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INTELLECTUAL PROPERTY AND DEVELOPMENT: OVERVIEW OF DEVELOPMENTS IN MULTILATERAL, PLURILATERAL, AND BILATERAL FORA

CONTENTS

I. ABOUT THE IP QUARTERLY UPDATE

1. Developing countries face complex challenges in the evolving scenario of international intellectual property policy-making. Multiple fronts of discussions and negotiations require a coordination of strategies and positions that is not always easy to achieve. Nonetheless, since the shift in fora has been carefully designed by developed countries to take advantage of these difficulties and thus attempt to circumvent the options, flexibilities, and unresolved issues present at the multilateral level, it is crucial to develop a global view of international intellectual property standard-setting and to take the larger context into consideration during any negotiation or discussion.

2. The South Centre and CIEL IP Quarterly Update is intended to facilitate a broader perspective of international intellectual property negotiations by providing a summary of relevant developments in multilateral, plurilateral, and bilateral fora. Moreover, each IP Quarterly Update focuses on a significant topic in the intellectual property and development discussions to demonstrate the importance of following developments in different fora and the risks of lack of coordination between the various negotiations. The present Update discusses, in Section II, the relationship between the TRIPS Agreement and the Convention on Biological diversity and the case for disclosure requirement. Then, Section III provides a brief factual update of international intellectual property-related developments in the third quarter of 2005.

II. THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CBD: THE CASE FOR DISCLOSURE REQUIREMENTS

II.1 Introduction

3. Intellectual property-related issues remain fundamental components of the Doha Round of negotiations, especially from the perspective of developing countries. The relationship between the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Convention for Biological Diversity (CBD), in particular, has been identified as a critical element of any decision in Hong Kong. During informal consultations in July, several developing countries, particularly India, Brazil, Peru and China, reaffirmed that any decision in Hong Kong should move forth with the introduction of disclosure requirements in the TRIPS Agreement to ensure its support for the objectives and principles of the CBD.[1] Moreover, in a letter to 31 trade ministers, the Indian Commerce and Industry Minister, Mr. Kamal Nath, called to amend the TRIPS Agreement to introduce these requirements, emphasizing the strong bearing of the issue on large numbers of people who are holders of traditional knowledge and are poor or disadvantaged.[2] In addition, on June 12 – 16, 2005, the countries of the G77 and China met at the Second South Summit in Doha, Qatar, and called for "accelerating the negotiations on the development-related mandate concerning the TRIPS agreement in the Doha Ministerial Declaration, especially the amendments of the TRIPS Agreement in order for intellectual property rules to dully support the objectives of the CBD."[3]

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[1] See South Centre and CIEL IP Quarterly Update, Second Quarter 2005.
[2] "India for amending WTO TRIPS accord," The Hindu, New Delhi, July 30.
[3] See Doha Declaration adopted at the Second Doha Summit, 12 – 16 June 2005, Doha, Qatar, Document G-77/SS/2005/1, Para 15(xiii).

4. Although developed countries have also emphasized the importance of a mutually supportive relationship between the TRIPS Agreement and the CBD, and even acknowledged the important role that disclosure requirements would have in this regard, several developed countries have nevertheless questioned whether there is clear mandate to move forth on these issues. These countries claim that Paragraph 19 of the Doha Ministerial Declaration refers to examining the relationship, rather than addressing it in any way. They also argue that, although paragraph 12 does clearly mandate negotiations, recommendations on the need to negotiate each specific implementation issue must first be made to the Trade Negotiations Committee. These technicalities may not be accurate or valid, but they do once again raise the need to highlight the importance and urgency of introducing disclosure requirements into the TRIPS Agreement.

5. The purpose of the present note is to highlight the amending the TRIPS Agreement to oblige WTO Members to require disclosure of source and country of origin of biological resources and traditional knowledge and of evidence of prior informed consent and benefit sharing under relevant national regimes in patent applications (disclosure requirements). The note will only provide a brief overview of the discussions in the Council for TRIPS to date and will address the more technical debate as to the terminology, scope, form, or consequences of non-compliance related to disclosure requirements.[4] Rather, it will focus on why disclosure requirements are essential not only to prevent the misappropriation, but also to ensure a development-oriented TRIPS Agreement. After this introduction, Section II will provide a brief background to the relationship between the TRIPS Agreement and the CBD. Then, Section III will look at three of the reasons why disclosure requirements provide an answer to the conflicts raised by the current impact of the TRIPS Agreement on the implementation of the CBD. Finally, Section IV will provide some concluding thoughts.

II.2. Background

6. The CBD is considered the single most important international agreement designed to both protect biodiversity and ensure its sustainable use. It was agreed upon during the 1992 Earth Summit and came into force in 1993. It is almost universally ratified at 188 Parties. The CBD establishes three main objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources.[5] The range of objectives was and is considered fundamental to address the conservation of biodiversity in a balanced and equitable manner. In particular, the importance of goals and provisions relating to access and benefit-sharing was emphasized by developing countries, which hold much of the global biological resources.[6] These provisions attempt to give full consideration to principles of equity and common but differentiated responsibilities, thus promoting an effective international cooperation to the protection of biodiversity. It was acknowledged, however, that the implementation of these objectives and provisions would be challenging, particularly due to the direct and indirect impact of intellectual property rules. As a

[4] An overview of negotiations during 2004 can be found in the South Centre and CIEL IP Quarterly Update, Fourth Quarter 2004. Discussion of the technical aspects of disclosure requirements can also be found in previous South Centre and CIEL publications.
[5] Convention on Biological Diversity (CBD), Article 1.
[6] The Group of Like Minded Megadiverse Countries (LMMC), for instance, represent between 60 and 70 % of the biodiversity of the planet. It is constituted by 17 members: Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela.

result, the CBD requires parties to cooperate to ensure that patents and other intellectual property rights "are supportive of and do not run counter to" its objectives.[7]

7. The TRIPS Agreement, adopted just six months after the entry into force of the CBD, did not, on the other hand, expressly address the relationship between its provisions and the CBD. [8] Nevertheless, developing countries did raise concerns about the link between the new intellectual property regime and biodiversity conservation during the negotiation about the patentable subject matter under the TRIPS Agreement, and only accepted the current text of Article 27.3 (b) with a provision for an early review – the only one provided for by the TRIPS Agreement.[9] Discussions under the review of Article 27.3 (b) indeed focused on the relationship between the TRIPS Agreement and the CBD, as well as touching upon a range of other issues repeatedly identified by developing countries as fundamental to the development dimension of the TRIPS Agreement.[10] Consequently, the Doha Ministerial Declaration referred to the relationship between the TRIPS Agreement and the CBD several times.[11] In particular, paragraph 19 instructed the Council for TRIPS to examine the relationship between the TRIPS Agreement and the CBD, guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and fully taking into account the development dimension. Moreover, as one of the outstanding implementation issues, the relationship between the TRIPS Agreement and the CBD was included in paragraph 12, that attaches utmost importance to finding appropriate solutions to these issues.

8. In that context, a number of developing countries, including Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand, and Venezuela presented, in the first meeting of the Council for TRIPS in 2004, a proposal to facilitate a more focused and result-oriented discussion on the need for coherence between the TRIPS Agreement and the CBD.[12] As the proposal explains, one of the major concerns of developing countries in regards to the TRIPS Agreement is that it allows the granting of patents for inventions that use genetic material and associated knowledge without requiring compliance with the provisions of the CBD. Consequently, the proposal aims to move forward the discussion by putting forth a checklist of elements that need to be addressed to prevent such misappropriation, developed on the basis of points made by delegations in previous discussions. These elements relate to disclosure of source and country of origin of biological resources and traditional knowledge and of evidence of prior informed consent and benefit sharing under relevant national regimes (disclosure requirements). The focus on disclosure requirements received wide and cross-regional support in the Council for TRIPS, and is also in line with the most recent assessments by other international organizations, countries, academia, and civil society.

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[7] CBD, Article 16.5.

[8] Howard Mann and Stephen Porter, *The State of Trade and Environment Law 2003: Implications for Doha and Beyond,* (IISD and CIEL, 2003).

[9] Id.

[10] For instance, other issues raised by developing countries include the patenting on life forms and the protection of plant variety through *sui generis* systems, as well as the protection of traditional knowledge and folklore.

[11] In addition to paragraphs 12 and 19, paragraph 31 (i) establishes negotiations in the Committee on Trade and Environment (CTE) on the relationship between trade rules and trade-related measures in multilateral environmental agreements, with paragraph 32 (ii) indicating the CTE to give particular attention to the relevant provisions of the TRIPS Agreement.

[12] Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand, and Venezuela, "The relationship between the TRIPS Agreement and the CBD: Checklist of issues," 2 March 2004, WTO documents IP/C/W/420 and Add. 1.

II.3. Need and Importance of Introducing Disclosure Requirements into the TRIPS Agreement

A. Preventing the grant of illegitimate patents

9. As a study commissioned by the Convention on Biological Diversity (CBD) points out, it is fairly easy to demonstrate the link between the misappropriation of genetic resources and traditional knowledge and flaws in the current patent system:

> For example, consider a scientist from a multinational corporation who visits Country A where indigenous people tell him about a natural herb that has been used for centuries to promote healing. The scientist returns to his native country… purifies the herb and patents [it] with the same claimed utility that the indigenous people had informed him of, thereby essentially "pirating" the indigenous knowledge.[13]

10. Far from a hypothetical situation, however, the number of cases of genetic resources and traditional knowledge patented without any improvement or with a value addition well below accepted benchmarks for inventiveness continues to grow. The CBD study highlights the case of turmeric, whose healing properties were known and used in India for centuries and nonetheless patented by the University of Mississippi Medical Center.[14] Other instances of biopiracy include the cases of quinoa, ayahuasca, neem, and maca.[15] In the case of maca, for example, Peru found two US patents exploiting the biochemical characteristics of the plant – grown in the mountains of Peru – which have been known and used by Peruvians since ancient times.[16] Growing concern in Peru led to the creation of a National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples, which, when it began monitoring patent databases, found several potential cases of biopiracy. A search of the Database of the Japan Patent Office turned up, for instance, 16 references to the "camu-camu," a tropical bush and fruit of Peru.[17]

11. Although disclosure requirements may not in themselves have impeded these instances of misappropriation, or indeed may not prevent all further cases of

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[13] Cynthia M. Ho, "Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights Based on Genetic Resources: A Technical Study of Implementation Issues," Final Report to the Convention on Biological Diversity (CBD), July 2003, UNEP document UNEP/CBD/WG-ABS/2/INF/2.

[14] Id.

[15] Developing countries have repeatedly called attention to and described these cases in international intellectual property fora.

[16] Begoña Venero Aguirre, "Addressing the Disclosure Requirement at the international level - The role of the TRIPS Agreement," ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement On the Road to Hong Kong WTO Public Symposium, Geneva, April 21 2005. Moreover, the Maca roots that were used for these inventions were taken from Peru and there is no evidence that such material was obtained legally or that the holders of these patents would have contemplated some kind of benefit sharing. The granting of these patents therefore runs counter to one of the three main objectives of the CBD, which is the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources".

[17] Peru, "Article 27.3(B), Relationship between the TRIPS agreement and the CBD and Protection of Traditional Knowledge and Folklore," 8 March 2005, WTO document IP/C/W/441.

misappropriation, it is widely recognized that they would significantly enhance patent examination and quality.[18] In the view of Switzerland, for instance, disclosing the source of genetic resources and traditional knowledge in patent applications would assist patent examiners and judges in the establishment of prior art, thus enabling them to avoid granting patents over claims that lack novelty or inventive step.[19] In addition, as noted by the Center for International Environmental Law (CIEL) in its comments to the US Patent and Trademark Office on improving the identification of prior art relating to traditional knowledge, submitted in the context of its challenge of the US patent on the ayahuasca vine on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and the Coalition for Amazonian Peoples and Their Environment (Amazon Coalition), the disclosure of traditional knowledge as part of prior art is crucial to achieving the objectives of innovation and scientific progress underlying the patent system.[20] By creating positive incentives for the recognition and thus preservation of traditional knowledge systems, CIEL states in its comments, such knowledge can continue to be an important resource in technologies based upon the manipulation, adaptation or use of biological resources.

[18] See, e.g., Carlos M. Correa, "The Politics and Practicalities of a Disclosure of Origin Obligation," QUNO January 2005. Correa notes that several cases of biopiracy would not have been prevented by disclosure requirements (for example, in the ayahuasca case, the application had disclosed the origin of the genetic resource and the plant patent was granted regardless) and highlights the need for a "misappropriation regime" to comprehensively address the problem. Other elements of the misappropriation regime would include prohibiting patents on elements as found or with minimum modification and a universal novelty requirement.

[19] See, e.g., Felix Addor, "Switzerland's proposals regarding the declaration of the source of Genetic Resources and Traditional Knowledge in patent applications and Switzerland's views on the Declaration of evidence of Prior Informed Consent and Benefit Sharing in Patent applications," ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement On the Road to Hong Kong WTO Public Symposium, Geneva, April 21 2005. Addor notes that disclosure requirements are particularly relevant to prior art regarding traditional knowledge, since disclosing the source would simplify searching the databases on traditional knowledge that are increasingly being established at the local, regional and national level.

[20] Center for International Environmental Law (CIEL), "Comments on Improving Identification of Prior Art - Recommendations on Traditional Knowledge Relating to Biological Diversity Submitted to the United States Patent and Trademark Office," 2 August 1999.

Other approaches

- *Pre-grant or post-grant opposition*: The UK Commission on Intellectual Property Rights noted that, while some challenges have been successful, they are costly and lengthy procedures – "it is extremely difficult and costly for developing countries to monitor and challenge intellectual property rights issued all around the world."[21] Challenging the US patent on the Enola bean, for example, was estimated to cost US$ 200,000 in legal fees.[22] It has also been noted, however, that the effectiveness of such procedures may significantly improve with the introduction of disclosure requirements.[23]
- *Databases*: In discussions in the Council for TRIPS, the United States and others have highlighted the potential for databases of genetic resources and traditional knowledge to aid in the discovery of prior art.[24] Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Peru, and Venezuela have noted, however, that, while databases "play a key role in facilitating a patent examiner's check," they cannot contain in a comprehensive and exhaustive manner all the traditional knowledge available.[25] Moreover, there are concerns regarding the trend for databases to put traditional knowledge into the public domain to ensure its protection from misappropriation.[26]
- *Contracts*: As noted in a survey prepared by the WIPO Secretariat: "Contractual agreements are, in the absence of or in addition to legislative forms of protection, often relied upon to capture benefits arising from traditional knowledge. The contractual approach, however, is also regarded as presenting some limitations, such as: the private bargain nature of contracts means they are not enforceable against third parties; disparities in bargaining power between contracting parties; high transaction costs; and, limited resources, access to legal advice and negotiating skills among some traditional knowledge holders may disable them from being able successfully to use contracts to regulate access to and secure benefit-sharing in their traditional knowledge."[27]

12. Disclosure requirements would also potentially impact the determination of patentable subject matter and entitlement to a patent. For example, disclosure requirements would facilitate ascertaining whether an application contains claims excluded from patent protection under provisions implementing Article 27.2 and Article 27.3 of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement).[28] Since patent applications may be rejected

[21] UK Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy."
[22] Lourdes Edith Rudino, "A proceso judicial, los derechos de propriedad del frijol 'Enola'," El Financiero, 10 January 2000, cited by ETC Group, "Mexican Bean Biopiracy," 17 January 2000.
[23] Brazil and India, "The relationship between the TRIPS agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge: Technical observations on issues raised in a Communication by the United States (IP/C/W/434)," 18 March 2005, WTO document IP/C/W/443.
[24] United States, "Article 27.3(b), Relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore," 26 November 2004, WTO document IP/C/W/434.
[25] Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Peru and Venezuela, "The relationship between the TRIPS agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge, 28 May 2003, WTO document IP/C/W/403.
[26] See, e.g., UNU-IAS, "The role of registers and databases in the protection of traditional knowledge," January 2004.
[27] WIPO, "Survey on Existing Forms of Intellectual Property Protection for Traditional Knowledge," 8 August 2001, WIPO document WIPO/GRTKF/IC/2/5.
[28] The CBD study, see *supra* note 13, highlights the example of the proposed changes to the Belgium Patent Act, which would exclude from patent protection, as contrary to *ordre public* and morality, any

on the ground that the applicant is not the true inventor of the claimed invention, disclosure requirements relating to genetic resources and traditional knowledge may also be relevant in this regard, by identifying groups or communities whose knowledge the claim derives from.[29]

13. Indeed, disclosure requirements related to genetic resources and traditional knowledge may enhance existing disclosure obligations under intellectual property instruments. In a study prepared for the CBD, the World Intellectual Property Organization (WIPO) notes that disclosure requirements may build on existing rationale or legal principles in the patent system.[30] Examples mentioned by WIPO include the disclosure of the source of genetic resources that is necessary to carry out the invention, the disclosure of traditional knowledge that is relevant to the validity of patent claims, and the disclosure of the origin of the traditional knowledge provided by one of the holders of that knowledge where the traditional knowledge itself forms a substantive contribution to the invention. In addition, in intellectual property law, equitable principles require authorities to refuse to grant or to enforce intellectual property rights when they would be or have been procured by fraud or deception, because not to do so would allow the intellectual property system to assist and reward the inequitable conduct. In the context of genetic resources and traditional knowledge, preventing such misuse would not only require specific disclosure obligations but also international recognition of these requirements, because the materials and information may originate in or the relevant inequitable conduct occurs in jurisdictions other than those where patents will be obtained.[31]

14. As a result, disclosure requirements are important tools for improving patent examination and grant processes and thus ensuring a well-functioning patent system. Indeed, several developing countries and least developed countries have noted that the patent system, by frequently giving rise situations in which inventions using the genetic resources or the traditional knowledge of their communities inappropriately pass the novelty or inventiveness tests or allow the exploitation of these resources or knowledge when they were obtained in an unauthorized or illegal manner, "do much to undermine the functioning of the patent system itself" and impact the ability of the countries concerned to fulfil their broader sustainable development goals.[32] Similarly, civil society

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invention developed on the basis of biological material collected or exported in breach of CBD requirements.

[29] See, e.g., Brazil, India, Pakistan, Peru, Thailand, and Venezuela, "Elements of the Obligation to Disclose the Source and Country of Origin of Biological Resource and/or Traditional Knowledge Used in an invention," 21 September 2004, WTO document IP/C/W/429. Also, the CBD study mentions 35 U.S.C. 102(f), which states that one of conditions that bars patentability is that the applicant "did not himself invent the subject matter sought to be patented." Similarly, EPC article 81 provides that "[t]he European patent application shall designate the inventor." Nevertheless, this issue is traditionally not one that patent offices independently verify.

[30] WIPO, "Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge," 2 May 2003, WIPO document WIPO/GRTKF/IC/5/10.

[31] CIEL, "CBD Request to WIPO on the Interrelation of Access to Genetic Resources and Disclosure Requirements: Observations from the Center for International Environmental Law (CIEL) on the First Draft of the WIPO Examination of the Issues," March 2005.

[32] Peru, "Article 27.3(B), Relationship between the TRIPS agreement and the CBD and Protection of Traditional Knowledge and Folklore," 8 June 2005, WTO document IP/C/W/447. Peru notes these concerns are shared by various other countries, including the Group of Like-Minded Megadiverse

groups have noted that disclosure requirements would "not only support the objectives of the CBD but also preserve confidence in the IP system. Giving monopoly rights to inventors which have bio-pirated genetic resources or traditional knowledge undermines this confidence."[33] The introduction of these requirements is particularly critical for the TRIPS Agreement in light of its objectives of contributing "to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[34]

B. Ensuring effectiveness of national measures against misappropriation

15. Disclosure requirements established at the national level are fundamental to preventing misappropriation, but they must be complemented by international measures in order to adequately achieve their objectives. In the Andean Community, for instance, decisions 391 and decision 486 establish that applications for patents must contain a copy of the contract or authorization for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or traditional knowledge originating in one of the Member Countries, and that intellectual property claims are not valid if obtained or used in violation of the terms of the contract or authorization for access.[35] Nevertheless, these provisions are considered "useless" when the misappropriation occurs in countries outside the Andean community that do not have similar provisions in their legislation: "the experience of Andean community countries shows that these national measures must be complemented by international measures such as disclosure requirements in order to be effective."[36]

16. In addition to the measures in the Andean Community, there is an increasing number of disclosure requirements in regards to genetic resources and traditional knowledge under regional and national laws, including: the 1998 Biodiversity Law of Costa Rica; the Indian Patent Second Amendment Act and Indian Biodiversity Bill; the Egyptian Patent Act; Provisional Measure No. 2.186-16 in Brazil; the European Directive on Biotechnological Inventions; the Patent Act of Norway; Implementing Regulation of the Patent Law of Romania; Patent Regulations of Sweden; the Danish Patent Act; and a draft revision of the Federal Law on Patents in Switzerland.[37] Notwithstanding, these disclosure obligations will only cover intellectual property applications made in those countries and will not be recognized and enforced by other countries in which applications for the same claim are made, hence the need for an international disclosure requirement.[38]

Countries, which has the following members: Brazil, Bolivia, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, Venezuela. The African Group has also stated that equity requires every WTO Member to prevent the misappropriation of genetic resources and traditional knowledge "through requirements for disclosure of the source of the genetic resources and traditional knowledge involved in the claimed invention." The United States, however, the United States, for instance, has rejected the notion of a problem with the legitimacy of the patent system.

[33] Berne Declaration, Comment on the Draft of the 'Examination of Issues relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Right Applications," March 2005.

[34] TRIPS Agreement, Article 7.

[35] These Decisions are available, inter alia, on the websites of the Comunidad Andina and of INDECOPI.

[36] Begona Venero Aguirre, *supra* note 16.

[37] The following summary follows descriptions made by Carlos Correa, WIPO, and Michael Blakeney in different works.

[38] Carlos M. Correa, *supra* note 18.

17. As a result, introducing disclosure requirements in existing international patent rules – which do not include such obligations – is progressively more important. Multilateral discussions on disclosure requirements are currently taking place in various intellectual property fora, including the Council for TRIPS and the Standing Committee on the Law of Patents (SCP), the Working Group for Reform of the Patent Cooperation Treaty (Working Group for PCT Reform), and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) in WIPO. While advancing disclosure requirements in these different international fora may have value in terms of consistency and complementarity, discussions in the context of the Council for TRIPS have been considered priority by developing countries and civil society organizations.

18. The TRIPS Agreement is indeed considered the most appropriate instrument to establish these requirements at the international level.[39] An amendment to the TRIPS Agreement would ensure that disclosure requirements would become mandatory for all WTO Members and be subject to the WTO's dispute settlement understanding.[40] In addition, regardless of the discussions in other international fora, addressing the relationship between the TRIPS Agreement and the CBD in the context of the WTO is fundamental as it is an outstanding implementation issue, which must be resolved to overcome imbalances in the TRIPS Agreement that developing countries continue to grapple with. As has been repeatedly noted, without addressing implementation issues and concerns, the Doha Work Programme, dubbed the "Development Round," would not amount to much from the development perspective. In this regard, while concerns have been raised as to whether an agreement can be reached on a mandatory requirement or whether developing countries should be willing to "pay" for a concession on this issue, it is clear that a mandatory solution would not only been an increased legal certainty to access to genetic resources and traditional knowledge, but also constitute "a clear political sign for the willingness of the international community to achieve the policy objectives of the disclosure requirement."[41]

C. Promoting the coherence and supportiveness of the TRIPS Agreement with international law and broader public policies

19. Despite the recognition of the nature of intellectual property as a tool for public policy rather than as an end in itself, there seems to be a historical tendency to consider the intellectual property system as insular from broader policy considerations.[42] In WIPO, the response to this unfortunate trend has been the call for a "WIPO Development Agenda" to ensure that WIPO activities – from norm-setting to technical assistance – advance development-oriented results, in particular internationally agreed goals such as the Programme of Action for the Least Developed Countries for the Decade 2001-2010, the Monterey Consensus, the Johannesburg Declaration on Sustainable Development and the Plan of Implementation agreed at the World Summit on Sustainable Development, the Declaration of Principles and the Plan of Action of the first phase

[39] Id.

[40] Begona Venero Aguirre, *supra* note 16, points out that "even if there was a negotiating mandate in WIPO, developed countries may choose not to be members of that particular instrument and the objective of making the disclosure requirements mandatory at an international level would not be achieved. This is a choice they wouldn't have in the WTO context. If the TRIPS Agreement was modified in order to include mandatory disclosure requirements, this would reach all its members."

[41] Martin A. Girsberger, "Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications," International Expert Workshop on Genetic Resources and Access and Benefit-Sharing, Mexico, October 2004.

[42] Graeme Laurie, " Should There Be an Obligation of Disclosure of Origin of Genetic Resources in Patent Applications? – Learning Lessons from Developing Countries" 2005.

of the World Summit on the Information Society, and the Sao Paulo Consensus adopted at UNCTAD XI.[43] In the WTO context, although the Declaration on the TRIPS Agreement and Public Health recognized the need for the TRIPS Agreement to be part of the wider national and international action on public health problems, considerably more needs to be done to ensure its provisions adequately advance broader policy goals and internationally agreed rules and objectives.[44]

20. Ensuring the supportiveness of the TRIPS Agreement with regard to the objectives and principles of the CBD is particularly significant, given that the conservation and sustainable use of biodiversity have been recognized as essential in achieving sustainable development goals.[45] In this regard, the United Nations (UN) Sub-Commission on Human Rights, for example, has recognized that conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights, including in relation to the misappropriation and reduction of indigenous and other local communities' control over their genetic resources and traditional knowledge.[46] Developing countries have also called attention to this conflict and the important role that disclosure requirements should play as a mechanism for increased transparency and thus for increased compliance with the objectives and principles of the CBD.[47] In addition, the UK Commission on Intellectual Property Rights emphasized the need for intellectual property to support the objectives of the CBD and argued that "no person should be able to benefit from any intellectual property rights consisting of, or based on, genetic resources or associated knowledge obtained in an illegal manner, or used in an unauthorized way."[48]

21. Consequently, the importance of introducing disclosure requirements in the TRIPS Agreement is not only legal, but also social, economic, and political. Peru, for example, has

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[43] Group of Friends of Development, "Proposal to Establish a Development Agenda for the World Intellectual Property Organization (WIPO): An Elaboration of Issues Raised in Document WO/GA/31/11," 6 April 2005, WIPO document IIM/1/4.

[44] Graeme Laurie, *supra* note 42, states in this regard that: "While we have, at least, reached the stage of accepting – and agreeing – the need to examine the dynamics between the patent system and the CBD regime, our policy options are very much constrained by an unwillingness in certain quarters to accept a *reality*: which is the interconnectedness of the patent regime, not only to CBD, but, potentially, to many other legal and ethical frameworks."

[45] The Johannesburg Declaration on Sustainable acknowledged the importance of biodiversity to human well-being and the livelihood and cultural integrity of people, and stated the loss of biodiversity can only be reversed if local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources, in accordance with Article 15 of the CBD.

[46] UN Sub-Commission on Human Rights, "Intellectual property rights and human rights," 17 August 2000, Sub-Commission on Human Rights resolution 2000/7. The Sub-commission noted the CBD echoes the International Covenant on Economic, Social and Cultural Rights on the right to self-determination and on the balance of rights and duties inherent in the protection of intellectual property rights, and its provisions relating to, *inter alia*, the safeguarding of biological diversity and indigenous knowledge relating to biological diversity, and the promotion of the transfer of environmentally sustainable technologies.

[47] Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, and Venezuela, "The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the obligation to disclose evidence of prior informed consent under the relevant national regime," 10 December 2004, WTO document IP/C/W/438. These countries pointed out that "prior informed consent by providers of genetic resources and arrangements for fair and equitable benefit-sharing are critical issues for biodiversity rich countries as well as local and indigenous communities. In this regard, the TRIPS Agreement and implementing national legislations have a critical role to play to ensure that the researchers and bio-prospectors that use the patent system fulfil these requirements."

[48] Commission on Intellectual Property Rights, *supra* note 21.

highlighted the economic significance of disclosure requirements for developing countries, since these requirements would promote a trust-based relationship between countries providing and using genetic resources and traditional knowledge and thus improve the conditions of access and commercial exploitation.[49] The social and political relevance of disclosure requirements derives, for example, from the recognition and furtherance of the principle of prior informed consent (PIC). The right of States to PIC is an essential principle in international relations as a necessary corollary to the permanent sovereignty of States over their natural resources.[50] The acknowledgement of PIC in Article 15 of the CBD is thus not only as an integral element of an appropriate access to genetic resources, but also recognition of the sovereignty of countries over their natural resources. The right of indigenous peoples and other local communities to PIC also has social, cultural, and human rights implications.[51] Although the CBD does not refer expressly to PIC of indigenous and other local communities, article 8 of the CBD establishes that each contracting party must respect, preserve and maintain knowledge, innovation and practices of indigenous and local communities and encourage the equitable sharing of the benefits arising from their utilization. PIC is considered critical to securing these rights.

II.4. Conclusion

22. Concerns about the impact of the TRIPS Agreement on the CBD were raised even as Article 27.3 (b) was being drafted. Since the review of Article 27.3 (b) began, moreover, developing countries have continued to call for the TRIPS Agreement to adequately recognize and support the objectives and principles of the CBD, as well as actively put forth several ideas and proposals as to the most adequate solutions. In this regard, the discussions that began with the Checklist Process have been the most comprehensive and constructive thus far, with significant substantive contributions from a range of developing and developed countries. In parallel, the misappropriation of genetic resources and traditional knowledge continues unabated.

23. As the Sixth Ministerial Conference draws near, the firm foundation of these discussions should be drawn on to achieve at last an effective solution to the legal, economic, social, cultural, and environmental problems raised by the gaps in the international intellectual property system that continue to allow misappropriation. If such a solution is out of reach, then any decision taken in Hong Kong should at least contain a clear mandate on the introduction of disclosure requirements in the TRIPS Agreement, as well as a concrete process to move forward on that mandate before the end of the Doha Round of negotiations. The urgency and significance of the issue for the people of developing countries requires nothing less.

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[49] IP/C/W/447, *supra* note 32.

[50] Article 3 of the CBD recognizes "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies." The right of States to some form of prior informed consent is thus recognized in various contexts, including the transboundary movements of hazardous and toxic materials, genetically engineered organisms, and persistent organic pollutants.

[51] Anne Perrault and Maria Julia Oliva, "Prior Informed Consent and Access to Genetic Resources," ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement On the Road to Hong Kong WTO Public Symposium, Geneva, April 21 2005. Perrault and Oliva note that official interpretations of several international instruments, including the Convention on the Elimination of Racial Discrimination (CERD), the American Convention on Human Rights, and the International Covenant on Economic, Social, and Cultural Rights, indicate that prior informed consent of indigenous peoples is central to effectuating rights within these conventions, including the right to non-discrimination and the right to property. In addition, PIC is indeed viewed by indigenous and other local communities as central to securing their rights in the context of logging, mining, resettlement, dam building, and access to genetic resources activities.

III. OVERVIEW OF RELEVANT IP DEVELOPMENTS IN VARIOUS FORA

III.1. World Trade Organization (WTO)

24. There was little movement on discussions in the Council for Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Working Group on Trade and Transfer of Technology (WGTTT) during the third quarter of 2005, as intellectual property-related issues are not in the spotlight in the lead-up to **Sixth Ministerial Conference, to be held from December 13 – 18, 2005.** As a result, the debate and positions on the issues remain largely unchanged. Nevertheless, since certain intellectual-property related issues remain fundamental components of negotiations, including the relationship between the TRIPS Agreement and the Convention for Biological Diversity (CBD) and geographical indications, it is likely discussions will intensify in the next few weeks. [52] In general, the **General Council meeting on October 19-20** is considered to be the moment in which the level of ambition for the Sixth Ministerial Conference will be defined.[53]

A. Council for TRIPS

25. Although the Council for TRIPS did not meet during the third quarter of 2005, informal consultations were held on a number of issues. **The next meeting of the Council for TRIPS is scheduled for 25 – 26 October 2005.**

A.1 TRIPS and Public Health: Implementation of paragraph 11 of the 30 August Decision[54]

26. In an effort to narrow the differences in the positions that for long have remained unchanged, the Chairman of the Council for TRIPS, Ambassador Choi Hyuck, Permanent Representative of the Republic of Korea, held informal consultations with Members. However, an agreement has yet to be reached among Members. One of most contentious issues remains the relationship between the 30 August Decision and the Statement of the Chairman of the General Council delivered on the adoption of this Decision. The African Group continues opposed to including the Chairman's statement as part of the amendment or in a footnote.[55] On the other hand, the United States, Japan and European Union maintain that the Chairman's Statement, while not part of the 30 August Decision, represents the shared understanding of Members States of the Decision, and thus should be referenced in any solution. Another contentious issue has been the call from the United States and others for direct transposition of the 30 August Decision into Article 31 of the TRIPS Agreement, as opposed to incorporating elements "where appropriate" as advanced by the African Group and supported by other developing countries. A new development in this regard was the informal paper circulated by the European Union in July, which proposes incorporating the 30 August Decision into the TRIPS Agreement by adding a

[52] For an in depth analysis of pending intellectual property issues and related development concerns in the WTO context, please see South Centre and CIEL IP Quarterly Update, Fourth Quarter 2004, Part II, available at www.southcentre.org and www.ciel.org.
[53] Alexandra Strickner and Carin Smaller, TIP/IATP, "The Twists and Turns of Trade Negotiations: Hong Kong Approaches," Geneva Update, October 6, 2005.
[54] See WTO Document WT/L/540.
[55] See Communication from Rwanda on behalf of the African Group, "The TRIPS Agreement and Public Health," 6 April 2005 (WTO document IP/C/W/445).

new subparagraph 2 to Article 31 referring to an Annex that would be introduced with all elements of the 30 August Decision, except the preamble and paragraph 11. The Chairman of the Council of TRIPS continues to hold informal consultations on this issue, with the view of reaching an agreement by the time of the next session of the Council for TRIPS in October.

A.2 Relationship between the TRIPS Agreement and the CBD: Disclosure Requirements

27. Please see Section II for an analysis of the discussion on disclosure requirements in the lead up to the Sixth Ministerial Conference.

B. Special and Differential Treatment Proposals referred to Council for TRIPS

28. The Chair of the Council for TRIPS reported in July to the WTO General Council on the state of the proposals on Special and Differential Treatment related to intellectual property that have been referred to the Council for TRIPS.[56] There are two such proposals. One is a proposal by the Least Developed Countries (LDCs) concerning the extension of their transition period under Article 66.1 of the TRIPS Agreement. It states that if at the end of the transition period the LDC Member has not established a viable technological base, a further extension of transition period shall be automatically granted by the TRIPS Council on request by the LDC Member. The second proposal, submitted by the African Group contains two parts. First, the proposal for an extension of the transition period under Article 65.4 of the TRIPS Agreement. Secondly, concerning Article 70.9, to clarify that there is no requirement to grant exclusive marketing rights unless marketing approval is granted.

29. The Chair reported that the Council for TRIPS reiterated its recommendation concerning the second part of the African Group proposal on exclusive marketing rights.[57] The Chair also provided a factual report on the state of the other two proposals (the proposal by LDCs concerning Article 66.1 and the African Group proposal concerning Article 65.4). He reported that these proposals have been on the agenda of the last three Council's meetings (in December 2004, March and June 2005) but no delegation has taken up these proposals at any of the meetings.

C. Special Session of the Council for TRIPS

30. The report of the Chairman of the Special Session of the Council for TRIPS to the Trade Negotiations Committee noted that the level of activity in the negotiations on the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits had increased.[58] Nevertheless, he stated that "the differences of view on the different proposals on the table…appear to be as large as ever and not to have narrowed since prior to

[56] See Report to the General Council by the Chair, WTO document IP/C/36. The proposals are reproduced in the report.
[57] This proposal forms part of the 28 agreement-specific proposals on which Members agreed in principle in 2003 in the context of the Cancun Ministerial. The text is reproduced in Annex II of the Report to the General Council by the Chair, WTO document IP/C/36.
[58] See Report by the Chairman to the Trade Negotiations Committee, WTO document TN/IP/13.

Cancun."[59] The report by the Chairman of the Trade Negotiations Committee to the General Council further reflected the deadlock in these discussions.[60]

31. For the last meeting of the Special Session, which took place on 16 September, the WTO Secretariat prepared a comparative text of the three current proposals to facilitate discussions.[61] However, the wide divergence of positions was again clear and the meeting ended without any substantial progress. Notwithstanding, some observers expect that the EU will push for an agreement on geographical indications at the Hong Kong Ministerial Conference,[62] in particular, given its September 15 agreement on wine with the United States, which holds one of the most divergent positions on geographical indications.[63] The EU-US agreement does not address the use of geographical indications, but it does provide for a second phase of negotiations to begin 90 days after the entry into force of this agreement, which would address other outstanding issues among parties.[64] **The next meeting of the Special Session is scheduled for October 27 – 28, 2005.**

D. Working Group on Trade and Transfer of Technology (WGTTT)

32. The last meeting of the Working Group on Trade and Transfer of Technology (WGTTT) took place on July 6, 2005.[65] A new proposal was submitted by Cuba highlighting the need for the Working Group to focus on identifying concrete and practical steps that should be taken within the WTO framework in order to facilitate the transfer of technology to developing countries.[66] The proposal calls for the Working Group to step up its work in the run up to the Hong Kong Ministerial Conference and agree on concrete recommendations for adoption at the Ministerial Conference on the basis of the recommendations made by a group of developing countries.[67] In particular, it establishes that proposals for concrete solutions should be submitted at least in regard to two recommendations, namely to 1) carry out the examination of the different provisions contained in various WTO agreement relating to technology transfer, with a view of making these provisions operational and meaningful from the point of view of developing countries, including Least Developed Countries, and 2) to look the provisions contained in various WTO agreements which may have the effect of hindering transfer of technology to developing countries and come up with recommendations as to how to mitigate the negative effects of these provisions.

33. Many developing countries agreed with this approach. However, several developed countries maintained that the relationship between trade and transfer of technology remained unclear and did not agree with focusing work on the basis of the two recommendations. The

[59] Supra, note 12, Para 3.
[60] See Report by the Chairman of the Trade Negotiations Committee to the General Council, WTO Document TN/C/5, pp. 9.
[61] See WTO document TN/IP/W/12.
[62] See Bridges Weekly Reporting, "Scant Progress in GI Discussions", September 21, 2005.
[63] See European Commission, "EU-US Wine Trade Accord will Enhance Protection of European Names and Safeguard EU's Biggest Market", Press Release IP/05/1145 and Press Release of the Office of the United States Trade Representative, "United States and European Community Reach Agreement on Trade in Wine", 15 September 2005. The agreement would limit the use of certain EU geographic names such as Champagne and Burgundy, currently considered as semi-generic names in the United States.
[64] The text of the Agreement is available in the website of the Office of the United States Trade Representative, www.ustr.gov.
[65] See Minutes of the Meeting of 6 July 2005, WTO document WT/WGTTT/M/12.
[66] See Communication from Cuba, WTO document WT/WGTTT/W/9.
[67] See WTO document WT/WGTTT/W/6.

Chairman has been holding informal consultations in order to advance in the discussions, particularly on the issue of the possible recommendations to be submitted to the forthcoming Hong Kong Ministerial Conference. **The next meeting of the Working Group is scheduled for October 11, 2005.**

III.2. World Intellectual Property Organization (WIPO*)*

34. The 41st WIPO Assemblies were held from 26 September to 5 October 2005. Member States were asked to provide direction on a number of issues of crucial importance to developing countries and civil society.

A. Matters Concerning a Development Agenda for WIPO

35. Given the third session of the Inter-sessional Intergovernmental Meeting (IIM), held from 20 to 22 July, did not reach an agreement on the future of discussions on the WIPO Development agenda, the issue was forwarded for consideration by the WIPO Assemblies. Discussions during the WIPO Assemblies were difficult, with most country positions remaining unchanged or becoming even more inflexible. An additional complication was the link made by some developed countries between the future of the IIM process and the potential advances on the Substantive Patent Law Treaty (SPLT). Nevertheless, eventually two alternatives for a decision were put forth: 1) One, supported by Group B, which called for a new body to be established for discussions of the WIPO Development Agenda – subsuming both the Permanent Committee on Cooperation Related to Intellectual Property (PCIPD) and the IMM process; and 2) The other, proposed by India and supported by a number of developing countries, asking for an ad hoc Task Force on Development reporting directly to the 2006 Assemblies.

36. The final decision created a Provisional Committee to replace the current IIM in carrying on discussions of the Development Agenda. Two one-week sessions of the Provisional Committee will be held in 2006, which should forward the next meeting of the WIPO Assemblies any recommendations. This continuation process is meant to accelerate and complete the work achieved until now by the IIM. In this regard, the submission of any new proposals should be completed by the first session of the Provisional Committee. The PCIPD will cease to exist.

B. Establishment of a New Work Plan for the Standing Committee on the Law of Patents (SCP)

37. After failing to reach agreement in the last WIPO Assemblies, consensus was reached as to a way forward that would enable adequate consideration of developing country concerns. The four-step agreement includes:

(i) **A three-day Informal Open Forum, to be held in Geneva in the first quarter of 2006. Proposals from Member States on issues and speakers will be accepted until November 15, 2005;**

(ii) A three-day informal session of the SCP, to be held after the forum in Geneva, to agree on a work program for the SCP and will take into account the discussion of the forum WIPO will provide limited financial assistance for the participation of developing countries;

(iii) An ordinary session of the SCP to commence work as agreed in the informal session; and

(iv) Consideration of progress by the 2006 WIPO Assemblies.

C. Standing Committee on Copyright and Related Rights (SCCR)

38. Differences remained clear in discussions during the WIPO Assemblies as to the proposed Broadcasting Treaty, with some countries asking for more time to discuss the possible consequences of new rights for broadcasting organizations, particularly for developing and least developed. Additionally, concerns were raised regarding the possible negative impact of an extra layer of broadcasting rights for access to knowledge and information and the public domain. As for the potential inclusion of webcasting as part of any future Diplomatic Conference, a clear majority of countries believed it was premature. Nevertheless, the WIPO Assemblies decided to enable the 2006 Assemblies "to recommend the convening of a Diplomatic Conference in December 2006 or at an appropriate date in 2007" on the basis that an agreement could be reached on a Basic Proposal during two additional meetings of the SCCR. **The next meeting of the SCCR will take place from November from 21 to 23, 2005.**

D. Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

39. The WIPO Assemblies extended the IGC mandate until 2007 as had been proposed by the Eight Session of the IGC. Notwithstanding, several developing countries expressed concern on the pace of negotiations asking for more focused and result-oriented debates. In particular, future renewal of the mandate during the next budgetary biennium may depend on concrete results from the deliberations under the current mandate.

E. CBD request to WIPO on Disclosure Requirements in Intellectual Property Applications

THE WIPO ASSEMBLIES DECIDED TO TRANSMIT THE WIPO RESPONSE TO THE CBD REQUEST TO THE NEXT CONFERENCE OF THE PARTIES OF THE CBD.

III.3. Other Multilateral For a

A. United Nations Conference on Trade and Development (UNCTAD)

40. UNCTAD has published its annual **Trade and Development Report** titled "New Features of Global Interdependence", highlighting increasing global trade imbalances.[68] The report expresses concern that continued dependence on developed-country markets exposes developing countries to possible pressure to link better access to those markets with binding commitments on other areas. These include the protection of intellectual property and open-door policy for Foreign Direct Investment (FDI), which also entails the risk of increasingly narrowing the policy space for developing countries.[69]

[68] See UNCTAD Trade and Development Report 2005, "New features of global interdependence", http://www.unctad.org/Templates/webflyer.asp?docid=6086&intItemID=3453&lang=1&mode=downloads.
[69] Supra, note 22, pp.154.

41. The UNCTAD **World Investment Report** 2005 likewise discusses the role of intellectual property, in the context of current trends on foreign direct investment (FDI) and the internationalization of research and development (R&D) by transnational corporations (TNCs) and its developmental effects.[70] In this respect, one of the conclusions of the report is that "the attractiveness of a location for conducting R&D may increase if the IPR regime is more effective, but a strong IPR regime is not necessarily a prerequisite for TNCs to invest in R&D. The policy challenge is to implement a system that encourages innovation and helps to secure greater benefits from such activity…At the same time, in order to balance the interests of producers and consumers, IPR protection needs to be complemented by appropriate competition policies."[71] The report also discusses, among other related issues, the need for governments to take into account their countries' economic needs as well as their capacity for implementation in designing IPR policy, and for additional technical assistance and capacity building to be provided to developing countries.[72]

42. On September 29, the Trade and Development Board held a half-day of informal hearings with civil society and private sector organisations that have observes status with UNCTAD. The issues discussed included the review of developments in TRIPS negotiations, in particular those issues that are of particular concern to developing countries.[73] Participants stressed that the importance of intellectual property in terms of access of developing countries to medicines, education and other essential goods and emphasized the role of UNCTAD as the coordinating agency on science, technology and innovation issues within the United Nations to help ensure that the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) was implemented in a manner supportive of public health and the protection of traditional knowledge and folklore. Specifically, participants suggested that UNCTAD could assist in intellectual property and sustainable development issues in three areas: (a) strengthening and mainstreaming a balanced holistic approach towards intellectual property and development into all of its work and activities; (b) drawing attention to particular issues of fundamental importance to developing countries; (c) promoting coherence between the work of UNCTAD on intellectual property and development and that of other UN organizations. The outcome of the informal hearings was forwarded to the Trade and Development Board to input to its discussions. The UNCTAD Trade and Development Board met on October 3 – 14, 2005.

B. United Nations Educational, Scientific and Cultural Organization (UNESCO)

43. In the 33rd session of the General Council in October 2005, the Director General of UNESCO will present for adoption a Preliminary Draft Convention on the Protection of the Diversity of Cultural Contents and Artistic Expressions.[74] The Preliminary Draft Convention was finalized at the May –June final meeting of the Intergovernmental Committee of Experts on the Convention on the Protection of the Diversity of Cultural Contents and Artistic Expressions, which recommended to the Director General that the draft be submitted for adoption without

[70] See UNCTAD World Investment Report 2005, "Transnational Corporations and the Internationalization of R&D", http://www.unctad.org/Templates/WebFlyer.asp?intItemID=3489&lang=1.
[71] Supra, note 24, Overview, pp.31.
[72] Supra, note 24, pp.209 – 210, and 233- 235.
[73] See Provisional Agenda, www.unctad.org/Templates/meeting.asp?intItemID=2068&lang=1&m=10742.
[74] See "Preliminary Report by the Director General Setting Out the Situation to be Regulated and the Possible Scope of the Regulating Action Proposed, accompanied by the Preliminary Draft of a Convention on the Protection of the Diversity of Cultural Contents and Artistic Expressions", UNESCO document 33 C/23,http://portal.unesco.org/en/ev.phpURL_ID=28354&URL_DO=DO_TOPIC&URL_SECTION=201.html.

changes. The draft convention now contains no substantive or declarative provisions regarding intellectual property, only a mention in the preamble. Over the drafting process, several developing country Member countries and observers expressed concern regarding such references.

C. United Nations Development Programme (UNDP)

44. The UNDP **Human Development Report** 2005 raises concerns with respect to the effects of the TRIPS Agreement and other intellectual property obligations contained in regional and bilateral free trade agreements, and more generally, on the effects of intellectual property rules on human development.[75] For example, the report states that the TRIPS Agreement as well as "TRIPS plus" rules contained in regional and bilateral agreements "strike the wrong balance between the interest of technology holders and the wider public interest"[76] and that "the TRIPS Agreement arguably should not have been brought on to the WTO agenda."[77] Furthermore, the TRIPS Agreement threatens to widen the technological divide between technology rich and technology poor countries, given the rising costs of technology imports due to increase pricing of patent technologies and the raising cost of technology transfer.[78] It also notes that the human development threats posed by the TRIPS Agreement are especially pronounced in public health, and that the challenge now is to strengthen the public health provisions in the TRIPS Agreement, increase the scope for technological innovation, and for developed countries to act on the TRIPS commitment to help finance technology transfer.[79]

D. The Economic and Social Council **(ECOSOC)**

45. At the June 29 – July 27 Substantive Session of ECOSOC 2005, and in view of the 2005 World Summit on 13 – 14 September[80], the Secretary General presented a report on "Achieving the internationally agreed development goals, including those contained in the Millennium Declaration, as well as implementing the outcomes of the major United Nations conferences and summits: progress made, challenges and opportunities".[81] The report, which incorporates inputs from a number of relevant UN organisations, makes several recommendations on issues related to intellectual property.

46. On TRIPS and public health, the report notes that "the flexibility contained in TRIPS in addressing public needs, such as access to essential medicines, ought to be utilized more fully and effectively for which political will need to be demonstrated."[82] The report also asserts that one of the mayor challenges for developing countries in the area of science and technology is the "high

[75] See Human Development Report 2005, "International cooperation at a crossroads: Aid, trade and security in an unequal world", http://hdr.undp.org/.
[76] Supra, note 29, pp.135.
[77] Supra, note 29, pp.148.
[78] Supra, note 29, pp.135.
[79] Supra, note 29, pp.148.
[80] The World Summit 2005 refers to the high-level review by the UN General Assembly of the progress made in the implementation of the United Nations Millennium Declaration and the internationally agreed development goals. See http://www.un.org/ga/59/hl60_plenarymeeting.html.
[81] See Report of the Secretary-General, "Achieving the internationally agreed development goals, including those contained in the Millennium Declaration, as well as implementing the outcomes of the major United Nations conferences and summits: progress made, challenges and opportunities", ECOSOC document E/2005/56, http://www.un.org/docs/ecosoc/documents.asp?id=846.
[82] Supra, note 24, Para 24.

concentration of technology generation in developed countries and overly protective IP rights regimes and global rules"[83] and that "intellectual property protection systems need to be designed that take into account the special needs of developing countries."[84]

E. UN Global Round Table Forum on Science and Technology for Development

47. The United Nations Information and Communication Technologies Task Force (UN ICT Task Force) and the United Nations Millennium Project, in association with the United Nations Fund for International Partnerships (UNFIP) organized on 13 September 2005 a Global Roundtable Forum on "Innovation and Investment: Scaling Science and Technology to Meet the Millennium Development Goals (MDGs)".[85] High-level representatives from governments, the private sector, civil society and academia participated in the forum, which focused on the critical role of science, technology and innovation, especially information and communication technologies, in scaling-up grassroots, national and global responses to achieve the MDGs.[86] The Chairman of the high-level segment, H.E. Pervez Musharaff, President of Pakistan and ECOSOC President, stated that "the TRIPS Agreement should be reviewed with a view to enhancing its contribution to development."[87]

F. The United Nations Human Rights Bodies and Committees

48. The Committee on Economic, Social and Cultural Rights (CESCR) at its 35th session from 7 - 25 November 2005[88] will consider the Draft General Comment on article 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Article provides for "the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author". The draft general comment has been subject of criticism among organisations working on intellectual property and development, in particular because the draft does not provide enough clarity on the appropriate distinction between intellectual property rights and the human right protected under Article 15.1 (1)(c).

G. World Summit on the Information Society (WSIS)

49. The second WSIS will be held in Tunisia, from 16 – 18 November 2005. An important input is the report of the Working Group on Internet Governance (WGIG), submitted on July 15.[89] One of the "public policy issues" which the report identifies as relevant to Internet

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[83] Supra, note 24, Para 79.
[84] Supra, note 24, Para 82.
[85] See UN Press Release DEV/2545/PI/1675, http://www.un.org/News/Press/docs/2005/note5961.doc.htm.
[86] An informal summary of the Global Roundtable Forum "Innovation and investment: scaling science and technology to meet the Millennium Development Goals", http://www.unicttaskforce.org/perl/documents.pl?id=1557.
[87] Supra, note 39, pp.2.
[88] See Draft Programme of Work of the CESCR, http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/E.C.12.2005.L.2.En?Opendocument.
[89] The first phase of the WSIS and requested the United Nations Secretary-General to establish a Working Group on Internet Governance (WGIG). The WGIG was then asked to present the result of its work in a report "for consideration and appropriate action for the second phase of the WSIS in Tunis 2005. For the final report of the WGIG, see http://www.wgig.org/.

governance and on which it makes recommendations is Intellectual Property Rights. However, the report does not go into detail on the relationship between intellectual property rights and the different issues identified as those of main importance for Internet Governance. The report includes one paragraph (23) on the application of intellectual property rights to cyberspace, which reflects the wide divergence of views on this issue.[90]

50. In preparation for the Summit, the third meeting of the Preparatory Committee (PrepCom-3) was held on September 19-30, 2005.[91] While most of the discussion of PrepCom-3 centered on the future governance of the Internet, issues such as open source and proprietary software; access to information; and the importance of human rights and fundamental freedoms for the Information Society were also addressed. In fact, several references to open source software in negotiating text for the second WSIS were agreed to. Paragraph 21 of the Political Chapeau, for example, refers to the importance of governments, the private sector, civil society, the scientific and academic community, and users to utilize the various technologies and licensing models in accordance with their interests and needs. In addition, the text reiterates "the need to encourage and foster collaborative development, inter-operative platforms and free and open source software, in ways that reflect the possibilities of different software models, notably for education, science and digital inclusion programs." Paragraph 70 of chapter on Internet Governance also supports the development of software that enables the user to choose among different software models, including open-source, free, and proprietary software.[92] Other relevant part of the document are still under negotiation, including paragraph 11 of the Political Chapeau, which refers in its actual drafting to the strengthening of global knowledge while removing obstacles to "equitable access to information" in economic, social political, health, cultural, educational and scientific activities.

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[90] Paragraph 23 states the following: "while there is agreement on the need for balance between the rights of holders and the rights of users, there are different views on the precise nature of the balance that will be most beneficial to all stakeholders, and whether the current IPR system is adequate to address the new issues posed by cyberspace. One the one hand, intellectual property rights holders are concerned about the high number of infringements, such as digital piracy, and the technologies developed to circumvent protective measures to prevent such infringements; on the other hand, users are concerned about market oligopolies, the impediments to access and the use of digital content and the perceived unbalance nature of current IPR rules".

[91] See WSIS website, http://www.itu.int/wsis/preparatory2/pc3/index.html.

[92] Paragraph 27 of the Declaration of Principles issued during the Geneva fase of WSIS states that "Access to information and knowledge can be promoted by increasing awareness among all stakeholders of the possibilities offered by different software models, including proprietary, open-source and free software, in order to increase competition, access by users, diversity of choice, and to enable all users to develop solutions which best meet their requirements. Affordable access to software should be considered as an important component of a truly inclusive Information Society". While the Plan of Action made reference in Sections C3 e) and C8 o). (e) "Encourage research and promote awareness among all stakeholders of the possibilities offered by different software models, and the means of their creation, including proprietary, open-source and free software, in order to increase competition, freedom of choice and affordability, and to enable all stakeholders to evaluate which solution best meets their requirements. C3. Access to information and knowledge" and o) "Governments, through public/private partnerships, should promote technologies and R&D programmes in such areas as translation, iconographies, voice-assisted services and the development of necessary hardware and a variety of software models, including proprietary, open source software and free software, such as standard character sets, language codes, electronic dictionaries, terminology and thesauri, multilingual search engines, machine translation tools, internationalized domain names, content referencing as well as general and application software.

51. Even if some progress has been achieved on clearing different chapters, large sections of the text still remained in square brackets (around 50% of the text has not reach consensus in this PrepCom) and negotiating procedures had to be foreseen before the Tunis phase of the World Summit on the Information Society (WSIS). Therefore, **PrepCom-3 was suspended and will be reconvened for a three-day session, from 13 to 15 November 2005, principally to attempt to reach an agreement on Chapter 3 on Internet Governance. Meanwhile, in Geneva the inter-sessional open-ended negotiation group (Negotiation Group) will hold two consecutive sessions from 24 to 28 October 2005**.[93]

F. Food and Agriculture Organization (FAO)

52. The Contact Group for the drafting of the Standard Material Transfer Agreement (SMTA) held its first meeting on July 18 – 25, 2005.[94] The Contact Group reviewed the draft SMTA and adopted the definite First Draft SMTA. In order to complete the preparation of the agreement the Contact Group agreed to hold a further meeting in late 2005 or early 2006.

53. The Third Session of the Intergovernmental Technical Working Group on Plant Genetic Resources for Food and Agriculture (ITWG-PGR) will be held on October 26 – 28 2005. The Working Group, a subsidiary body of the Commission on Genetic Resources for Food and Agriculture (CGRFA) has the mandate of identifying and advising on activities undertaken by FAO to support the work of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[95]

III.4. Regional and Bilateral Trade Agreements with Intellectual Property Provisions

54. The following section highlights the latest developments in the bilateral and regional free trade negotiations of the United States and Europe with developing country counterparts on in the third quarter of 2005, as they relate to intellectual property.

A. Free Trade Agreements involving the United States

US - CAFTA.

55. The US House of Representatives passed on July 27 the Central American Free Trade Agreement-Dominican Republic (CAFTA-DR) by a narrow margin of 217 to 215.

[93] Since there was a decision coming from this PrepCom to split the Summit outcome into two parts, a political and a operational document, the first session of the Negotiation Group, on 24 and 25 October 2005, will direct its attention to negotiations on the Political Chapeau and on the paragraphs remained in brackets of Chapter 2 of the Operational Part, and in its second session, from 26 to 28 October 2005, the Negotiation Group will aim to finalize Chapters 1 and Chapter 4 of the Operational Part.
[94] For the report of the First Meeting of the CGRFA, document CGRFA/IC/CG-SMTA-1/05/REPORT, see www.fao.org/ag/cgrfa/cgmtal.htm.
[95] For more information on the Third Session of the ITWG/AnGR, see www.fao.waicent/FaoInfo/Agricult/AGP/AGPS/pgr/ITWG3rd/docsp1.htm.

US-Andean FTA.

56. The negotiations for a free trade agreement among the United States and Colombia, Ecuador and Peru that started in 2003 have greatly intensified in the third quarter 2005. An agreement now seems likely to be reached by mid-November.[96] In this regard, a meeting of heads of state is now scheduled for October 11 to evaluate the state of the FTA negotiations. **A political round of talks will take place in Washington from October 19 to 21, 2005. The next round of negotiations (potentially the last) is expected for the third or fourth week of November.**

57. The negotiating round held in Miami on July 18-22 advanced on two of the 24 issues under negotiations; customs procedures and competition policy. The latest (12th round) of negotiations ended on September 23 with preliminary agreements having been reached on certain issues related to services, market access and technical assistance. Intellectual property related issues have proven along with agriculture, to be the most difficult areas in the negotiations and on which the highest stakes are involved.

58. Divisions within the negotiating teams have also surfaced on the issues related to intellectual property. The three technical experts from the Colombian negotiating team on intellectual property resigned after the 12th round of negotiations were concluded, noting that the while intellectual property chapter as it stands is highly detrimental to the countries' public health interests, the lead negotiator for Colombia had announced that the final decisions were to be political, not technical.[97] Two of the most divisive intellectual property-related issues in the negotiations remain the protection of test data for pharmaceutical products, and the inclusion of disclosure requirements with regards to genetic recourses in patent applications.

B. Free Trade Agreements involving the European Union

59. The European Union Trade Commissioner, Peter Mandelson, in a speech delivered on September 26, 2005 on "Europe's Global Trading Challenge and the Future of Free Trade Agreements"[98] stated that the European Union will continue to pursue the current agenda of FTA negotiations with a number of regional groups, including Mercosur (Argentina, Brazil, Uruguay, Paraguay) and the GCC (Kuwait, United Arab Emirates, Bahrain, Oman, Qatar and Saudi Arabia). The Commissioner also noted that the European Union "desperately need[s] better recognition of intellectual property rights and improved IPR enforcement…the key to Europe's position in the knowledge economy".[99] As regards to the Economic Partnership Agreements (EPAs) between the European Union and the African, Caribbean and Pacific (ACP) countries, the Commissioner referred to these as "development tools" that will lead in time to the growth of regional markets and trade with the European Union.

The emphasis made by the Commissioner on enforcement of intellectual property rights is made soon after the European Commission adopted on July 12 a proposal for a second Directive and a Framework Decision on Intellectual Property Rights Enforcement.[100] The Enforcement Directive

[96] See "Colombia: US-Andean free trade talks could wrap up by November", Dow Jones Newswires, September 23, 2005, www.bilaterals.org.
[97] See "Renuncian los miembros del equipo negociador colombiano en el tema de medicamentos en el TLC", September 23, 2005, www.eltiempo.terra.com.co.
[98] See European Commission, SPEECH/05/551, September 26, 2005, www.europa.eu.int.
[99] Supra, note 49, pp.4.
[100] See European Commission Press Release IP/05/906, www.europa.eu.int.

IPRED2 includes several "TRIPS-plus" deep-reaching obligations. For example, Article 3 would oblige Member States to "ensure that all international infringements of an intellectual property right on commercial scale, and attempting, aiding or abetting and inciting such infringements, are treated as criminal offences".[101] Several civil society groups have expressed strong concern and opposition to both the Directive and Framework Decisions, highlighting the dangers of this approach.[102]

Negotiation of Economic Partnership Agreements (EPAs)

60. During the third quarter of 2005 the EPA negotiations have focused on technical preparations for all of the ACP regions.[103] The EU seeks to sign a large number of EPAs before early 2008, deadline which marks the expiry of the WTO waiver authorizing the EU to offer preferential access to ACP products. Several Ministerial meetings are now planned for the fourth quarter of 2005. The Pacific ACP Trade ministers (PACPTM) are to meet sometime in November.[104] The Second CARIFORUM-EC Ministerial meeting commenced on September 30 where a decision will be taken on the timing, orientation and scope of Phase III negotiations.[105]

[101] See Directive 2005/0127(COD), Article 3.
[102] See Europe Free Software Foundation, "IPRED2", www.fsfeurope.org/projects/ipred2/ipred2.en.html.
[103] See Melissa Julian, "EPA Negotiations Update", in Trade Negotiations Insights, Vol. 4, No.4, July – August 2005, ECDPM – ICTSD.
[104] See "Pacific Islands win Agreement with EU", Radio Australia, July 28, 2005, www.epawatch.net/general/text.php?itemID=297&menuD=26.
[105] See Caribbean Regional Negotiating Machinery, "News Release", No.17/2005, September 22, 2005.