not include any additional obligations. European counterproposals on biodiversity have aimed to reduce the scope and content of relevant obligations, transform proposed provisions into best endeavour clauses, and avoid compliance measures.

On other issues, such as co-operation, European negotiators have been open to more concrete provisions in the following areas:

- clarifying the issues and the concept of misappropriation of genetic resources;
- exchanging information on patents related to genetic resources and traditional knowledge;
- training of patent examiners;
- recognising the usefulness of databases on traditional knowledge;
- supporting the compliance with relevant national legislation;
- cooperating in achieving common objectives in multilateral forums.

The negotiations featured in-depth dialogue and frank exchanges on the subject, and the consideration of several alternatives. While some differences remained, the positions did become closer and generated a final legal outcome. The new legal text has not yet been released officially but the text is available from civil society sources.[14] The outcome is encouraging and goes beyond any previous provisions on biodiversity in EU FTAs or EPAs.

The IP chapter of the EU Colombia-Peru FTA explicitly reaffirms rights and obligations under the CBD in the section related to the nature and scope of obligations. This has an important interpretative value. Indeed, it requires the specific obligations and the implementation of the IP section and the CBD should be mutually supportive and not undermine each other.

In addition, this EU FTA incorporates – directly in the main text – a new section on "protection of biodiversity and traditional knowledge". This practice was undertaken for the first time in the FTA between EFTA and Colombia. The title of the section in the EU FTA is even more pro-active than the EFTA one, as it indicates the need for "protection of biodiversity and traditional knowledge". This is particularly relevant due to the legal value that the word "protection" has in the IP context: it usually implies the existence of measures against unfair competition, patrimonial and moral rights, as well as exclusive rights.

The section on protection of biodiversity and traditional knowledge has been excluded from the list of IP categories covered by the chapter and it indicates that enforcement provisions do not apply to it. This, however, does not mean that those provisions cannot be subject to the general dispute settlement rules of the EU FTAs with Colombia and Peru.

In order to get a better understanding of the main obligations under the new EU FTA with Colombia and Peru, Table III presents an analysis of the most relevant provisions.

Table 3: Analysis of selected provisions related to the protection of biodiversity and traditional knowledge in the EU FTA with Colombia and Peru

Provisions	Comments
The Parties recognize the importance and value of biological diversity and its components and of the associated traditional knowledge, innovations and practices of indigenous and local communities . . .	While of an exhortatory nature, this provision is important to justify the protection given to biological diversity in this section, and to recognize the role and value added of indigenous and local communities to CBD objectives and local development. It must be noted that this recognition covers biodiversity and its components, which is a wider concept than genetic resources. It could include biological resources, derivatives and even services provided by ecosystems. Additional goals that could be included in future negotiations could include halting acts of "biopiracy" and "misappropriation".
The Parties recognize the contribution of indigenous and local communities to the conservation and sustainable use of biological diversity and all of its components, and in general, (. . .) and their contribution to the culture and to the economic and social development of nations.	
The Parties will collaborate in further clarifying the issue and concept of misappropriation of genetic resources and associated traditional knowledge.	This provides an example of the difficulties found in defining acts that could be considered abusive or illegal in relation to the access and use of genetic resources and traditional knowledge. Developing countries need to be more straightforward and take the risk of providing key definitions or illustrative list for terms such as "biopiracy" and "misappropriation". For example below there are two possible definitions based on the existing literature[15] that could be of use: **"Biopiracy"** could be defined as unauthorised or illegal access to and use of genetic resources. The concept has also been extended to traditional knowledge. This is usually considered a violation of international and national law. Consequences could be various, depending on the action, and include administrative and criminal sanctions. There could also be civil consequences. **"Misappropriation"** tends to include the concept of taking the value of genetic resources or traditional knowledge through intellectual property or other use. In the context of biodiversity, misappropriation may be more specifically defined as the consequence of biopiracy, of violating authorized conditions of access, or of using the genetic resources to derive unjustified or inequitably shared benefits. These types of acts are usually considered as abusive, anti competitive or unjustified enrichment under civil law or administrative law. In some jurisdiction they can have effects on patents or titleholders rights themselves.

Table 3: *Continued*

Provisions	Comments
The Parties reaffirm their obligation under the Article 15.7 of the CBD to take measures with the aim of sharing in a fair and equitable way the benefits arising from the utilization of genetic resources, and recognise that mutually agreed terms may include benefit-sharing obligations in relation to intellectual property rights arising from the use of genetic resources and associated traditional knowledge.	This provision simply reaffirms existing access requirements in relation to genetic resources established by the CBD. Such reaffirmation could be of assistance when interpreting the link between article 15 and the IP provisions. The recognition that specific clauses in mutually agreed terms may be relevant in relation to intellectual property could provide additional legal support in EU courts for the claims over the economic benefits arising from a particular patent. However, nothing is mentioned on what the legal consequence would be in cases where genetic resources have been used but there are no contracts.
The Parties acknowledge the usefulness of requiring the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications, considering that this contributes to the transparency about the uses of genetic resources and associated traditional knowledge.	The acknowledgement of the usefulness of the disclosure requirement in patent applications gives a legal and political basis for the application of such mechanisms in the national legislation of the parties. The mention of transparency gives stronger basis to arguing that disclosure is supportive to both the IP system and sustainable use of genetic resources and traditional knowledge.
The Parties will provide, in accordance with their domestic law, for applicable effects of any such requirement so as to support compliance with the provisions regulating access to genetic resources and associated traditional knowledge, innovations and practices.	These provisions may be the most important gain for Colombia and Peru in the IP section. They will prove to be controversial in the implementation of this FTA in the EU side. This provision requires giving legal effects to disclosure or similar type of requirements in order to support the enforcement of access and traditional knowledge regulations. Even if this is done in accordance with domestic legislation, it would imply amending current EU Directive on Biotechnology (1998) in order to determine the effects for lack of fulfilment. Giving the lack of compliance no effect at all would undermine the objectives of this and the previous provision. Possible effects to be given upon lack of compliance can be diverse – they could include consequences in the intellectual property field but also civil, administrative or criminal sanctions. The effects of lack of fulfilment should be strong enough to ensure that disclosure and other requirements are respected, transparency is addressed in future patent applications, and compensation is provided when there has been unauthorised or illegal access and use of the genetic resources and traditional knowledge. Examples of possible sanctions include declaring the non-enforceability of the patent as a consequence for fraudulent declaration, compensation for damages, fines, or even penal sanctions.

Table 3: *Continued*

Provisions	Comments
The Parties will endeavour to facilitate the exchange of information about patent applications and granted patents related to genetic resources and associated traditional knowledge, with the aim that in the substantive examination, particularly in determining prior art, such information can be considered.	While this provision is just a "best endeavour clause" and not enforceable, its content could be very useful when seeking to adress and solve individual cases of "biopiracy" and "misapropiation". Exchange of information during the patent examination phase could avoid the granting of erroneous patents and shed light over the examination of prior art and, in some cases, inventive step. Greater cooperation and admission of relevant information over patentability and possible acts of biopiracy would reduce pressure, build trust, advance political and technical solutions and improve the quality of the patentabilty examination. There are already experiences in this regard in Peru, with the National Anti-biopiracy Commission[16] in preparing and submiting prior art dossiers and making oppositions against specific patents in foreing jurisdictions with positive results in several specific cases.

During the negotiations, the Andean countries, as the *demandeurs*, also raised the issue of geographical indications explicitly in the context of biodiversity.[17] This link was also made in the context of the WTO: a proposal made by more than 110 countries on possible modalities for current TRIPS negotiations clearly recognises the relationship between these topics.[18]

The section on geographical indications in the FTA between the EU and the two Andean countries contains a set of fairly comprehensive provisions granting broad exclusive rights to producers who meet the technical requirements stated therein. These provisions include the extension of the higher levels of protection for wines and spirits as granted under the TRIPS Agreement, to other products. Moreover, it incorporates a mutual protection scheme as well as a fast track procedure to protect listed GIs according to the levels set in the FTA. Currently, the EU has listed 229 GIs while the lists from Colombia and Peru have not yet been disclosed. However the lists are likely to include *Café de Colombia* (coffee), *Pisco* (wine liquor), *Mais Guigante del Cusco* (corn), *Pallar de Ica* (beans) and *Chulucanas* (ceramics). Moreover, there are about a dozen pending GI requests in Colombia and Peru for other products including mostly food products and handcrafts. These can be listed once national GI protection is granted.[19]

It is important to note, that although Colombia and Peru have considerable expectations concerning the use of GIs to encourage exports of certain products, the overall economic impact of GI protection may be lower than expected and substantial investments may be necessary for the creation of regulatory councils, quality controls, certification of compliance with norms, marketing and, notably, for the enforcement of GI rights in foreign jurisdictions.

In comparison, in the ongoing negotiations between the EU and Central American countries, issues linked to biodiversity do not appear to be a priority. There is only one GI in Central America, though several are in the process of being developed. According to a recent study by the International Centre for Trade and Sustainable Development (ICTSD) and the Andean Development Corporation (CAF), there are several products in Central America that could potentially benefit from protection as GIs, including coffee and some alcoholic beverages.[20] The text of the EU-Central American FTA has not yet been made public.

6. BIODIVERSITY IN THE FTA BETWEEN EFTA AND COLOMBIA

In November 2008, an FTA was signed between EFTA and Colombia. This agreement is in the process of ratification both in Colombia and in the countries comprising the European economic bloc. According to information provided by the Swiss Federal Institute of Intellectual Property (SFIIP) and the Swiss Secretariat for Economic Affairs (SECO), ratification should be completed in mid-2010. Although Colombia and Peru began negotiations with EFTA jointly, they then took different routes, which led to the treaty with Colombia being finalised first.

The EFTA-Colombia agreement contains, for the first time, a section in the chapter on intellectual property called "measures related to biodiversity", a title which in itself implies a pro-active approach. As explained by the SFIIP and SECO, this section came about as the result of a specific request made by Colombia and Peru during the negotiations.

As background for this development, it should be mentioned that Norway and Switzerland have progressive legislation on intellectual property and biodiversity, including the disclosure of origin and legal provenance of genetic resources.[21] This explains the fact that they were receptive to these issues, even without obligations deriving from a multilateral agreement or any related commercial benefits. Norway has a history of promoting legal access and sustainable use of biodiversity and traditional knowledge. It has even supported the development of specific measures in the intellectual property system to reduce biopiracy, improve patent quality and ensure legal access and benefit sharing.[22] Switzerland, meanwhile, has submitted several proposals in which it positions itself as a "facilitator" on biodiversity issues in multilateral negotiations. The Swiss proposals include amending the Patent Cooperation Treaty (PCT) to incorporate a specific description of when disclosure requirements are relevant, as well as sanctions for lack of compliance such as the rejection or withdrawal of the patent at issue.

As a result, the two countries accepted the Colombian and Peruvian proposals, along with the new section on biodiversity in the chapter on intellectual property. This part of the trade agreement includes provisions that reaffirm the objectives and main principles of the CBD. Principles such as sovereign rights over genetic resources and the need for legitimate access and benefit sharing of resulting benefits were added to the text. The contribution of indigenous peoples and local communities, and their knowledge, to economic and social development are also recognised. It is important to note that measures related to biodiversity in the EFTA-Colombia FTA have a strong bearing on patent law, as they will affect national granting and examination. Table IV illustrate some of the most relevant provisions related to biodiversity.

Table 4: Analysis of selected measures related to biodiversity in the EFTA FTA with Colombia

Provisions	Comments
The Parties shall consider collaborating in cases regarding non-compliance with applicable legal provisions on access to genetic resources and traditional knowledge, innovations and practices.	Although this is a "best endeavour" clause, it could be implemented with effective results, through collaboration - such as joint actions to prevent or resolve specific cases of illegal access and the use of genetic resources and traditional knowledge.

Table 4: *Continued*

Provisions	Comments
According to their national law, the Parties shall require that patent applications contain a declaration of the origin or source of a genetic resource, to which the inventor or the patent applicant has had access.	Perhaps the most innovative element in this FTA in terms of intellectual property, this provision addresses the main measure proposed by the biodiversity-rich countries to tackle the lack of synergy between the TRIPS Agreement and the CBD. This provision would mean that patent applicants are obliged to indicate the country of origin of all relevant genetic resources. Such a requirement would enable assessment of geographical origin or legal source and – perhaps even more importantly – jurisdiction.[23]
As far as provided for in their national legislation, the Parties will also require the fulfilment of prior informed consent (PIC) and they will apply the provisions set out in this Article to traditional knowledge as applicable.	This provision aims to advance the CBD objectives and their implementation. Prior informed consent (PIC) is a principle widely recognised in international environmental law – it has been included in several multilateral environmental agreements. PIC goes beyond requiring mere approval, and involves full disclosure of relevant information and consultations among all stakeholders so as to allow an informed decision. This principle is particularly important when it comes to actors and/or groups in weaker negotiating positions, as is the case of indigenous peoples in the context of access and benefit sharing. The aim of the measure clearly goes beyond the aim of improving patent quality, by also attempting to prevent biopiracy.
The Parties, in accordance with their national laws, shall provide for administrative, civil or criminal sanctions if the inventor or the patent applicant wilfully make a wrongful or misleading declaration of the origin or source. The judge may order the publication of the ruling.	This is the first time that intellectual property rules in a bilateral trade agreement include provisions for enforcement in cases of erroneous or false statements on the origin or source of genetic resources. Of course, such provisions are essential to address effectively issues related to biodiversity and intellectual property, providing actual means for dealing with them in practice. The dispute settlement provisions in Chapter 12 of the agreement give this particular article additional potential for being successfully implemented. The text, consistent with the positions of Norway and Switzerland in other forums, does not foresee that inaccurate statements or lack of disclosure of origin or source will affect the validity of the patent.

Table 4: *Continued*

Provisions	Comments
Each Party shall take policy, legal and administrative measures, with the aim of facilitating the fulfilment of terms and conditions for access established by the Parties for such genetic resources.	This provision refers to obligations that are important for Parties that act as providers of genetic resources: it requires Parties to facilitate compliance with regulations and agreements on the access to genetic resources. There have been a number of criticisms of excessive regulation and administrative inefficiency in access rules. This provision could create some pressure for the improved development and implementation of domestic legislation on access, which should not only seek to control but also promote the legal flow of genetic resources.
The Parties shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring the fair and equitable sharing of the benefits arising from the use of genetic resources or associated traditional knowledge. Such sharing shall be based on mutually agreed upon terms.	This provision, through language more common in intellectual property rules, responds to the calls of various stakeholders on the need to ensure an equitable sharing of benefits.
. . . a Party that does not provide for patent protection for plants, shall undertake reasonable efforts to make such patent protection Available . . .	This "best endeavour" clause was proposed by EFTA as a way to create consistency between the scope of patentability and disclosure requirements. The reasoning put forth was that if patents are not available for plant-based inventions, there will then be no cases for disclosure requirements. Of course, inventions linked to parts of plants or biochemical compounds would still be subject to patents. Nevertheless, it was argued that, in order to advance benefit sharing, various types of incentives should be explored, which was a reason that was finally accepted by Colombia.

These provisions in US FTAs have significant value as a precedent. However, the chapter was a response to requests from Peru and Colombia and will, therefore, not necessarily be reproduced in other EFTA negotiations. Nevertheless, these provisions are likely to constitute a template for the Peruvian text.

Another important issue to consider in terms of the implications of this type of provisions is the role of the national treatment and most-favoured nation disciplines under the TRIPS Agreement. On one hand, under Article 4 of the TRIPS Agreement, any privilege granted to one of the Parties would automatically extend to other WTO members. Similarly, national treatment would imply the extension of any privilege established by domestic law. In the case of Switzerland and Norway there should not be any problem as both countries already have internal legislation on the matter that sometimes goes beyond what is in the EFTA FTA. On the other hand, there could be a discussion if "measures related to biodiversity" do not fall under the categories of intellectual property rights foreseen in the TRIPS Agreement or

WIPO treaties. Moreover, it should be assessed whether these provisions are in fact creating or increasing the level of protection of intellectual property rights for the Parties of the agreement. In the case of the EU FTA with Colombia and Peru this discussion seems to be clear as provisions on the "protection of biodiversity and traditional knowledge" have been explicitly excluded from the list of IP categories and the enforcement provisions.

Arguably, the new provisions on biodiversity relate directly to the patent provisions. The "measures related to biodiversity" may affect consideration of the patentability criteria (novelty, inventive step and industrial applicability), the description of the invention and the assessment of the claims made in a patent application. It could also be argued that the protection of traditional knowledge foreseen in that section of the EFTA-Colombia agreement implies the recognition of new "positive" intellectual property rights for indigenous and local communities. Nevertheless, these types of requirements could also be considered outside the patent system. In any case both lines of reasoning would find support in the proposals and various statements made in current TRIPS negotiations and reviews and future FTAs. Whatever the perspective, an in-depth discussion on the topic would be relevant because of its systemic implications.

7. CONCLUSIONS

An assessment of the evolution of the treatment of the link between biodiversity and intellectual property in bilateral trade agreements shows how much progress has been made towards a more balanced and sustainable approach in recent years. The risks posed by rising levels of intellectual property protection remain – the proposals of developed countries in bilateral negotiations have not changed in this regard. The big difference is that, due to the more proactive participation of developing countries, particularly in Latin America, biodiversity is no longer just a defensive interest. It has become an offensive interest, and the topic of a series of intellectual property measures related to biodiversity included into bilateral and regional trade agreements.

- *At a systemic level*, it is important to emphasise that the new side letters in the case of US FTAs and provisions on biodiversity create significant challenges for the interpretation and implementation of the trade agreements. The measures related to biodiversity, as an integral part of the agreement, will need to be put into practice and be subject to the dispute settlement mechanisms.

- In regard to the side letters, it is important to remember the rule of treaty interpretation contained in Article 31.2 (a) of the Vienna Convention.[24] This Article states the relevance of "any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" for the interpretation of the treaty in question. As a result, the side letters will have an impact on the interpretation of the objectives and specific obligations both in the intellectual property and environment chapters of the agreements.

  As for the content of the obligations related to biodiversity, agreements vary significantly. The approaches differ in terms of objectives, issues addressed and recognised, technical obligations and co-operation commitments.

- Beyond systemic implications, there are also effects at the bilateral and multilateral levels.

- *In regard to FTAs signed by the United States*, intellectual property rules remain a challenge for the protection of biodiversity, given their clear goal of eliminating policy space maintained by multilateral agreements. It is difficult to assess whether the progress made by Peru and Colombia in their side letters on biodiversity and traditional knowledge provides a balanced "trade-off" from the perspective of developing countries. These side letters do show the possibility of achieving concessions from the United States on this issue – a precedent that could be followed up on in future negotiations, as well as in the implementation of the environmental co-operation provisions in agreements already in force. In the context of a new US administration that appears to have shifted attitudes on sustainable development, future negotiations could show similar flexibility on issues linked to the conservation and sustainable use of biodiversity.

- *In regard to the FTAs signed by Canada*, the clauses on biodiversity achieved in the environmental co-operation agreements with Peru and Colombia are important precedents. This is particularly true in light of ongoing negotiations with the Andean Community, CARICOM and Central American countries — for all of which the protection of biodiversity, and specifically preventing its misappropriation, is of great significance. In the context of these negotiations, the challenge will be to achieve equal or greater definition in access and benefit sharing issues, and to attempt to integrate these issues in the trade agreement itself. For Peru and Colombia, which have already achieved these clauses, the challenge will

be to achieve co-operation to advance the effective implementation of CBD principles.

- *In the context of EPAs,* progress towards the inclusion of specific measures to promote synergies between intellectual property and the conservation of biodiversity have been relatively timid. The EPA between the EU and the CARIFORUM is a positive yet limited development. The texts adopted contain hortatory and "best endeavour" clauses rather than concrete obligations. Andean and Central American countries may do better, mainly due to the European Union's interest in obtaining higher levels of protection for geographical indications. The section on co-operation can also be interesting from a biodiversity perspective, if these provisions can turn into projects and concrete results in areas such as improved quality of biotechnology patent searches and examinations.

- *In the context of the recent EU FTAs with Colombia and Peru,* the new section on "protection of biodiversity and traditional knowledge" contains several provisions that would assist in generating more biodiversity-friendly interpretations of intellectual property obligations, as well as to generate some level of cooperation on these topics. It is true that most of the provisions are exhortative and best endeavour in nature. Only one provision could provide some basis for making the disclosure mechanism effective in the EU context. The level of "effectiveness" will, however, depend on the willingness of the EU to address biodiversity concerns internally. In the opinion of the authors, it should be the EU Directive on Biotechnology of 1998 that is amended in order to effectively implement the EU-Colombia and EU-Peru FTA and provide legal effects in case of lack or fraudulent disclosure of origin and source in patent applications. There is ample scope to define the potential effects of non-compliance, including administrative civil and criminal sanctions. Trade-offs with the GI section could have been a part of the overall deal. Developing countries in the pipeline for bilateral negotiations with the EU need to add further clarify, strengthen and further develop this section.

- *In regards to trade agreements signed by EFTA*, the new section on "measures related to biodiversity" in the intellectual property chapter of the agreement with Colombia shows the potential for mutual supportiveness between these two issues, without affecting the rights of patent holders. This section shows the receptiveness of EFTA to some of the concerns raised by biodiversity-rich countries with regards to intellectual property. Although the section could have been further developed, the text includes several of the proposals that have been put forth in the WTO, WIPO and bilateral trade negotiations. In this regard, the text includes – in unprecedented provisions – concrete measures backed by some degree of enforcement. This development bodes well for ongoing negotiations between EFTA and Peru, as well as other future agreements with EFTA.

- *There are also lessons for ongoing negotiations at the multilateral level*. The relationship between biodiversity and intellectual property remains unresolved in several multilateral forums. A proposed amendment to the TRIPS Agreement, which would require disclosure of origin, has wide ranging support among WTO members, including from several developed countries. The EU-CARIFORUM agreement, which successfully linked biodiversity provisions with those on the protection of geographical indications, the EU-Peru and EU-Colombia FTA and EFTA-Colombia Agreement, which include specific provisions on disclosure, suggest that a similar arrangement could be achieved in the WTO context. Moreover, these developments also allow for more ambitious thinking on the proposal on negotiation modalities that links, both technically and politically, disclosure requirements with the extension of higher levels of protection for geographical indications other than wine and spirits.

These developments are similarly relevant for the negotiations of an international regime on access and benefit sharing in the context of the CBD. In these negotiations, references to intellectual property have generally been limited to disclosure requirements, but there is increasing consideration of additional mechanisms, from information exchange to compliance measures. There has always been concern that developed countries would use multiple forums to strategically advance their objectives on intellectual property. However, on the issue of biodiversity, and based on recent developments in the bilateral context, there could be an emerging trend in which developing countries begin consolidating their positions through a coherent strategy and careful coordination in different forums.

ENDNOTES

1 The views expressed in this paper are those of the authors alone and do not necessarily reflect the views of any of the sponsoring institutions nor of the United Nations Conference on Trade and Development (UNCTAD) with which one of the authors is currently affiliated. David Vivas-Eugui developed this paper when working at the International Centre for Trade and Sustainable Development (ICTSD) as Deputy Programmes Director.

2 For a definition of "biopiracy" and related concepts, see below Table III on the analysis of the EU FTA with Colombia and Peru. An introductory video on patent-based "biopiracy" is also available at http://www.ethicalbiotrade.org/media/videos.html.

3 Correa, C. (2001). *Traditional knowledge and intellectual property: Issues and options surrounding the protection of traditional knowledge*. QUNO, Geneva, 2001.

4 "Evergreening" is an informal concept that usually occurs when the brand-name manufacturer literally "stockpiles" patent protection by obtaining separate 20-year patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolised by the patient. European Generic Medicines Association (EGA), 2007.

5 See, e.g., Robinson, D. (2009). *Biopiracy concerns heat up over chili pepper.* BioRes Review, Volume 3, Number 2. October 2009.

6 See, e.g., the UPOV position on an international regime on access and benefit sharing, adopted by the UPOV Council on October 23 2003, available at http://www.upov.int/en/news/2003/intro_cbd.html.

7 See, e.g., Understanding on Biodiversity and Traditional Knowledge of 12 April 2006, Annex to the Free Trade Agreement between the United States and Peru, available at http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text.

8 Fletcher, S. (1995). *Biological Diversity: Issues Related to the Convention on Biodiversity.* CSR Report for Congress, 95-598 ENR. 15 March 1995.

9 See, e.g., Opening of markets should not affect biodiversity, editorial in the "El Comercio" of Peru, 9 April 2009.

10 Ruiz, M. (2006). *The not-so-bad US-Peru side letter on biodiversity*. Bridges, Year 10 Number 1. January-February 2006.

11 This is even though there is no legislation on access and benefit sharing at the European level.

12 Santa Cruz, M. (2007). Intellectual property provisions in the European Union trade agreements and implications for developing countries. ICTSD, 2007, available at http://www.iprsonline.org/resources/docs/Santa-Cruz%20Blue20.pdf

13 See Recital 27 of Directive (98/44/CE) of the European Parliament and of the Council, 6 July 1998, on the legal protection of biotechnological inventions.

14 See bilaterals.org

15 See definitions proposed by Sarnoff and Correa, UNCTAD 2006. Also interesting definitions in Dutfield, G. (2004) and Smith, S. (2004).

16 See http://www.biopirateria.gob.pe/recurso17.htm

17 Peru and Colombia have about a dozen geographical indications protected at the national level, but they were not "demandeurs" on this issue in the negotiations with the European Union.

18 *Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey,the ACP Group and the African Group,* WTO document TN/C/W/52, 19 July 2008.

19 *Carlos Correa, Geographical indications and the obligation to disclose the origin of biological materials: is a compromise possible under TRIPS?, ICTSD, BMZ and GTZ, 2009.*

20 Paz J. y Pomareda C. (2009). *Indicaciones geográficas y denominaciones de origen en Centroamérica: situación y perspectivas*. ICTSD/CAF Policy Discussion paper, March 2009.

21 See Section 8b) of the Norwegian Law No. 9 on patents, of 15 December 1967, as amended by Law No. 20 of 7 May 2004. See Article 49a) fo the Federal Law on Patents for Inventions of Switzerland, 2007.

22 See WTO documents IP/C/W/491 of 2007 and IP/C/W/473 of 2006 .

23 In the case of Switzerland, this would also require knowing which entity is competent to grant access or participate in benefit sharing. See WTO document IP/C/W/433, November 2004.

24 See Vienna Convention on the Law of Treaties of 1969.

REFERENCES

Correa, C. (2001). *Traditional knowledge and intellectual property: Issues and options surrounding the protection of traditional knowledge*. QUNO, Geneva, 2001.

Dutfield, G. (2004), *What is biopiracy? Discussion paper for the International Expert Workshop on Access to Genetic Resources and Benefit-sharing*, Cuernavaca, Mexico, October 24-27, 2004.

Sarnoff J. and Correa C. (2006). Analysis of options for implementing disclosure of origin requirements in intellectual property applications. UNCTAD, 2006.

Smith, S. (2004), *Access to genetic resources and intellectual property rights: What is biopiracy? Discussion paper for the International Expert Workshop on Access to Genetic Resources and Benefit-sharing,* co-sponsored by the Governments of Canada, Mexico and Switzerland, Cuernavaca, Mexico, October 24-27, 2004.

Robinson, D. (2009). *Biopiracy concerns heat up over chili pepper.* BioRes Review, Volume 3, Number 2. October 2009.

Fletcher, S. (1995). Biological Diversity: *Issues Related to the Convention on Biodiversity.* CSR Report for Congress, 95-598 ENR. 15 March 1995.

Ruiz, M. (2006). *The not-so-bad US-Peru side letter on biodiversity*. Bridges, Year 10 Number 1. January-February 2006.

Santa Cruz, M. (2007). Intellectual property provisions in the European Union trade agreements and implications for developing countries. ICTSD, 2007, available at http://www.iprsonline.org/resources/docs/Santa-Cruz%20Blue20.pdf.

Paz J. y Pomareda C. (2009). *Indicaciones geográficas y denominaciones de origen en Centroamérica: situación y perspectivas.* ICTSD/CAF Policy Discussion paper, March 2009.

SELECTED ICTSD ISSUE PAPERS

Agriculture Trade and Sustainable Development

How Would A Trade Deal On Cotton Affect Exporting And Importing Countries? By Mario Jales. Issue Paper No.26, 2010.

Simulations on the Special Safeguard Mechanism: A Look at the December Draft Agriculture Modalities. By Raul Montemayor. Issue Paper No.25, 2010.

How Would a Trade Deal on Sugar Affect Exporting and Importing Countries? By Amani Elobeid. Issue Paper No.24, 2009.

Constructing a Composite Index of Market Acess. By Tim Josling. Issue Paper No.23, 2009.

Comparing safeguard measures in regional and bilateral agreements. By Paul Kruger, Willemien Denner and JB Cronje. Issue Paper No.22, 2009.

Competitiveness and Sustainable Development

Trade, Economic Vulnerability, Resilience and the Implications of Climate Change in Small Island and Littoral Developing Economies. By Robert Read. Issue Paper No.12, 2010.

The Potential Role of Non Traditional Donors 'Aid in Africa. By Peter Kragelund. Issue Paper No.11, 2010.

Aid for Trade and Climate Change Financing Mechanisms: Best Practices and Lessons Learned for LDCs and SVEs in Africa. By Vinaye Dey Ancharaz. Issue Paper No.10, 2010.

Resilience Amidst Rising Tides: An Issue Paper on Trade, Climate Change and Competitiveness in the Tourism Sector in the Caribbean. By Keron Niles. Issue Paper No.9, 2010.

El sector textil y confección y el desarrollo sostenible en Nicaragua. Por Ana Victoria Portocarrero Lacayo. Documento de Fondo No.7, 2010.

El sector textil y confección y el desarrollo sostenible en Guatemala. Por Pedro Prado et al. Documento de Fondo No.6, 2010.

Dispute Settlement and Legal Aspects of International Trade

Burden of Proof in WTO Dispute Settlement: Contemplating Preponderance of the Evidence. By James Headen Pfitzer and Sheila Sabune. Issue Paper No.9, 2009.

Suspension of Concessions in the Services Sector: Legal, Technical and Economic Problems. By Arthur E. Appleton. Issue Paper No.7, 2009.

Trading Profiles and Developing Country Participation in the WTO Dispute Settlement System. By Henrik Horn, Joseph Francois and Niklas Kaunitz. Issue Paper No.6, 2009.

Developing Countries, Countermeasures and WTO Law: Reinterpreting the DSU against the Background of International Law. By Andrea Bianchi and Lorenzo Gradoni. Issue Paper No.5, 2008.

Fisheries, International Trade and Sustainable Development

The Importance of Sanitary and Phytosanitary Measures to Fisheries Negotiations in Economic Partnership Agreements. By Martin Doherty. Issue Paper No.7, 2008.

Fisheries, Aspects of ACP-EU Interim Economic Partnership Agreements: Trade and Sustainable Development Implications. By Liam Campling. Issue Paper No.6, 2008.

Fisheries, International Trade and Sustainable Development. By ICTSD. Policy Discussion Paper, 2006.

Intellectual Property Rights and Sustainable Development

The Technical Assistance Principles of the WIPO Development Agenda and their Practical Implementation. By C. Deere-Birkbeck and R. Marchant. Issue Paper No.28, 2010.

Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border. By Xavier Seuba. Issue Paper No.27, 2010.

Evaluación del impacto de las disposiciones de ADPIC + en el mercado institucional de medicamentos de Costa Rica. Por Grevin Hernandez-González y Max Valverde. Documento de Fondo No.26, 2009.

Access to Climate Change Technology by Developing Countries: A Practical Strategy. By Cynthia Cannady. Issue Paper No.25, 2009.

Trade in Services and Sustainable Development

Facilitating Temporary Labour Mobility in African Least-Developed Countries: Addressing Mode 4 Supply-Side Constraints. By Sabrina Varma. Issue Paper No.10, 2009.

Advancing Services Export Interests of Least-Developed Countries: Towards GATS Commitments on the Temporary Movement of natural Persons for the Supply of Low-Skilled and Semi-Skilled Services. By Daniel Crosby, Issue Paper No.9, 2009.

Maritime Transport and Related Logistics Services in Egypt. By Ahmed F. Ghoneim, and Omneia A. Helmy. Issue Paper No.8, 2007.

Environmental Goods and Services Programme

Harmonising Energy Efficiency Requirements – Building Foundations for Co-operative Action. By Rod Janssen. Issue Paper No.14, 2010

Climate-related single-use environmental goods. By Rene Vossenaar. Issue Paper No.13, 2010.

Technology Mapping of the Renewable Energy, Buildings, and transport Sectors: Policy Drivers and International Trade Aspects: An ICTSD Synthesis Paper. By Renee Vossenaar and Veena Jha. Issue Paper No.12, 2010.

Deploying Energy-Efficiency and Renewable-Energy Technologies in Residential and Commercial Buildings. By Rene Vossenaar and Veena Jha. Issue Paper No.11, 2010.

Trade Flows, Barriers and Market Drivers in Renewable Energy Supply Goods: The Need to Level the Playing Field. By Veena Jha. Issue Paper No.10, 2009.

Trade and Sustainable Energy

International Transport, Climate Change and Trade: What are the Options for Regulating Emissions from Aviation and Shipping and what will be their Impact on Trade? By Joachim Monkelbaan. Background Paper, 2010.

Climate Change and Trade on the Road to Copenhagen. Policy Discussion Paper, 2009.

Trade, Climate Change and Global Competitiveness: Opportunities and Challenge for Sustainable Development in China and Beyond. By ICTSD. Selected Issue Briefs No.3, 2008.

Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuel and Wind Technologies. By John H. Barton. Issue Paper No.2, 2007.

Regionalism and EPAs

SPS and TBT in the EPAs between the EU and the ACP Countries. By Denise Prévost. Issue Paper No.6, 2010.

Los acuerdos comerciales y su relación con las normas laborales: Estado actual del arte. By Pablo Lazo Grandi. Issue Paper No.5, 2010.

Revisiting Regional Trade Agreements and their Impact on Services and Trade. By Mario Marconini. Issue Paper No.4, 2010.

Trade Agreements and their Relation to Labour Standards: The Current Situation. By Pablo Lazo Grandi. Issue Paper No.3, 2009.

Legal and Systematic Issues in the Interim Economic Partnership Agreements: Which Way Now? By Cosmas Milton Obote Ochieng. Issue Paper No.2, 2009.

Environmental Issues in Economic Partnership Agreements: Implications for Developing Countries. By Beatrice Chaytor. Issue Paper No.1, 2009.

Global Economic Policy and Institutions

The Microcosm of Climate Change Negotiations: What Can the World Learn from the European Union? By Håkan Nordström, Issue Paper No.1, 2009.

These and other ICTSD resources are available at http://www.ictsd.org

Other publications of ICTSD's Programme on Natural Resources, International Trade and Sustainable Development include:

- Thinking Outside the Box Innovative Options for an Operational Regime on Access and Benefit Sharing. By Manuel Ruiz Muller. Issue Paper No.1, 2010

- The Political Economy of the International ABS Regime Negotiations. By Jorge Cabrera Medaglia. Issue Paper No.2, 2010.

- The Disclosure of origin Requirement in Central America: Legal Texts, Practical Experience and Implementation Challenges. By Jorge Cabrera Medaglia. Issue Paper No.3, 2010.

For further information, visit www.ictsd.org

ABOUT ICTSD

Founded in 1996, the International Centre for Trade and Sustainable Development (ICTSD) is an independent non-profit and non-governmental organisation based in Geneva. By empowering stakeholders in trade policy through information, networking, dialogue, well targeted research and capacity building, the Centre aims to influence the international trade system such that it advances the goal of sustainable development.