

# INTELLECTUAL PROPERTY QUARTERLY UPDATE



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CENTER FOR INTERNATIONAL  
ENVIRONMENTAL LAW

## THE 6 DECEMBER 2005 TRIPS AMENDMENT AND PUBLIC HEALTH AT THE WTO

### Introduction

The relationship between intellectual property (IP) and innovation in the pharmaceutical sector as well as access to essential medicines has been a central issue in the debate on IP and development within and outside of the World Trade Organization (WTO). In this context, there have been, in recent years, a number of high profile events and processes including, the adoption at the Fourth WTO Ministerial Conference in Doha in 2001 the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).<sup>1</sup> The implications of the rules under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>2</sup> have been at the centre of the WTO debate. Other important recent decisions include the World Health Assembly (WHA) Resolution on Intellectual Property Rights, Innovation and Public Health.<sup>3</sup>

These developments demonstrate, at least at the formal level, the growing international recognition that public health considerations condition the manner in which IP policies are formulated and implemented.

At the WTO, the Doha Declaration defined the relationship between IP protection and public health. The Declaration affirmed that the TRIPS Agreement can and should be interpreted and implemented in a manner that supports WTO Members right to protect health, particularly ensuring access to medicines for all.<sup>4</sup> A key issue at Doha, which the Ministers, however, failed to resolve was how countries which desired to exercise the right to protect public health through the use of compulsory licensing but had insufficient or no manufacturing capacity in the pharmaceutical sector could be assisted. Consequently, under paragraph 6 of the Declaration, the Ministers, recognizing that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licens-

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ing instructed the Council for TRIPS to find an expeditious solution to the problem. Based on this mandate, and due to mounting pressure towards the Fifth WTO Ministerial Conference in Cancun in September 2003, the WTO General Council adopted a decision to implement paragraph 6 (the Decision) on 30 August 2003.<sup>5</sup>

The Decision took the form of two main waivers.<sup>6</sup> The first waiver related to the obligations of Members under article 31(f) and the second to the obligation under article 31(h) of TRIPS. In essence, the Decision waived the provisions of article 31 which require that: (1) where the law of a Member allows for compulsory licensing, including use by the government or third parties authorized by the government such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use<sup>7</sup>; and (2) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. In addition, the Chairman of the General Council read out a statement before the adoption of the Decision setting out "several key shared understandings" of Members regarding the Decision.<sup>8</sup>

The Decision has 12 main components, namely: the product and disease coverage; eligibility of Members to import or export; the waiver to article 31(f) and the conditions attached; the terms of the waiver to article 31(h); safeguard measures; special rules for re-export; transfer of technology; annual review; the relationship between the Decision and existing rights, obligations and flexibilities; non-violation and situation complaints; the process for adopting a permanent solution including the relationship between the permanent solution and the Decision; and determination of lack of manufacturing capacity. There is also the Chairman's Statement whose legal status is important. Correa in a 2004 publication discusses each of these elements in detail.<sup>9</sup>

However, the Decision was adopted as a temporary mechanism.<sup>10</sup> In this regard, there was an agreement written into the Decision that the Council for TRIPS would prepare an amendment to replace the waivers for each Member on the date on which the amendment took effect for that Member.<sup>11</sup> It is within this context that the

General Council, acting on behalf of the Ministerial Conference<sup>12</sup>, adopted an amendment to the TRIPS Agreement as the permanent solution to the paragraph 6 problem on 6 December 2005.<sup>13</sup> This became the first time that a core WTO Agreement has been amended since the establishment of the organization in 1995. The timing of the amendment, barely a week before the Sixth WTO Ministerial Conference in Hong Kong, reminds one of the timing of the adoption of the Decision on 30 August 2003, just ten days before the Fifth Ministerial Conference in Cancun. In both cases, it was considered that failure to address the public health issue would paint the WTO in bad light and put in danger progress on other issues at the Ministerial.

### **The Relationship between the Amendment and the 30 August 2003 Decision**

The relationship between the Decision and the amendment is defined in paragraph 11 of the Decision. First, it was decided that the Decision would only cease to apply to a WTO Member on the date on which the amendment to the TRIPS Agreement takes effect for that Member. This means that the adoption of the amendment does not terminate the Decision.<sup>14</sup> Second, paragraph 11 provides that the amendment will be based, where appropriate, on the Decision. This suggests that although the amendment need not contain the same terms as the Decision, appropriate elements of the Decision would be incorporated in the amendment.

During the negotiations on the amendment, the Africa Group argued that this wording in paragraph 11 meant that:

Members ... explicitly agreed that "*the amendment will be based, where appropriate, on the Decision*". In this regard, the appropriateness of particular elements should be understood to mean those elements in the Decision that are necessary to ensure the amendment is legally predictable, secure and economically and socially sustainable.<sup>15</sup>

The African Group therefore proposed substantial modification of the Decision arguing that certain elements of the Decision were not appropriate for the amendment.<sup>16</sup> Notwithstanding the African Group's argument, however, the amendment contains

essentially the same elements as the Decision.

### **Analysis of the Amendment**

Since the amendment contains essentially the same elements as the Decision the analysis of the various elements of the Decision by Correa and others applies equally to the amendment provisions.<sup>17</sup> It is therefore not necessary to analyse each of the elements here. However, additional analysis is warranted considering that the structure of the Decision and the amendment is different and that there are some slight changes to the terms of the Decision in the amendment. There is also the issue of the date of entry into force of the amendment, dispute settlement and the legal status of the Chairman's Statement which warranted discussion here.

#### The Structure of the Amendment

The amendment to the TRIPS Agreement consists of three parts. First, there is article 31*bis* which is made up of 5 paragraphs corresponding in substance to the main text of paragraph 2, 3, sub-paragraph 6(i), paragraph 10, and 9 of the Decision respectively. The second part of the amendment is the Annex to the TRIPS Agreement which is made up of 7 paragraphs which correspond in substance to paragraph 1, sub-paragraphs 2(a), 2(b), and 2(c), paragraphs 4 and 5, sub-paragraph 6(ii) and paragraphs 7 and 8 of the Decision respectively. Finally, there is the Appendix to the Annex to the TRIPS Agreement which corresponds in substance to the Annex to the Decision.

The Chairman's Statement, which is not part of the Protocol, was re-read at the adoption of the amendment following the same chronology as during the adoption of the Decision. The Statement will be reproduced in the Minutes of the General Council meeting at which the amendment was adopted. This means that the legal status of the Chairman's Statement remains the same as under the Decision.

#### The Differences between the Terms of the Amendment and the Decision

The substantive content of the amendment, in terms of rights and obligations of WTO Members, remains essentially the same as under the Decision. There are, however, at least 5 changes and hence, differences, between the Decision and the amendment. First, in all the three main parts making up the amendment, editorial changes were made to eliminate references to the Decision and for the cross references to be in line with the three part structure. The numbering of footnotes and their order also changed to fit into this structure. Second, the preamble to the Decision is not contained in the amendment text though some of the text is included in the General Council's decision adopting the amendment.

In the third instance, paragraph 6 of the Decision was broken up into two parts with the first part (paragraph 6(i) of the Decision) contained in paragraph 3 of article 31*bis* and the other, paragraph 6(ii), contained in paragraph 5 of the Annex to the TRIPS Agreement. Paragraph 6(i) establishes special rules for re-export. This provision arose because there was concern that a legal solution not taking into account economic realities would not enable, for example, Sub-Saharan African countries with small markets, make effective use of compulsory licensing under the system.<sup>18</sup> Essentially, the paragraph 3 of article 31*bis* provides that in order to create economies of scale and facilitate local production of pharmaceutical products, the requirement under the Annex that only the amount necessary to meet the needs of the importing Member would be manufactured under the license would not apply if the products were exported or re-exported to other developing countries or LDCs within a regional trade agreement where half of the members are LDCs. Paragraph 5 of the Annex deals with issue regarding systems of regional patents.

The fourth difference between the Decision and the amendment is that paragraph 8 of the Decision was modified to eliminate the last sentence which referred to the annual review being deemed to fulfilling the requirements of article IX(4) of the WTO Agreement. The reason for this modification, as argued by the African Group, is that the review under article IX(4)

is only applicable to waivers and since this is an amendment the provisions do not apply.<sup>19</sup> Finally, paragraph 11 which provided a mandate for the amendment, defined the relationship between the Decision and the amendment and established timelines for the work on the amendment was eliminated. This was a straight forward case of what the African Group called self-eliminating elements.

#### The Date for the Entry into Force of the Amendment

The date for the entry into force of the amendment will be determined in accordance with the rules on amendments under the WTO Agreement. Article X(3) of the WTO Agreement which addresses this question provides that:

Amendments to provisions of this Agreement, or of the Multilateral Trade Agreements in Annexes 1A and 1C, other than those listed in paragraphs 2 and 6, of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it. The Ministerial Conference may decide by a three-fourths majority of the Members that any amendment made effective under this paragraph is of such a nature that any Member which has not accepted it within a period specified by the Ministerial Conference in each case shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference.<sup>20</sup>

The Protocol provides that it shall be open for acceptance to Members until 1 December 2007, about two years from the date of its adoption, or such other date as decided by the Ministerial Conference.

The exact date for the entry into force of the amendment is therefore not known and is dependent on the acceptance (ratification) of the amendment by two thirds of WTO Members.<sup>21</sup> The exact date could therefore be before or after 1 December 2007. In addition, even after the entry into force of the amendment, it is possible that the amendment will not be in force with respect to up to one third of the WTO Members. As already noted, the Decision would

still apply to this group of Members. The effect is that after the entry into force of the Protocol, there is likely to be, at least for some time, Members operating under the amendment and those operating under the Decision. The General Council does not seem to have decided specifically, by a three-fourths majority, that the amendment is of such a nature that any Member which has not accepted it within a specified period shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference. Though it could be argued that setting the date of 1 December 2007 has this effect, it is fairly clear that article X(3) gives the Ministerial (in this case the General Council) a discretionary power whose exercise should be specific and not presumed.

The possibility of two classes of Members, that is, some operating under the Decision (the minority) and others under the amendment (the majority) raises questions about the effect of the differences between the Decision and the Amendment. It is submitted that this question is essentially moot. However, it would have mattered if the substantive terms of the Decision and the amendment were significantly different. A dichotomy with respect to substantive provisions could have been a cause of problems as it is conceivable that the exporting and importing Members could be operating under different regimes with different requirements. In such case, it would then have been critically important that the General Council exercises the discretionary power under article X(3) and declared the amendment to be of a nature that any Member which has not accepted it within a specified period shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference.

#### Settlement of Disputes Related to the Amendment

Disputes and disagreements regarding the TRIPS Agreement and public health have largely been dealt with politically. Except for a few cases which have been decided by panels and the Appellate Body (AB) of the WTO, other legal challenges such as the South Africa dispute and the United States case against Brazil on local working requirements were resolved politically or withdrawn largely due to political consid-

erations. Indeed, the Decision as well as the amendment, though expressed in legal instruments, is political compromises. The significance of this is that TRIPS and public health issues have been resolved, in large measure, based on power relations as opposed to legal interpretation or economic analysis.<sup>22</sup>

The amendment endorses the political route as the primary route for the settlement of disputes related to its provisions but also bars certain types of disputes related to the amendment. There are two levels at which the political route is endorsed. To start with, paragraph 4 of the Annex to the TRIPS Agreement provides that a Member who considers that the legal means provided by another Member for preventing importation and sale of products under the system are insufficient may request the Council for TRIPS to review the matter.

Secondly, paragraph 5 of the Chairman's Statement provides that Members shall seek to resolve any issues arising from the use and implementation of the amendment expeditiously and amicably and, in particular, that "any member may bring any matter related to the interpretation or implementation, including issues related to diversion, to the Council for TRIPS for expeditious review" and that, "if any Member has concerns that the terms of the amendment have not been fully complied with, the Member may also utilise the good offices of the Director-General or the Chair of the TRIPS Council, with a view to finding a mutually acceptable solution". While these provisions can not be seen as ousting the jurisdiction of panels or the AB to deal with disputes relating to the amendment, WTO Members have shown a preference for the political route as opposed to the dispute settlement route.

In addition to discouraging revolving disputes through the dispute settlement system, the amendment also ousts the jurisdiction of WTO panels and the AB with respect to certain disputes. Paragraph 4 of article 31*bis* explicitly ousts the jurisdiction of panels and the AB with respect to non-violation and situation complaints on matters relating to the amendment. This means that the scope of the application of these types of complaints, even if it is determined

that they apply to TRIPS generally, and modalities established under article 64(3), disputes related to the amendment would not fall under their scope.<sup>23</sup> This is an important precedent. The Decision seems to be an explicit acceptance of the argument of a significant number of WTO Members that non-violation and situation complaints if applied to TRIPS would:

Encourage unilateral pressure and speculative claims to force countries to raise protection beyond minimum requirements, or to refrain from using TRIPS-consistent measures such as compulsory licensing to ensure access to essential medicines..., or to guarantee access to technology.<sup>24</sup>

There is no reason why the reasoning justifying the non-application of these claims to the paragraph 6 mechanism would not apply equally to public health-related and other flexibilities in the TRIPS Agreement.

#### The Legal Status of the Chairman's Statement

The Statement of the Chairman of the General Council setting out certain "key shared understandings" on how the amendment provisions would be interpreted and implemented was highly controversial when it was agreed in August 2003 under the Decision. The Statement read at the adoption of the amendment is the same. The shared understandings contained in the Statement relate to: good faith use of the mechanism; anti-diversion measures including illustrative best practice guidelines; measures to ensure that any issues arising from the use of the mechanism are resolved expeditiously and amicably; use of information gathered on the implementation of the amendment; and countries which, wholly or partially, voluntarily exclude themselves from using the mechanism under the amendment.

A key question that arose during the negotiations of the amendment was the legal status of Statement. Developing countries, in particular, were concerned that the effect of the Statement would be to discourage the use of the system by, for example, preventing or hindering incentives

for generic producers to use the Decision. The emphasis on non-industrial and non-commercial policy objectives was of particular concern.<sup>25</sup>

It is important to note that the Chairman's Statement is not an integral part of the amendment and its only relevance is therefore for purposes of interpretation of the amendment. In this regard, the Statement cannot be read as creating any new rights or obligation or conditions for the use of the system under the amendment. For example, notwithstanding the understanding that the mechanism under the amendment would be used in good faith to protect public health but not as an instrument of industrial or commercial policy, measures necessary for building pharmaceutical manufacturing capacities as contemplated under paragraphs 5 and 6 of the Annex to the TRIPS Agreement, are not affected.

The exact legal status of the Chairmen's Statement depends on the interpretation of the Vienna Convention on the Law of Treaties.<sup>26</sup> The Convention provides that treaty interpretation should take into account the context of the terms of the treaty<sup>27</sup> and in certain circumstances recourse could be had to supplementary means of interpretation.<sup>28</sup> The legal status depends on whether the Statement is context or supplementary means of interpretation. In this regard, if the Chairman's Statement is taken to constitute context, then under the rules of treaty interpretation, it must be taken into account whenever the provisions of the amendment are interpreted. On the other hand, if the Statement only constitutes a supplementary means of interpretation, then it can only be taken into account if the application of the general rule of interpretation leaves the meaning of the terms of the amendment ambiguous or obscure, or where such interpretation would lead to manifestly absurd or unreasonable results.

Context is defined under article 31(2) of the Convention to include the text of the treaty including the preamble and annexes as well as "any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;" and "any instrument which was made by one or more parties in connection to the conclusion of the treaty and accepted by other parties as an instrument related to

the treaty." Supplementary means of interpretation under article 32, on the other hand, include preparatory work of the treaty, for example, the minutes of the of the Council for TRIPS and General Council relating to the discussions on the amendments, and the circumstances of its conclusion such as what transpired at the meeting of the General Council.

The Chairman's Statement is contained in the Minutes of the General Council session at which the amendment was adopted. The Minutes of the General Council meeting constitute preparatory work with respect the amendment as defined under the Vienna Convention. Consequently, while on the face of it an argument could be made that the Chairman's Statement constitutes an agreement relating to the amendment, and is in connection with the conclusion of the amendment, a careful reading and review of the circumstances, taking into account that the fact that Statement is not contained in a separate instrument but in the Minutes of the General Council, would lead to the conclusion that the Statement is only a supplementary means of interpreting the provisions of the amendment.

## Conclusion

The amendment to the TRIPS Agreement marks an important stage in the debate on IP and public health. To some, such as the WTO Director-General and the brand-name pharmaceutical industry (commonly known as big pharma) the amendment marks the end of the debate.<sup>29</sup> They consider it final solution to the concerns regarding the effect of TRIPS on public health. To others, especially health groups, however, it is questionable if the amendment solves any problem. To them, the amendment is definitely not a final solution to questions regarding the effects of the TRIPS Agreement on public health.<sup>30</sup> Only time will tell who is correct. There is, however, some evidence to support those who do not see the amendment as the end of discussion.

The role of patent regimes and other IP rights in the pharmaceutical sector is complex. There is no doubt that, more and more, patents are becoming a critical determinant for access to fundamental research, essential products and services and to economic development generally. It is for this reason that patent, and IPR policies more generally, have increasingly come under closer scrutiny by policy makers and researchers, particularly outside WTO and WIPO circles. With respect to public health, this trend is evidenced by the WHA resolution on IP Rights, Innovation and Public Health.

The resolution, among other things, firmly places on the global agenda the need for rethinking the approach to IP rights and innovation in the pharmaceutical sector as framed under TRIPS and other IP treaties. In addition, it places on the agenda the need to think beyond IP systems in addressing the questions around funding and incentives for R&D, especially for diseases that disproportionately affect developing countries. The attempts at WHO, through the CIPIH, to address these issues as well as other efforts and the evidence generated through these other processes may well mean fundamental changes to the TRIPS Agreement in future. For example, in the CIPIH process alternatives to the current system embodied in the TRIPS Agreement, such as a treaty on R&D, have been proposed. Though CIPIH may not address these alternatives at all or sufficiently, discussions on such alternatives will only grow.

## **AN OVERVIEW OF RELEVANT IP DEVELOPMENTS IN VARIOUS FORA**

The following is an overview of the developments in the various fora dealing with intellectual property issues in the fourth quarter of 2005.

### **World Trade Organization (WTO)**

The Sixth Ministerial Conference of the WTO took place in Hong Kong from 13 to 18 December 2005. IP issues were not high on the agenda. Nevertheless, the Hong Kong

Ministerial Declaration did refer to several ongoing IP discussions and negotiations. It also welcomed previous decisions taken in regard to the TRIPS Agreement in Geneva. Moreover, the IP-related provisions of the Hong Kong Ministerial Declaration were among the most noted by both governments and non-governmental organizations when assessing the results of the Ministerial Conference.<sup>31</sup> IP issues addressed by the Hong Kong Ministerial Declaration will be briefly analyzed below. **The next meeting of the Council for TRIPS is scheduled to take place on 14 to 15 March 2006.**

### TRIPS and Public Health

Please see Section I above for an analysis of the Decision of the General Council of 6 December 2005 on an Amendment of the TRIPS Agreement.

### Extension of Transition Period for Least Developed Countries (LDCs)

Paragraph 47 of the Hong Kong Ministerial Declaration welcomed the decision by the Council for TRIPS to extend the transition period under article 66.1 of the TRIPS Agreement for Least Developed Countries (LDCs).<sup>32</sup> The Council for TRIPS, in response to a request presented in October by the LDCs, had taken a decision to extend the transition period for the implementation of the TRIPS Agreement on 29 November 2005, with LDCs thus not being required to apply the provisions of the TRIPS Agreement until 1 July 2013, or until they cease to be an LDC, whichever date is earlier.<sup>33</sup> The decision, however, was criticized as having several shortcomings.

First, it was significantly less time than that requested by the LDCs – fifteen years. Second, certain provisions limit the ability of LDCs to effectively benefit from the longer transition period. For example, paragraph 5 of the November Decision states that any changes in the laws, regulations and practice made during the additional transitional period cannot result in a lesser degree of consistency with the provisions of the TRIPS Agreement. The provision thus establishes new requirements for LDCs, which had previously been excluded from a similar provision in the TRIPS

Agreement. In addition, the inability to "roll back" IP legislation will restrict the flexibility the extension is meant to provide, making it difficult for LDCs to develop strategies for establishing a viable technological base.

#### The relationship between the TRIPS Agreement and the CBD

Despite calls from several developing countries for the Hong Kong Ministerial Declaration to pave the way for negotiations on the relationship between the TRIPS Agreement and the CBD, the final text maintains the ambiguity that has led some developed countries to block the proposed introduction of disclosure requirements by denying a negotiating mandate. On one hand, in the paragraph on implementation issues, one of which is the relationship between the TRIPS Agreement and the CBD, the Ministerial Declaration requests the Director-General to intensify the consultative process and to report to each regular meeting of the TNC and the General Council. The General Council will review progress and take any appropriate action no later than 31 July 2006. On the other hand, in the paragraph relating to Paragraph 19 of the Doha Ministerial Declaration, which also refers to the relationship between the TRIPS Agreement and the CBD, Ministers instructed that work continue on the basis of the mandate contained in the Doha Declaration. The General Council will report on this work to the next Ministerial Conference. Nevertheless, developing countries noted the importance of the momentum created by a specific deadline and more intense discussions.

#### Geographical Indications

The extension of the protection for geographical indications (GIs) to products other than wine and spirits, as an outstanding implementation issue, is also addressed in paragraph 39 of the Hong Kong Ministerial Declaration. Indeed, the procedural links between discussions on extension of GIs and the relationship between the TRIPS Agreement were significant political considerations during the Ministerial Conference. With regard to the negotiations on the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits,

mandated in article 23.4 of the TRIPS Agreement and paragraph 18 of the Doha Ministerial Declaration, the Hong Kong Declaration urges Members to intensify negotiations in order to complete them within the round of negotiations.

#### Non-violation and Situation Complaints

There were no developments in the Hong Kong Ministerial Declaration in regards to non-violation and situation complaints, with discussions on the applicability of these complaints to the TRIPS Agreement set to continue and the moratorium being extended once again. In particular, the Declaration directs the Council for TRIPS to continue its examination of the scope and modalities for non-violation and situation complaints and make recommendations to the next Ministerial Conference. It also establishes that, in the meantime, WTO Members will not initiate such complaints under the TRIPS Agreement – language that had previously been bracketed given the United States call for an end of the moratorium.

#### **World Intellectual Property Organization (WIPO)**

##### Standing Committee on Copyright and related Rights (SCCR)

The Thirteenth Session of the Standing Committee on Copyright and Related Rights (SCCR) was held in Geneva on 21-23 November 2005. Immediately beforehand, WIPO held an "Information Meeting on Educational Content and Copyright in the Digital Age," which included presentations on the impact of copyright on education and libraries and on national experiences in copyright exceptions.<sup>34</sup> Issues discussed during the formal SCCR session included exceptions and limitations to copyright and the proposed broadcasting treaty.

Chile, which had called for the discussion on exceptions and limitations, presented a proposal for work in three areas: i) identifying national models and practices concerning exceptions and limitations; ii) analyzing exceptions and limitations needed to promote creation and innovation and the dissemination of such creations and inventions; and iii) establishing minimum exceptions and limitations for purposes of public



interest that must be envisaged as a in all national legislations for the benefit of the community; especially to give access to the most vulnerable or socially prioritized sectors.<sup>35</sup> The Chilean proposal received wide support both from many WIPO Members and civil society organizations such as the International Federation of Library Associations (IFLA) and the World Blind Union. In particular, the importance of focusing the debate on access to knowledge, of adequately safeguarding the public interest and the public domain, and of conducting studies on the availability and use of exceptions was highlighted. A few countries and various industry and rights-holders groups, however, expressed concern regarding the use of exceptions and limitations for safeguarding public policy objectives, and warned regarding the stripping of the substance of copyright protection.<sup>36</sup>

Two new submissions were put forth in the SCCR in regards to the proposed broadcasting treaty. First, a proposal by Brazil highlighted the need to strike an appropriate balance between the protection of the rights of broadcasting organizations and the public interest, as well as the rights of other right-holders under the copyright system. Consequently, it called for any new instrument protecting broadcasting organizations from signal theft to include provisions on access to knowledge and the protection of cultural diversity, as well as to allow exceptions and limitations to preserve the social dimension of broadcasting activities.<sup>37</sup> Second, a similar list of exceptions and limitations was put forth by a Chilean proposal, which additionally submitted provisions to allow Contracting Parties to prevent any abuse of IP rights that have an adverse effect on competition.<sup>38</sup>

Both proposals had significant support from other Member States in their focus on preventing signal piracy and ensuring there was no negative impact on other rights-holders. Nevertheless, the Brazilian references to article 21 of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) Convention on the Protection and Promotion of the Diversity of Cultural Expressions, which establishes that "Parties undertake to promote the objectives and principles of this Convention in other international forums," proved somewhat contentious.<sup>39</sup> In addition to question-

ing the legal relationship between the treaties, some Member States, including the United States, expressed concern that references to cultural diversity could be misused to undermine rights in the proposed broadcasting treaty.

Discussion of the proposed broadcasting treaty focused, for the first time, on the "Second Revised Consolidated Text for a Treaty on the Protection of Broadcasting Organizations," and was organized around two clusters of issues. The first cluster of issues centred on the scope of protection of the proposed treaty (i.e. the technologies to be covered) and the second cluster on the substantive rights foreseen by the proposed treaty.<sup>40</sup> On scope, the majority of Member States restated their opposition to addressing webcasting in any form. In particular, there was concern in relation to the "Working Paper on Alternative and Non-Mandatory Solutions on the Protection in Relation to Webcasting," prepared by the Chair at the suggestion of the Russian Federation, which set out three possible solutions (opting in or out of webcasting protection and having a protocol on webcasting accompanying the proposed treaty on broadcasting). As one African country pointed out, these three doors all seemed to go to the same room. Nevertheless, the United States indicated that it remained committed to including webcasting in the treaty. There were no firm decisions made on the substance of these discussions, but the Chair proposed to continue working on the Consolidated Text, with a fair and equitable treatment of all positions and proposals, and providing it to Member States as soon as possible. **There will be two further meetings of the SCCR before the 2006 WIPO General Assembly, possibly in April and June.**

#### The Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT)

The Fifteenth Session of the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT) was held in Geneva from 28 November to 2 December 2005. Given that a Diplomatic Conference for the adoption of a Revised Trademark Law Treaty will take place in Singapore from March 13 to 31,

2006, the SCT focused on the future work of the Committee. Proposals were mostly from developed countries and addressed topics such as the harmonization of substantive trademark law, well-known marks, protection of trademarks on the Internet, marks and international non-proprietary names of pharmaceutical substances, geographical indications, and Internet domain names.<sup>41</sup> The SCT agreed to undertake work in a limited number of areas and requested further information from the International Bureau about other proposed issues, which will be presented before the next session.<sup>42</sup> **The tentative dates for the Sixteenth Session of the SCT are 13-17 November 2006.**

#### Upcoming WIPO Meetings

In the first quarter of 2006, important WIPO meetings relevant for IP and development include: the **Ninth Session of the Program and Budget Committee, to be held from 11-13 January** and the first meeting of the new body discussing the WIPO Development Agenda, the **Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA), which will take place from 20-24 February**; and the **Informal Open Forum on the Draft Substantive Law Treaty (SPLT) to take place from 1 – 3 March**. All these meetings take place in Geneva. In addition, **the Diplomatic Conference for the Adoption of the Revised TLT will take place between 13-31 March in Singapore.**

#### **Other Multilateral Fora**

##### Convention on Biological Diversity (CBD)

**The fourth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing will be held from 30 January to 3 February 2006 in Granada, Spain.** The main issue on the agenda remains the elaboration and negotiation of an international regime on access to genetic resources and benefit-sharing, with the view of adopting an instrument/s to effectively implement the relevant provisions of the CBD. Other important items to be discussed include the use of terms not defined in the CBD and measures to support compliance with prior informed con-

sent. For continuing discussions on the international regime, the Working Group will have before it a consolidated text of the initial review of the nature, scope, and potential objectives and elements to be considered for inclusion in the regime – conducted by third meeting of the Working Group – and the comments and proposals submitted by Parties, Governments, indigenous and other local communities, international organizations, and all other relevant stakeholders.<sup>43</sup> A revised matrix to facilitate analysis of gaps in existing national, regional, and international legal and other instruments relating to access and benefit-sharing will also be presented.<sup>44</sup> **The Working Group will present any recommendations concerning future work to the Eighth Ordinary Meeting of the Conference of the Parties to the CBD, which will take place in Curitiba, Brazil, on 20-31 March 2006.**

##### Food and Agriculture Organization (FAO)

The thirty-third session of the FAO Conference, which convened on 19-26 November 2005, approved a memorandum of understanding between the FAO and WIPO.<sup>45</sup> The agreement aims to “establish a mutually supportive relationship” between the FAO and WIPO and to establish “appropriate arrangements for cooperation between them.”<sup>46</sup> Provisions of the agreement encourage exchange of information; joint activities such as studies, seminars and workshops; and technical assistance or cooperation. The text of the agreement also contains a list of issues in which the organizations’ work may intersect, including: farmers’ rights and traditional knowledge; agricultural biotechnology; genetic resources for food and agriculture; promotion of innovation and the effective capture of benefits from public investment in research; use of distinctive signs in the food and agriculture sector; and ethical issues in food and agriculture.

Another relevant discussion took place at the 14-17 December 2005 meeting of the Open-Ended Working Group on the Rules of Procedure and the Financial Rules of the Governing Body, Compliance, and the Funding Strategy.<sup>47</sup> This Working Group was established under the Commission on Genetic Resources for Food and Agriculture (CGRFA), which is still acting as the Interim

Committee for the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).<sup>48</sup> Issues discussed included the preparation of drafts for rules of procedure and funding for the Governing Body and of draft procedures and mechanisms to promote compliance and to address issues of non-compliance.<sup>49</sup> Also presented to the Working Group was a background paper on non-mandatory benefit sharing, which analyzed existing non-monetary benefit-sharing arrangements – including information exchange, capacity building and technology transfer – and considered if and how such arrangements could be applied in the implementation of the ITPGRFA.<sup>50</sup>

#### Second Global Congress on Combating Counterfeiting and Piracy

On 14-15 November 2005, the Interpol and the World Customs Organization (WCO) convened the Second Global Congress on Combating Counterfeiting and Piracy. This Congress brings together senior government and business leaders to analyze measures in combating product and trademark counterfeiting and piracy, identify opportunities for collaboration, and develop a set of recommendations for national governments.<sup>51</sup> Organizations providing support for the Congress included WIPO, the Global Business Leaders Alliance Against Counterfeiting (GBLAAC), the International Chamber of Commerce (ICC), the International Security Management Association (ISMA), and the International Trademark Association (INTA). The main result of the meeting was a declaration encouraging the development and enforcement of stronger anti-counterfeiting and piracy practices.<sup>52</sup> The declaration also encourages the consideration of a proposal by Japan to create a new international treaty on counterfeiting and piracy to complement the TRIPS Agreement. During the Congress, another call was to adopt a convention against dangerous or useless counterfeit medicines.<sup>53</sup>

**WIPO will host the Third Global Congress in January of 2007.**

#### United Nations Committee on Economic, Social and Cultural Rights (CESCR)

On 22 November 2005 the thirty-fifth session of the CESCR adopted a General Comment on article 15(1)(c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which affirms the right of everyone “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.”<sup>54</sup>

During the elaboration of the General Comment, significant concerns had been raised by developing countries and non-governmental organizations regarding text in relation to IP that was susceptible to misinterpretation and could have negative implications not only by hindering the promotion and protection of human rights but by hampering various development processes in general.<sup>55</sup> The General Comment alleviated some of these concerns. In the introductory section, the text clearly states that it is “important not to equate intellectual property rights with the human right recognized in article 15, paragraph 1 (c).”<sup>56</sup> In particular, the General Comments highlights that:

- Human rights, including the right recognized in article 15, paragraph 1 (c), are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances, groups of individuals and communities. As a result, they differ from IP rights, which are of a temporary nature, and can be revoked, licensed or assigned to someone else.
- The scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as IP rights under national legislation or international agreements.
- Article 15, paragraph 1 (c) is intrinsically linked to the other rights recognized in article 15 of the Covenant, i.e. the right to take part in cultural life (paragraph 1 (a)) and to enjoy the benefits of scientific progress and its applica-

tions (paragraph 1 (b)), and the freedom indispensable for scientific research and creative activity (article 15, paragraph 3).

#### United Nations Educational, Scientific and Cultural Organisation (UNESCO)

On 20 October 2005 the thirty-third session of the UNESCO General Council adopted the Convention on the Protection and Promotion of the Diversity of Cultural Expressions. The objectives of the convention include the protection and promotion of cultural diversity and the affirmation of a State's right to implement policies with the aim of protecting their diversity of cultural expressions.<sup>57</sup> While IP issues are not central to the Convention, earlier drafts did include references to these issues, including proposed provisions on the relationship between the Convention and international IP treaties.<sup>58</sup> The adopted text only contains one explicit reference to IP.

The Preamble of the Convention recognizes "the importance of intellectual property rights in sustaining those involved in cultural creativity."<sup>59</sup> Nevertheless, the Convention, which applies to "the policies and measures adopted by the Parties related to the protection and promotion of the diversity of cultural expressions," will clearly be relevant for IP discussions in relation to traditional knowledge; publishing, printing and literature; music and the performing arts; visual arts; audiovisual and new media. As noted by the Brazilian proposal<sup>60</sup> to the SCCR (see above), Parties to the Convention are obliged to further the objectives and principles of this Convention in other international forums, including those addressing IP. **The Convention on the Protection and Promotion of the Diversity of Cultural Expressions will enter into force three months after its ratification by 30 States.**

#### UN World Summit on the Information Society (WSIS)

The second and last phase of the World Summit on the Information Society (WSIS) was held in Tunis on 16-18 November 2005. The meeting concluded the work on implementation and follow-up for the 2003 Geneva Declaration of Principles and Ge-

neva Plan of Action. Specifically, this phase focused on financing mechanisms and Internet governance. Issues relating to IP, which had received some attention in the final Preparatory Committee meeting, remained mostly off the agenda. In this regard, some observers considered more could have been accomplished toward ensuring access to information and encouraging free and open source software.<sup>61</sup>

Nevertheless, the main documents adopted in Tunis – the Tunis Commitment and the Tunis Agenda for the Information Society – do contain some relevant references.<sup>62</sup> The Tunis Commitment refers to – "the need to encourage and foster collaborative development, inter-operative platforms and free and open source software," while "(t)aking into account the importance of proprietary software in the markets of the countries."<sup>63</sup> The Tunis Agenda for the Information Society contains a reference to improving access to health and agricultural knowledge as well as a paragraph that supports educational, scientific and cultural institutions in providing access to information.<sup>64</sup> **The Summit requested that the United Nations General Assembly (UNGA) make an overall review of the implementation of WSIS outcomes in 2015.**<sup>65</sup>

#### The World Health Organization (WHO)

The CIPIH, after discussing a series of preliminary drafts of its report during 2005, decided to hold one further meeting to review the final draft and refine its recommendations.<sup>66</sup> **The final meeting of the CIPIH will be held on 16 and 17 January 2006**, just before the 117th session of the WHO Executive Board (EB) scheduled for 23 – 28 January 2006. The CIPIH thus requested deferment of the **submission of its report**, which was due at that session of the Executive Board, until **April 2006**. The report will consider both technical and policy issues and is likely to be structured as follows: Chapter 1 provides an overview and defines the problems being addressed; Chapter 2 outlines the issues at the discovery stage, Chapter 3, at the development stage, and Chapter 4, at the delivery stage; Chapter 5 considers how to foster innovation in developing countries; Chapter 6 suggests ways to promote a sustainable

framework for encouraging innovation and improving access.

In the meantime, in November 2005, the Government of Kenya submitted a proposal on "Global Framework on Essential Health Research and Development" for discussion at the 117<sup>th</sup> EB session. The resolution, which has since been mired in a procedural merry-go-round and has not been distributed by the WHO Secretariat, essentially seeks action at the WHO level to:

- Direct research and development (R&D) priorities according to the needs of patients, especially those in resource-poor settings and harness collaborative R&D initiatives involving disease-endemic countries;
- Establish a global framework for defining global health priorities, supporting essential medical R&D predicated upon the principle of equitable sharing of costs of R&D etc.; and
- Ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products including drugs, vaccines and diagnostics.

### **Regional and Bilateral Trade Agreements with Intellectual Property Provisions**

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 in the fourth quarter of 2005, with a specific focus on IP issues.

#### Free Trade Agreements involving the United States

Since 1994, the United States has signed free trade agreements (FTAs) with 13 countries – Chile, Singapore, Australia, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Morocco, Bahrain, Oman and Peru. Negotiations are under way with ten more countries: Colombia, Ecuador, United Arab Emirates, Panama, Thailand, and the five nations of the Southern African Customs Union (SACU).

All of them contain a chapter on IP protection.

#### ***US-Peru***

On 7 December 2005, the United States and Peru announced that they had successfully concluded their work on a bilateral FTAs. The US Trade Representative (USTR) Policy Brief on the "U.S. Peru Trade Promotion Agreement" explains that the agreement "makes a number of important improvements" to the protection of intellectual property rights, including granting copyright owners rights over temporary copies of their works on computers, protection for technological protection measures,<sup>67</sup> limiting the grounds for revoking a patent, and granting exclusive rights over test data and trade secrets submitted to a government for the purpose of product approval for a period of 5 years for pharmaceuticals and 10 years for agricultural chemicals".<sup>68</sup>

The summary of the chapter on IP prepared by the Peruvian government notes several achievements from the Peruvian perspective. One example provided is the US recognition of the importance of genetic resources and traditional knowledge, prior informed consent and fair and equitable benefit-sharing. Nevertheless, the synopsis of the provisions on biodiversity includes references to prior informed consent and fair and equitable benefit-sharing being adequately addressed through contracts, which has been the US rather than the Peruvian position on the issue. Moreover, Peru has agreed to make efforts towards patent protection for plants. Provisions that could be significant from a sustainable development perspective, however, include those highlighting the importance of exceptions and limitations in regards to technological protection measures and those avoiding the grant of exclusive rights to broadcasting organizations.<sup>69</sup>

#### ***Other Andean countries***

Colombia and Ecuador are scheduled to resume negotiations with the United States in early 2006. The US-Colombia round of negotiations is tentatively set for the week of 23 January, while the US-Ecuador round would take place the first week of February. Nevertheless, Ecuador and Colombia are

currently discussing a joint negotiation on controversial issues such as IP. Meanwhile, Evo Morales, the president elect of Bolivia, which has been participating in negotiations as an observer, said in an interview that he remains open to an agreement with the United States, as long as it includes fair terms.<sup>70</sup>

### **US-SACU**

After indefinite postponement of a "mini-round" of negotiations that was to take place in November 2005 and focus on agriculture market access, the negotiations are now scheduled for February and April 2006.

### **US-Oman**

On 18 November 2005, the USTR announced it had transmitted to the US President and Congress reports from 27 trade advisory committees regarding the recently completed US-Oman Free Trade Agreement, noting widespread support for the agreement. The Industry Trade Advisory Committee 15 (IFAC 15), which focuses on IP, expressed satisfaction that the agreement, with only minor exceptions, reflected the highest standards of protection in the areas of copyright, trademarks, geographical indications and enforcement, and called for the precedent to be carried forward in other negotiations.<sup>71</sup> The Committee, however, stated its disappointment at the lack of a requirement for Oman to implement patent protection for transgenic plants and animals. On the other hand, a minority within the Trade and Environment Policy Advisory Committee (TEPAC) considered that the agreement's IP provisions would be harmful to consumers, particularly by reducing their access to affordable generic medicines.

### **US-Bahrain**

During December 2005, both the US House of Representatives and the Senate passed the US-Bahrain agreement.

### **US-Morocco**

On 19 December 2005, Christin Baker, USTR Spokesperson on the Implementation

of the US-Morocco Free Trade Agreement, announced the Moroccan government had taken the final steps in completing its internal process to implement the FTA, which thus enter into force on 1 January, 2006, as scheduled.

### **CAFTA-DR**

The entry into force of CAFTA-DR, however, also foreseen for 1 January 2006, is still uncertain. The United States is still reviewing whether the Central American countries have taken sufficient steps in implementing their commitments. Nevertheless, USTR Spokesperson Christin Baker announced the agreement would enter into force even if one of these countries were prepared, with the others then joining on a rolling basis. Costa Rica has yet to ratify the agreement, but the other Central American signatories – the Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua – have already ratified it and are at various stages in the process of implementation. IP-related laws and regulations have been particularly controversial in the implementation process.

### **Upcoming FTAs**

The United States and Egypt are currently holding technical discussions as a preliminary step to the launch FTA negotiations. Fourteen working groups have been set up by the two countries to work on issues related to chapters of a future FTA, including one on IP rights. Negotiations are expected to be launched in early 2006. Other countries that have approached the United States in relation to FTAs include Pakistan. In addition, some news services recently reported that the United States is planning to conclude negotiations on a bilateral FTA with Malaysia by early 2007.

### **Free Trade Agreements involving the European Union**

The European Union is currently pursuing a number of regional trade negotiations, including with Mercosur (Argentina, Brazil, Uruguay, and Paraguay) and the Gulf Cooperation Council (GCC) (Kuwait, United Arab Emirates, Bahrain, Oman, Qatar and Saudi Arabia), as well as negotiations to-

wards Economic Partnership Agreements (EPAs) between the European Union and the African, Caribbean and Pacific (ACP) countries.

In October 2005, the European Commission's Directorates for Trade and for Development and EuropeAid prepared a Commission Staff Paper detailing the state of negotiations with ACP countries.<sup>72</sup> EPA negotiations are currently taking place with regional groups, namely West Africa, Central Africa, Eastern and Southern Africa, the Caribbean, Southern Africa / SADC, and the Pacific. Issues and priorities, as well as progress, are reported to vary by region. Discussions on IP are taking place in West Africa, where the next phase of negotiations is set to begin in January 2006 with remaining technical work, including on IP continuing in parallel, and in the Caribbean, where Phase III of negotiations was launched on September 2005 and IP has been identified as an area important to the negotiations and implementation of the EPA from a development standpoint.

#### ENDNOTES

1. The Declaration is contained in WTO document WT/MIN(01)/DEC/2.
2. The text of the TRIPS Agreement which is Annex 1C to the Agreement Establishing the WTO is contained in WTO, *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations*, Cambridge University Press, Cambridge, 1999.
3. Resolution WHA56.27, May 2003. It is on the basis of this resolution that the World Health Organization (WHO) Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) was established in 2004 to "Collect data and proposals from different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products for the diseases that disproportionately affect developing countries..."
4. See para 4 of the Decision, *supra* note 1.
5. The Decision is contained in WTO document WT/L/540.
6. Waivers can be granted to WTO Members with respect to their obligations under article IX(3) and IX(4). Article IX(3) provides that "in exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Agreements" where such decision is taken by three fourths of Members and sets out the procedure for submitting and processing requests for waivers. However, footnote 4, provides that waivers relating to obligations subject to a transition period or a period of staged implementation that the requesting Member has not performed by the end of the period can only be taken by consensus. Article IX(4) requires that each waiver state the exceptional circumstances justifying the decision, the terms and conditions of the waiver and the date when the waiver terminates. For waivers lasting more than a year, an annual review is required to determine that the circumstances justifying the waiver still exist.
7. See article 31(f) of the TRIPS Agreement, *supra* note 2.
8. The Statement is reproduced in the Minutes of the General Council, WTO document WT/GC/M/82.
9. See Carlos M. Correa "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", *Essential Drugs and Medicines Policy*, WHO (2004). For additional discussion see Paul Vandoren and J. Van Eeckhaute, "The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health-Making it Work", *6 J.W.I.P.*, 779-793, 2003.
10. Note, however, that the phrasing of the Decision makes it effectively a permanent waiver.
11. See paragraph 11 of the Decision, *supra* note 3.
12. Under article IV(2) of the WTO Agreement, the General Council acts on behalf of the Ministerial during the intervals between Ministerial Conferences.
13. The amendment Protocol is contained in WTO document IP/C/41.
14. It is for this reason that it is argued above that although the Decision was adopted as a temporary solution, it could remain in force for along time, *supra* note 8. It can also be argued that the review provision of the Decision (para 8), has a built-in presumption that the circumstances justifying the waiver will exist for a long time.
15. See para 2 of the proposal of the African Group for an amendment, WTO document IP/C/W/437.
16. See the legal arguments of the African Group, WTO document IP/C/W/440. The Group argued that there were certain elements in the Decision whose purpose had already been served or that would be redundant in the context of an amendment. These were termed as self-eliminating elements of the Decision. In addition, there were other elements whose purpose, the Group argued, would otherwise be served by other provisions of TRIPS, such as the Agreement's provisions on enforcement and the already existing provisions of Article 31.
17. *Supra* note 9.
18. For further discussion of this issue and possible options for using the Decision in this context, see Sisule Musungu, Susan Villanueva, and Roxana Blasetti, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South*

- Regional Frameworks*, South Centre, Geneva, 2004, pp. 59-65.
19. See the legal arguments of the African Group, *supra* note 16.
  20. The TRIPS Agreement is contained in Annex 1C.
  21. Until then the Decision will continue to apply to all WTO Members as discussed above, *supra* section I.2.
  22. For further discussion on this point, see Sisule Musungu, "Intellectual Property and Public Health -Will it be Peace or War?" *The Journal of World Intellectual Property*, Vol. 7 No. 2, pp. 249-252, 2004.
  23. Article 64(2) of the TRIPS Agreement, *supra* note 2, provides that the application of non-violation and situation complaints to the TRIPS Agreement would be excluded for the first five years after the entry into force of the Agreement, that is, between 1995 and 2000. Article 64(3) provides that thereafter, these types of complaints would only be applicable subject to the establishment of their scope and modalities, to be agreed by consensus. So far no decision has been taken on the issue and there is a subsisting moratorium which was recently extended at the Hong Kong Ministerial Conference. See paragraph 45 of the Hong Ministerial Declaration, WTO document WT/MIN(05)/W/3/Rev.2.
  24. See the Communication from Argentina, Bolivia, Brazil, Ecuador, Egypt, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela on "Non-violation and Situation Nullification or Impairment under the TRIPS Agreement, WTO document IP/C/W/383.
  25. Vandoren and Van Eeckhaute, *supra* note 9, have argued that the Statement was an attempt to incorporate "comfort language" designed to enable the United States join the consensus on the Decision.
  26. The text of the Convention is contained in the United Nations Treaty Series, vol. 1155, p.131.
  27. See article 31 of the Convention, *id*.
  28. See article 32 of the Convention, *supra* note 25.
  29. See e.g., the press release by the WTO Director-General (available at [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm)) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) press release on 6 December 2005 (available at <http://www.ifpma.org/News/NewsReleases.aspx>)
  30. See e.g., the assessment of Doctors Without Borders (MSF) in the press release of 6 December 2005 on the amendment (available at <http://www.accessmed-msf.org/>).
  31. US Trade Representative Rob Portman, for instance, when explaining the different respects in which the Doha Development Agenda was moved forward in Hong Kong at the Closing Press Briefing, noted the formalization of "the landmark breakthrough in the TRIPS agreement regarding pharmaceuticals that balances the need of protecting patent rights with the need for life-saving medicines." On the other hand, Greenpeace, calling the meeting "a failure for environment and development," highlighted the Ministerial Declaration "failed to adequately address demands by developing countries to prevent the legitimisation of an assault on their biological resources for the benefit of developed country corporations."
  32. Article 66.1 of the TRIPS Agreement accorded LDCs a ten-year exemption on implementation, thus expiring on 31 December 2005.
  33. The transition period does not apply to Articles 3, 4 and 5 of the TRIPS Agreement. In addition, the decision is without prejudice to the Decision of the Council for TRIPS of 27 June 2002 on "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with respect to Pharmaceutical Products" (IP/C/W/25) and the right of LDCs to seek further extensions of the period provided for in article 66.1.
  34. The agenda of this information meeting, as well as several of the presentations, are available at [http://www.wipo.int/meetings/en/details.jsp?meeting\\_id=9462](http://www.wipo.int/meetings/en/details.jsp?meeting_id=9462). In addition, informal notes of this meeting can be found in the A2K mailing list, Vol. 1 # 250, November 22, 2005 at <http://lists.essential.org/pipermail/a2k/>.
  35. The Chilean proposal can be found in WIPO document SCCR/13/5.
  36. Although the report of the meeting is not yet available, informal notes of the SCCR meeting can be found in the A2K mailing list, Vol. 1 # 255, November 27, 2005 at <http://lists.essential.org/pipermail/a2k/>.
  37. The Brazilian proposal can be found in WIPO document SCCR/13/3. Brazil also reaffirmed its position that obligations in regards to technological protection measures, because they could undermine exceptions and limitations, should be excluded.
  38. The proposal by Chile can be found in WIPO document SCCR/13/4.
  39. For a description of the adoption of this Convention, please see below, *infra* section II.3.
  40. The Second Revised Consolidated Text for a Treaty on the Protection of Broadcasting Organizations can be found in WIPO document SCCR/12/2 Rev.2.
  41. The following members of the SCT submitted proposals: Barbados, France, Latvia, Mexico, Morocco, New Zealand, Norway, Russian Federation, Slovakia, Switzerland, the former Yugoslav Republic of Macedonia, United Kingdom, United States of America and the European Community. See WIPO Document SCT/15/2.
  42. See Summary by the Chair in WIPO Document SCT/15/4.
  43. The consolidated text can be found in document UNEP/CBD/WG-ABS/4/2.
  44. The matrix can be found in document UNEP/CBD/WG-ABS/4/3.
  45. The Conference is the supreme governing body of the FAO and meets every two years.
  46. See Agreement Between FAO and the World Intellectual Property Organization (WIPO), November 2005, FAO Document C 2005/LIM/6
  47. See CGRFA website,



- <http://www.fao.org/ag/cgrfa/ico1.htm>.
48. <sup>1</sup> A Governing Body should replace the CGRFA sometime in 2006.
  49. In the discussion of compliance, for instance, a chart was presented detailing government's views on the objectives, principles and nature of compliance. See Compilation and analysis of Governments' views on Compliance with the International Treaty on Plant Genetic Resources for Food and Agriculture, November 2005, FAO document CGRFA/MIC-2/04/3.
  50. See Background Study Paper No. 30, Options for Non-monetary Benefit-sharing: An inventory, October 2005, downloaded from <ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp30e.pdf>.
  51. See Second Global Congress on Combating Counterfeiting and Piracy website, <http://www.ccapcongress.net/>.
  52. The declaration is available at <http://www.ccapcongress.net/Files/Rome%20Declaration.doc>.
  53. Nigeria made a plea in this regard.
  54. See Article 15(c)(1), the International Covenant on Economic, Social and Cultural Rights, 16 December 1966, accessed from CESCR website, <http://www.ohchr.org/english/bodies/cescr/>.
  55. See overview of debate in South Centre and CIEL IP Quarterly Update, Fourth Quarter 2004, available at [www.southcentre.org](http://www.southcentre.org) and [www.ciel.org](http://www.ciel.org).
  56. See Para 3, CESCR General Comment No. 17, 21 November 2005, CESCR document E/C.12/2005.
  57. See Article 1, UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions, 20 October 2005.
  58. See an overview of these references in the South Centre and CIEL IP Quarterly Update, Third Quarter 2004, available at [www.southcentre.org](http://www.southcentre.org) and [www.ciel.org](http://www.ciel.org).
  59. See Preamble, UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions, 20 October 2005.
  60. See discussion above, *supra* section II.2.
  61. See *Intellectual Property Watch* "Intellectual Property Issues Kept Off WSIS Agenda", 30 November 2005, <http://www.ip-watch.org/weblog/index.php?p=158&res=1024&print=0>.
  62. See WSIS website, overview, <http://www.itu.int/wsis/basic/about.html>.
  63. See Para 29, Tunis Commitment, 16-18 November 2005, WSIS-05/TUNIS/DOC/7.
  64. See Para 90, Tunis Agenda for the Information Society, 16-18 November 2005, WSIS-05/TUNIS/DOC/6 (rev. 1).
  65. *Id.* Para 111.
  66. See Intellectual property rights, innovation and public health, Report by the Secretariat, 22 December 2005, WHO Document EB117/9.
  67. An overview of debate on technological protection measures (TPMs) can be found in South Centre and CIEL IP Quarterly Update, First Quarter 2005, available at [www.southcentre.org](http://www.southcentre.org) and [www.ciel.org](http://www.ciel.org).
  68. The USTR Policy Brief is available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Peru\\_TPA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Section_Index.html).
  69. Summaries of the FTA chapters are available, in Spanish, at <http://www.tlcperu-eeuu.gob.pe/index.php?ncategoria1=209&ncategoria2=210>.
  70. "Ya no tendremos más chantajes de EE.UU.," Página 12, December 21, 2005, available, in Spanish, at <http://www.pagina12.com.ar/diario/elmundo/4-60754-2005-12-21.html>.
  71. The Advisory Committee Reports for the US-Oman FTA are available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Oman\\_FTA/Reports/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Oman_FTA/Reports/Section_Index.html).
  72. The Commission Staff Paper is available at <http://www.epawatch.net/general/text.php?itemId=312&menuID=24>.

## ABOUT THE IP QUARTERLY UPDATE

The IP Quarterly Update is published on a quarterly basis by the South Centre and the Center for International Environmental Law (CIEL). The aim of the Update is to facilitate a broader understanding and appreciation of international intellectual property negotiations by providing analysis and a summary of relevant developments in multilateral, plurilateral, and bilateral fora as well as important developments at the national level. In each IP Quarterly Update, there is a focus piece analysing a significant topic in the intellectual property and development discussions.

Today, in addition to the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), there are other multiple fronts of discussion and negotiation on intellectual property. These other fora range from international organisations, such as the United Nations Educational and Scientific Organization (UNESCO), the Food and Agriculture Organization (FAO), the World Health Organization (WHO), the United Nations Conference on Trade and Development (UNCTAD), the World Customs Organization (WCO), INTERPOL, and the UN human rights bodies to regional and bilateral fora such as in the context of free trade agreement (FTAs) or economic partnership agreements (EPAs). In some cases, national processes or decisions, for example, invalidation of a key patent may have important international ramifications.

Consequently, all these processes constitute an important part of the international intellectual property system and require critical engagement by developing countries and other stakeholders such as civil society organisations. Multiple fronts of discussions and negotiations require a coordination of strategies and positions that is not always easy to achieve. The Quarterly Update is meant to facilitate such coordination and strategy development, and is therefore a vehicle for awareness raising as well as capacity development.



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