

INTELLECTUAL PROPERTY QUARTERLY UPDATE



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CENTER FOR INTERNATIONAL
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INNOVATION, ESSENTIAL HEALTH RESEARCH AND IPRS: THE WHO WORKING GROUP

I. Introduction

The relationship between intellectual property and the protection of public health has been a major issue of debate in several international forums, particularly at the World Trade Organization (WTO) and the World Health Organization (WHO). The debate centres on whether the intellectual property system is providing enough incentives into research and development (R&D) of medicines for diseases that disproportionately affect developing countries; and allowing access to existing medicines. Countries have made important efforts towards gaining a clear understanding of the debate and seeking to find solutions to the problems identified. In the context of the WTO, key achievements to date have been the WTO Doha Declaration on the Agreement on Trade Related Aspects of Intellectual Prop-

erty Rights (TRIPS) in 2001¹ that reinforced the utilisation of TRIPS flexibilities to address public health needs, and a permanent Amendment to Article 31 of TRIPS in December 2005 to make it easier for poorer countries to access cheaper generic medicines.² Although the WTO and its TRIPS Agreement continue to remain the major focus in dealing with public health and intellectual property-related issues, the WHO is increasingly playing its role as a forum for these discussions and one that is taking action to find solutions. In this regard, recent breakthroughs that have also contributed to strengthening the role of the WHO are the work of the independent Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) set up by the WHO and the adoption of a World Health Assembly (WHA) resolution towards the establishment of a global frame-

¹ See WTO (2001), WT/MIN(01)/DEC/W/2, Doha Declaration on the TRIPS Agreement and Public Health

² See WTO (2005), WT/L/641, Amendment of the TRIPS Agreement.

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work to implement the recommendations of the CIPIH. However, it is yet unclear to what extent these developments may in practice contribute to tackling intellectual-property related challenges.

The present note provides a brief overview and analysis of the processes that have been taking place in the context of the WHO in the past four years towards clarifying the relationship between intellectual property rights (IPRs), Innovation and Public Health and seeking solutions to the unequal burden of disease on developing countries and the limitations of the current IPR-based system for promoting medical R&D. Part I focuses on the CIPIH Commission, presenting a brief background to its establishment and short description and analysis of its work and key findings contained in its Report. Section II reviews the antecedents leading to the adoption of the WHA Resolution WHA59.24 and briefly analyses the Resolution and decision to create an intergovernmental working group on Public Health, Innovation, Essential Health Research and IPRs. Section III presents an overview of the current process towards the establishment of the intergovernmental working group and some of the challenges that lie ahead. Finally, Section IV provides some concluding comments.

II. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) and Its Report

In February 2004, the CIPIH ('the Commission') was established at the World Health Organization in accordance with the World Health Assembly (WHA) Resolution WHA56.27. The Resolution requested the Director-General "to establish the terms of reference for an appropriate time-limited body to collect data and proposals from the 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 against diseases that disproportionately affect developing countries."³

³ See WHO (2003), Resolution WHA56.27, "Intellectual Property Rights, Innovation and Public Health."

The Resolution WHA56.27 indicated a shared sense of urgency among WHO Members to address the enormous burden of disease that disproportionately affects developing countries, including the imbalance in current global efforts made towards developing new medicines and treatments for such diseases.⁴ It also signalled the emerging global consensus on the relationship between intellectual property rights and public health, in accordance with the WTO Doha Declaration on the TRIPS Agreement and Public Health.⁵

The Commission was set up as an independent, time-limited body to analyse the relationship between intellectual property rights, innovation and public health. In pursuing its analysis, the Commission was to gather evidence, consult with a wide range of stakeholders, and commission studies. The Commission was asked to present a final Report with concrete recommendations and proposals to the WHO Executive Board for action on how to address the problems identified by Member States, in particular how governments and other stakeholders can set R&D priorities to promote innovation relevant to developing country diseases and develop a global framework to achieve these objectives.⁶

⁴ See WHO (2004), CIPIH, Framework Paper, available at <http://www.who.int/intellectualproperty/documents/en/Framework.paper.pdf>.

⁵ See Musungu Sisule, "Benchmarking Intellectual Property", *Bulletin of the World Health Organization*, 84(5); May 2006, 366-370

⁶ The terms of reference of the Commission were the following: 1) Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact; 2) Review the volume and distribution of existing research, development and innovation efforts directed at these diseases; 3) Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases; 4) Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them; 5) Produce concrete proposals for action by national and international stakeholders

The Commission faced several difficulties in the process leading up to the presentation of the Report to the WHO Executive Board in April 2006, and then to the WHO Members at the WHA in May 2006. Among these were deep disagreements between the 10 Members of the Commission⁷, who although working in an independent capacity came from diverse backgrounds and affiliations as well as a leak of the Commission's draft Report to the pharmaceutical industry.⁸ Such setbacks, divergence of views and contested evidence led the Commission to delay the presentation of the Report to the WHO Executive Board for over a year.⁹ The outcome of the Report was a compromise. While it was accepted by all Members of the Commission, some expressed their reservations and made comments which are contained in an Annex to the Report.

The Report of the Commission: Public Health innovation and intellectual Property rights

The Report of the Commission makes a significant contribution to the understanding of the impact of intellectual property on public health, particularly the need for alternative mechanisms to stimulate R&D for diseases that disproportionately affect developing countries.¹⁰ The Report presents extensive evidence on the extent of the burden of disease on developing countries and the flaws in the current system for medical R&D. For example, the Report points out that while the technical capacity exists to provide access to lifesaving medicines, vaccines and other interventions, which are widely available in the developed world, millions of people suffer and die in the developing world because such means are not available or accessible there.¹¹ The Report also notes

that in contrast to developed countries, developing countries are increasingly suffering from a double burden of disease because of the continuing scourge of communicable, maternal, prenatal and nutritional diseases, combined with injuries and noncommunicable diseases.¹² In addressing the problem, the Report finds that there is a wide gap between rhetoric and action by governments.¹³

The Report warns Member States about the possible negative consequences of negotiating bilateral and free trade agreements that include TRIPS-plus standards of intellectual property protection.¹⁴ Another key finding of the Report is that intellectual property rights may have a limited or non-existent role in promoting innovation in respect to public health.¹⁵ In particular, the Report recognizes that patents are irrelevant for the development of the products needed to address diseases that disproportionately affect developing countries, where there is little purchasing power. Rather, the report concludes, patents may hamper innovation by blocking follow-on research or access to research tools.¹⁶ Moreover, the report finds that the current market-based system of R&D incentives for medicines fails to induce adequate investment in products needed by developing countries.¹⁷

The Report presents over 50 recommendations to be implemented by different stakeholders; including the WHO, governments, international organizations, the pharmaceutical industry, universities and non-profit foundations involved in research and development of medicines. The recommendations call upon governments, the WHO and other stakeholders for improved mechanisms and new measures to be put in place to promote innovation relevant to developing country diseases.¹⁸ The Report recognizes the need for an international mechanism to increase global coordination and funding of medical R&D.¹⁹ It further calls for the WHO to play a leading role in promoting a more sustainable and better-funded effort to address unresolved issues, and in particular, to develop a Global Plan of Action to secure enhanced

⁷ For the list of Members, see the Commission's webpage available at <http://www.who.int/intellectualproperty/background/members/en/index.html>

⁸ See Intellectual Property Watch, "WHO IP Commission Seeks to Overcome Leak of Report to Industry", 23 January 2006.

⁹ The WHA 56.27 Resolution requested the Commission to present the report to the Executive Board at its 115 Session in January 2005

¹⁰ WHO (2006), Commission on Intellectual Property Rights, Innovation and Public Health, "Public Health: Innovation and Intellectual Property Rights", available at <http://www.who.int/intellectualproperty/documents/thereport/CIPRH23032006.pdf>

¹¹ Supra, note 10, p.21

¹² Supra, note 10, p.15

¹³ Supra, note 10, p.21

¹⁴ Supra, note 10, p.34, 145

¹⁵ Supra, note 10, p.35, 196

¹⁶ Supra, note 10, p.33

¹⁷ Supra, note 10, p.31

¹⁸ E.g. supra, note 10, p.63

¹⁹ Supra, note 10, p.107

and sustainable funding for developing and making accessible products for diseases that disproportionately affect developing countries.²⁰

The Report was met with mixed reactions, including criticism and disappointment that the Report did not go far enough, for example, in calling for concrete changes in the intellectual property system.²¹ The Report was also criticized for "lacking teeth, or novelty, and failing to provide alternatives and concrete new and action-oriented proposals"²², as had been requested by the WHA. While the Report developed several recommendations, there are important questions regarding the extent to which it has contributed towards addressing the challenges faced in relation to intellectual property, development and public health. Nonetheless, the Report and the analysis presented on the impact of intellectual property on public health, building upon the analysis of the UK Commission on Intellectual Property Rights, is the first of its kind.²³ The implementation of the recommendations could significantly improve our ability to address the challenges of the disease burden on developing countries.

III. WHA Resolution WHA59.24

The Commission Report was reviewed by the WHO Executive Board on 28th April 2006, along with a draft resolution prepared and presented by the Commission.²⁴ The draft resolution aimed at establishing a global

framework and plan of action for promoting R&D for developing country diseases and access to medicines and the establishment of a working group to develop the global strategy and plan of action. The Commission Report and draft resolution were subsequently discussed by governments at the WHA session from the 22nd to 29th May, 2006, along with another draft resolution presented by Brazil and Kenya for the establishment of a global framework on R&D on essential medicines. The final outcome was Resolution WHA59.24 on "Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of Action," which merged the two resolutions.

The resolution by Brazil and Kenya for a new global framework for R&D was first submitted by Kenya in November 2005 to the WHO, in order for it to be discussed at the January 2006 meeting of the Executive Board. There were several difficulties in getting the resolution to be discussed in the January meeting of the Executive Board. Apparently, the official reason for the delay was that Kenya in its submission had not indicated clearly under which agenda item the proposed resolution was to be discussed, and thus was asked to re-submit the resolution with the indication. Brazil later co-sponsored the proposal, and the re-submission of the resolution to the Executive Board thus became a joint proposal by Brazil and Kenya.

In addition to their direct engagement in the intellectual property and public health policy debates in the WTO and WHO, Brazil and Kenya have been proactively involved in seeking practical solutions to address the continued R&D gap for diseases that disproportionately affect developing countries. For example, public sector institutions from both countries are currently engaged in collaborative R&D projects for the development of new medicines to tackle developing country diseases, as part of the Drugs for Neglected Diseases (DNDi) Initiative.²⁵ Other elements that helped build momentum for the proposal included the on-going work of the CIPIH as well as other proposals for needs-

²⁰ Supra, note 10, p.209

²¹ See Intellectual Property Watch, "WHO IP Report Comprehensive, But No Calls for Major Change in the IP System", 3 April 2006

²² See for example, Ellen t'Hoen, "Report of the Commission on Intellectual Property Rights, Innovation and Public Health, A Call to Governments", Bulletin of the World Health Organization, 84(5), May 2006; and Report of the Meeting of the Executive Board on the Commission on Intellectual Property Rights, Innovation and Public Health, WHO document A59/16Add.1, dated 18 May 2006, paras 3-8.

²³ See United Kingdom (2003), Commission on Intellectual Property Rights (CIPR), "Integrating Intellectual Property Rights and Development Policy", available at <http://www.iprcommission.org>.

²⁴ WHO (2006), Report of the Meeting of the Executive Board on the Commission on Intellectual Property Rights, Innovation and Public Health, WHO document A59/16Add.1.

²⁵ Oswaldo Cruz Foundation/Fiocruz (Brazil) and Kenya Medical Research Institute (Kenya). See www.dndi.org with respect to the Drugs for Neglected Diseases (DNDi) Initiative.

based R&D incentives for medicines to target developing country diseases.

One of the main proposals that preceded the Brazil and Kenya R&D resolution was one for the development of a medical R&D treaty. The medical R&D treaty grew from discussions that started in 2002 among a number of civil society actors, including economists, scientists, and public health experts, towards developing an alternative trade framework for medical R&D. This led to the proposal for a new treaty framework that would ultimately replace existing or planned trade agreements that focus on patents or drug prices.²⁶ The proposal for a medical R&D treaty was submitted by 162 people from academia, government, politics and civil society to the CIPIH Commission for consideration.²⁷ The Commission reviewed the proposal and in its Report acknowledged its value by recommending that "the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision."²⁸

The proposed R&D resolution by Brazil and Kenya was ground breaking since it was the first time that governments submitted a proposal to create a new mechanism to address R&D priorities and to promote R&D for new medicines. The resolution was presented as a response to a growing concern over the inadequacy of the current global system for supporting innovation in new medicines and other health technologies, as well as concern about the impact of an increasing percentage of people without access to essential medicines and other technologies for health care, both in terms of their availability and financial affordability.²⁹ Accordingly, the aim of the Resolution, in line with current efforts being undertaken by countries, was to address some of the identified shortcomings of the current R&D sys-

tem and trade agreements. It is also based on the recognition that there are inadequate mechanisms to enhance the capacity of all countries to contribute and participate in medical innovation efforts.

The Resolution identified intellectual property rights as one of the many tools available to promote innovation, creativity and transfer of technology and the need to balance intellectual property rules with the public interest. Thus, the Resolution sought the establishment of a global framework supporting essential medical R&D based on the principle of equitable sharing of the costs of R&D, and incentives to invest in useful R&D in the areas of patients' need and public interest. The Resolution would demand that the WHO play a greater role in shaping R&D policies for medicines.

A large part of the text of the Brazil and Kenya proposed R&D Resolution that arrived at the WHA in May 2006 was bracketed, signalling the divergences in the positions among Members on the key elements of the Resolution. At the WHA there was intense debate and negotiations on the proposed two proposed resolutions; the draft resolution on the CIPIH Report and the resolution on R&D proposed by Brazil and Kenya. A working group of interested Member States of the WHA, chaired by Switzerland, worked towards reconciling the two resolutions on intellectual property and public health, and presented a new draft resolution that merged the two separate resolutions.

On the 27th May 2006, the WHA adopted Resolution WHA59.24 which significantly contributes to transforming the global framework for medical R&D. The Resolution established "an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action to provide a medium term framework to implement the recommendations of the CIPIH Commission."³⁰ The working group is to Report to the 60th WHA in 2007 through the Executive Board on the progress made, "giving particular attention to needs-driven research and other potential areas for early implementation action". The working group would then on submit the final global strat-

²⁶ See Consumer Project on Technology, "The Proposed medical R&D Treaty". Available at <http://www.cptech.org/workingdrafts/rndtreaty.html>

²⁷ See Letter from the Consumer Project on Technology to the CIPIH Commission, "Request to Evaluate Proposal for New Global R&D Treaty", Geneva, CIPIH Submission, 2005. Available at

²⁸ *Supra*, note 8, p.200

²⁹ See "Background Document for Proposed Resolution on Global Framework on Essential Health Research and Development," prepared by the Delegation of Kenya, January 2006.

³⁰ WHO (2006), Resolution on Public Health, Innovation, Essential Health Research and intellectual property rights: towards a global strategy and plan of action, WHA59.24.

egy and plan of action to the Sixty-first WHA through the Executive Board in 2008.

The Director General of the WHO was called on to convene "immediately the intergovernmental working group and to allocate the necessary resources to it", invite other intergovernmental and non-governmental organizations in official relations with the WHO as observers to the sessions of the working group, as well as experts and "a limited number of concerned public and private entities" to attend the sessions and to "provide advice and expertise, as necessary, and upon request of the Chair, taking into account the need to avoid conflict of interests". The WHO was also given a continued role in examining the relationship between intellectual property rights and public health, as the Director General was also called upon to continue to monitor, from a public health perspective, the impact of intellectual property rights and other issues addressed in the CIPIH Commission Report, on the development of and access to medicines, and to Report thereon to the General Assembly.

The purported aim of the global strategy and plan of action, as contained in the Resolution, is to secure an enhanced and sustainable basis for needs-driven, essential-health R&D relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and stimulating funding needs in this area.

The Resolution also called on Member States to, among other things, 1) make global health and medicines a priority sector and prioritize a needs-based approach to R&D; 2) consider the recommendations of the CIPIH Report and contribute actively to the development of a global strategy and plan of action; 3) encourage trade agreements to take into account the flexibilities allowed under TRIPS and recognized by the Doha Declaration.

The approval of the Resolution was an important step in addressing some of the pressing problems facing developing countries in relation to diseases that disproportionately affect them, including R&D in areas of public health priority and greater access to new medicines. The fact that a global framework is to be designed is another important achievement for developing coun-

tries. The challenge now is to ensure an effective outcome from the intergovernmental working group.

IV. The Intergovernmental Working Group on Public Health, Innovation, Essential Health Research and Intellectual Property Rights

Although the Resolution WHA 59.24 called on the WHO Director General to immediately establish an Intergovernmental Working Group, it has yet to be established. In sharp contrast to the CIPIH, which was set up in a timely manner and at the outset provided access through a public website to updated information concerning its objectives and activities,³¹ to date there is no publicly-available information about the working group, other than from the press. According to the press, the past few months have been dedicated to the preparatory process of determining the composition of the group, including the representatives of the WHO that will manage the group, the interested governments, and intergovernmental and non-governmental observers that will participate. Moreover, the WHO Secretariat has been working on defining of the scope of the substantive issues to be addressed by the working group, the process for the discussions, and preparation of background documents.³²

One of the difficult political issues that has been settled is the appointment of the WHO officials that will lead the working group. Howard Zucker, assistant director for health technology and pharmaceuticals at the WHO since January 2006, and previously assistant secretary of health at the United States' department of Health and Human Services (HHS), will be leading the intergovernmental working group. Elil Renganathan, a national of Malaysia and previously director for the WHO Mediterranean Centre for Vulnerability Reduction in Tunis, Tunisia, will be the executive secretary of the working group. However, there are several pending issues before the working group actually begins its work. These include, for example, discussions among six WHO Regional Committees to propose a selected number of Member

³¹ See webpage of the CIPIH, <http://www.who.int/intellectualproperty/en/>.

³² Intellectual Property Watch, "WHO Intergovernmental Working Group on IP Ready 'In Days'", dated 23 June 2006

states to compose a management group to lead the working group.³³ Other issues include public consultations currently being organized by the WHO to take place in November for non-governmental organizations, experts, academics and the general public to provide input in the form of a Report to a meeting open to all WHO Member states to be held in December.³⁴

Ensuring that the working group effectively carries out its work with the input of all interested Member states on equal footing, as well as ensuring that it is guided by the participation of other intergovernmental and non-governmental organizations and the advice of experts and other possible entities avoiding conflict of interests will prove a difficult task. For example, concerns have been raised as to whether Zucker will be objective and withstand apparent pressure from the United States on the working group and allow WHO experts to participate in the process. Such concerns have surfaced since it became known that a senior official of the United States HHS and former colleague of Zucker, in a formal letter to the WHO, demanded that the organization withdraw and remove the WHO logo from a co-publication by the WHO and the South Centre that critically reviewed the United States' trade policy in relation to public health. The publication was commissioned by the CIPIH and before publication was presented at a workshop at the WHO in May 2005, first to an expert panel and later to all interested parties.³⁵

The experience and setbacks of the CIPIH, starting from the setting up process and ending with the Report as the outcome, might be valuable in avoiding such mishaps. The Working Group should avoid problems such as report leaks, conflict of interests and pressure from parties that compose or are involved in the working group, as well other situations that may seriously undermine its work, credibility and legitimacy. To this aim transparency in the process and all aspects of the activities of working group is funda-

mental. The real and substantive engagement of developing countries is among the core challenges that lie ahead. Nonetheless, the working group presents a crucial and unique opportunity for developed and developing countries alike to design and implement an alternative, effective and workable global framework for the medium term for promoting R&D for new medicines, based on public health needs.

V. Conclusion

Important efforts have been made by Member States in the context of the WHO for the past four years towards gaining a greater understanding of the impact of intellectual property on the development of medicines for diseases that disproportionately affect developing countries, setting research priorities based on public health needs and determining a more equal share of the costs of promoting essential health R&D. In this regard, the CIPIH Report and the WHA Resolution WHA59.24 are important breakthroughs. However, it is still unclear whether the findings and recommendations of the Commission's Report will be actually implemented. The pro-active engagement of developing countries and civil society in the work and discussions of the Intergovernmental Working Group on Public Health, Innovation, Essential Health Research and IPRs is a necessary requirement in order to ensure that the working group can develop an appropriate framework to implement the Commission's recommendations, as mandated by the WHA Resolution WHA59.24, and in order to drive further initiatives in the WHO to address the many intellectual-property challenges that developing countries face in achieving their public health goals.

³³ Id., "Newcomer Howard Zucker, Former US Official, To Head WIPO IP Group", dated 19 September 2006

³⁴ Id., "WHO Plans Public Hearing on IP Group by December", dated 2 October 2006

³⁵ Id., "US Seeks Review Of WHO Publication Policy After Report On US Trade Deals", dated 28 September 2006

AN OVERVIEW OF RELEVANT DEVELOPMENTS IN THE VARIOUS IP FORA

The following is an overview of the developments in the various fora dealing with intellectual property issues in the Third Quarter of 2006.

World Trade Organization (WTO)

The Third quarter of 2006 was marked by an indefinite suspension of the negotiations of the Doha Round. The halting of the talks was sparked, in part, by the inability of WTO Members to reach agreement on commitments to be undertaken on key issues, including non-agricultural market access (NAMA) and agriculture. The impasse has in turn resulted in the slowing down of intellectual property-related discussions of significant importance to developing countries, including the proposal by a number of developing countries for the amendment of the TRIPS agreement to incorporate a mandatory requirement to disclose the origin of biological resources and/or associated traditional knowledge in patent applications.³⁶

WTO TRIPS Council

Although the TRIPS Council did not meet in a regular session during the third quarter of 2006, new communications have been submitted by Member States to the Council. A new paper submitted by Brazil provides responses to questions raised on the proposed draft amendment to TRIPS – Article 29*bis*.³⁷ Some of the issues addressed include: 1) the need to disclose both the country of origin and the source; 2) the use of the term biological resources instead of genetic resources, in accordance to the CBD, with the intention to ensure, among other things, that all possible cases of biopiracy are covered; 3) the use and meaning in practice of the three triggers for the disclosure requirement; 4) the application of the requirement for correction of information that applies to both the pre-grant and post-grant periods.

The next formal TRIPS Council meeting is scheduled for 25-26 October.

World Intellectual Property Organization (WIPO)

WIPO Program and Budget Committee (PBC)

The tenth session of the WIPO Program and Budget Committee was held at the headquarters of WIPO from July 11 to 13, 2006. Members discussed the "Proposal on A New Mechanism to Further Involve Member States in the Preparation and Follow Up of the Program and Budget, (document WO/PBC/10/2). The proposal aimed at strengthening the involvement and participation of Member States in the elaboration of the Program and Budget of WIPO.

In general, Members supported the proposal for a new mechanism and proposed a number of amendments with respect to the transitional implementation of the mechanism for 2006/7 (Annex III) and the full implementation as of 2008-onwards (Annex IV).

This meeting also briefed Member States on the second session of the Audit Committee and the progress Report on the Desk-to-Desk Review Project. Some Members, concerned about potentially sensitive issues that could arise from this process, refrained from supporting the recommendations of the Audit Committee on the pre-assessment phase of human and financial resources of the Organization, where the external firm would validate "its understanding of the expected evolution of the world IP environment".³⁸

Among the recommendations agreed by the PBC to be made to the annual WIPO General Assemblies in their 2006 session, where 1) the adoption of the transitional and full implementation of the new mechanism (Annexes III and IV of document WO/PBC/10/2); 2) and the amendment of WIPO Financial Regulation 3.2 to facilitate the implementation of the proposed new mechanism.

³⁶ WTO (2006), IP/C/W/474.

³⁷ WTO document IP/C/W/475, dated 26 July 2006

³⁸ See WIPO (2006), WO/PCB/10/3, paragraph 10.

WIPO Standing Committee on Copyright and Related Rights' (SCCR)

The 15th session of the Standing Committee on Copyright and Related Rights (SCCR) took place in Geneva from 13 to 15th September. This additional meeting of the SCCR, prior to the WIPO General Assemblies, was held at the request of Members who were unable during the 14th session of the SCCR to fulfil the Committee's 2005 mandate, i.e., "agreeing and finalizing a basic proposal for a treaty on the protection of the rights of broadcasting organizations, to enable the 2006 WIPO General Assembly to recommend the convening of a Diplomatic Conference in December 2006, or at an appropriate date in 2007".

Members remained divided as they considered a revised Draft Basic Proposal (document SCCR 15/2). Several developing as well as developed countries argued that the Draft Basic Proposal contained inherent inconsistencies and as such, did not constitute a sufficient basis to proceed to a Diplomatic Conference, while others felt that the draft document formed a sufficient basis for convening the Diplomatic Conference. Despite concerns expressed by many Member States, the SCCR recommended to the General Assembly the convening of a Diplomatic Conference on the Protection of the Rights of Broadcasting Organizations, including cablecasting organisations, to be held from July 11 to August 1, 2007, as well as a meeting of a preparatory committee and a "special meeting" aimed at reaching some form of consensus on substantive issues.

The 2006 WIPO General Assemblies

The 33rd session of the WIPO General Assemblies was held in Geneva from 25 September –03 October 2006, amidst existing divergences among Members States, particularly on matters of critical importance to most developing countries. While various issues formed the agenda, three required urgent direction from the Assemblies: 1) The development agenda proposals and the way forward for the Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA); 2) patent law harmonization and the future work programme of the Standing Committee

on Patents (SCP); 3) the convening of a diplomatic conference for a proposed treaty on the protection of broadcasting organizations. Considering the longstanding impasse on these issues, informal consultations were held, in addition to the formal meetings, as Members sought to iron out their differences.

The WIPO Development Agenda and the fate of the PCDA

For many developing countries, the most significant decision taken at the General Assemblies concerned the future of the WIPO development agenda. During the discussions, most Member States highlighted the importance of continuing the development agenda discussions in WIPO and for a balanced and inclusive treatment of all PCDA proposals.³⁹ The decision was adopted after significant informal consultations. The decision provides for the renewal of the PCDA mandate for a period of one year and that the PCDA hold "two 5-day sessions, in a manner that allows for structured in-depth discussions, on all 111 proposals made so far, during the sessions of the IIM and PCDA in 2005 and 2006 respectively, taking into account the decision of the 2005 General Assembly...". The first session of the PCDA in 2007 will consider the proposals attached in Annex A. The second session of the PCDA in 2007 will consider the proposals as attached in Annex B.⁴⁰

Furthermore, The PCDA is requested "to narrow down the proposals, in order to ensure that there is no repetition or duplication, to note those proposals which relate to existing activities in WIPO and those which do not, to separate the proposals which are actionable, from those which are declarations of general principles and objectives." The PCDA is also called to Report to the 2007 General Assembly, with recommendations for action on the agreed proposals, and on a framework for continuing to address, and where possible to

³⁹ See PCDA 2 report

⁴⁰ The format of Annex A proposals, stem from proposed PCDA recommendations to the 2005 General Assembly made by Chairman at PCDA 2. These were rejected by several developing country members. At the end of the PCDA 2, the Chairman's proposal was adopted by the Kyrgyz Republic as its own. Annex B proposal contain most of the proposals made by the Group of Friends of Development

move forward, on the other proposals following the 2007 General Assembly."

Despite this inclusiveness, several Member States expressed concern as to the manner in which the proposals will be narrowed down, and the consequences of separating so-called "actionable proposals" from those which are declarations of principles and objectives. Nonetheless, some Members were reassured by the fact that the production of working documents under the narrowing process will be carried out by the Chairman of the General Assembly, the Philippines Ambassador Enrique Manolo, rather than the Chairman of the PCDA, the Paraguayan Ambassador Rigoberto Gauto Vielman, who has lost the trust of the majority of Members

The Proposed Treaty on the Protection of Broadcasting Organizations

With regards to the protection of broadcasting organizations, and following the outcome of informal consultations, the WIPO General Assembly adopted a decision approving the convening of the Diplomatic Conference on the Protection of the Rights of Broadcasting Organizations from November 19 to December 7, 2007, a later date than was initially recommended by the 15th session of the SCCR. The Assembly also agreed that the Revised Draft Basic Proposal (Document SCCR/15/2) would form the basis to conduct the Diplomatic Conference. Two formal sessions of the committee will be held (in January and June 2007 in addition to a meeting of the preparatory committee, in June 2007 before the holding of the Diplomatic Conference.

The adopted decision further stipulates that "it is understood that the session of the SCCR should aim to agree and finalise, on a signal-based approach, the objectives, specific scope and object of protection with a view to submitting to the Diplomatic Conference a revised basic proposal, which will amend the relevant parts of the Revised Draft Basic Proposal referred to in paragraph 2 of the draft decision."⁴¹ However, paragraph 4 of the decision stipulates that convening the Diplomatic Conference may be conditional on whether an agreement on amending the relevant parts of the Revised

Draft basic proposal is achieved. Otherwise the basis for discussions remains the original Revised Draft Basic Proposal.

Standing Committee on Patents (SCP)

The General Assemblies were called to decide how to guide the future work plan of the Standing Committee on Patents (SCP). In particular, how to proceed with the discussions on the Substantive Patent Law Treaty (SPLT). WIPO Members remain deadlocked regarding their expectations of what should be included in the SCP work plan, especially with respect to the SPLT.

The decision reached at the General Assemblies was a compromise. The decision calls on Members to submit their proposals on the work programme of the SCP, including proposals on the way forward, and for the Chair of the General Assembly to hold inclusive informal consultations aimed at discussing the proposals made, and to formulate recommendations for a work plan for the SCP to the General Assembly in 2007.

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Divergences remain among Member countries concerning the expected outcome of the IGC discussions. Developing countries on the one hand continue to press for an inclusive discussion of documents WIPO/GRTFK/IC/9/4 and WIPO/GRTFK/IC/9/5, including the possibility of a legally binding international instrument for the protection of TK and TCE against misappropriation. On the other hand, developed countries continue to maintain that the timing is not yet ripe for the establishment of a legally binding instrument. Given that a decision was not required, the General Assembly took note of the Committee's work in progress.

The Tenth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore will be held in Geneva, Switzerland, Nov 30, 2006 to Dec 08, 2006.

⁴¹ WIPO General Assembly decision adopted 30 September 2006 (which decision)

The WIPO Coordination Committee

The committee, in closed session, discussed a proposed agreement between the WIPO and the Food and Agricultural Organization (FAO). The agreement, having already been approved by the FAO, proposed cooperation across a wide range of areas, 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; Access to, and transfer of, technology in the food and agriculture sector; and Plant protection and production. The agreement also provided for the development of joint positions and statements by both organizations. Some Members raised concerns that such a significant agreement had been concluded between the FAO and the WIPO Secretariat without sufficient consultation with Member States. After some discussion, the committee decided to delay consideration of the agreement until the next meeting of the Coordination Committee.

Other upcoming WIPO Meetings.

The Sixteenth Session of the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications, will take place in Geneva, Switzerland, Nov 13, 2006 to Nov 17, 2006.

A colloquium on "Standards and Patents", will take place in Geneva, Switzerland, in Room A at the WIPO Headquarters on Wednesday, November 29, 2006, as part of a series of colloquia on selected patent issues between October 2006 and September 2007.⁴² The colloquia, which are open to the public, are intended to provide information on different patent-related topics and to provide a forum for an exchange of information among participants on these topics.

⁴² See <http://www.wipo.int/patent/colloquia/en/2006/11/index.html>.

Other Multilateral Fora

United Nations Conference on Trade and Development (UNCTAD)

UNCTAD has published its annual Trade and Development Report titled "Global Partnerships and national policies for development."⁴³

The Report indicates that while the TRIPS provisions dealing with protection of IP are of a binding nature, including the fact that non-compliance can be challenged under the WTO dispute settlement mechanism, "provisions regarding technology transfer and technical cooperation, which are of importance mainly for developing countries, are of a "best endeavour" nature and difficult to enforce, and non-compliance is not subject to a penalty."⁴⁴ The Report also highlights that "regional and bilateral trade agreements with developed countries often foreclose part of the autonomy left open to developing countries by TRIPS."⁴⁵

UNCTAD will be hosting an Ad hoc Expert Meeting: International arrangements on intellectual property and measures to improve developing country productive capabilities in the supply of essential medicines at Palais des Nations, Geneva, Switzerland, 19-20 October.

Regional and Bilateral Trade Agreements with Intellectual Property Provisions

The following section highlights the latest developments in the bilateral and regional trade negotiations of the United States and Europe with developing country counterparts in the third quarter of 2006, with specific focus on IP issues.

⁴³ See UNCTAD Trade and Development Report 2006. "Global Partnerships and national policies for development", available at http://www.unctad.org/en/docs/tdr2006_en.pdf.

⁴⁴ Id, pp. 172.

⁴⁵ Ibid, pp. 174

Free Trade Agreements involving the United States

Despite an expressed commitment on the part of the United States to successfully conclude the Doha Round, Susan Schwab, the United States Trade Representative (USTR), has indicated that the United States intends to pursue "more actively" bilateral and regional free trade agreements.⁴⁶ In addition, the USTR announced a review of the General Systems Preferences (GSP) programme set to expire on 31 December 2006. The GSP mechanism allows lower duty imports for a wide range of products from 133 major beneficiary countries. The review process aims at determining the eligibility of thirteen major beneficiary countries, and to establish whether trade preferences under such a programme should be limited, suspended or withdrawn with respect to such countries.⁴⁷ The office of the USTR is currently reviewing a proposal by the Chair of the House Ways and Means Committee, Bill Thomas, in respect of which Brazil and India would cease to benefit from trade preferences under the GSP programme.

Andean countries

Peru-FTA

With the US Congressional elections due to take place in November 2007, it is unlikely that the Peru FTA will receive Congress approval beforehand. Major objections are likely to come from Democratic representatives citing inadequate labour provisions.

Other Andean Countries

On 8 August 2006, the United States Congress received a presidential notice, which notifies the President's intention to enter into an FTA with Colombia. Considering the 90 days time limit, and the

⁴⁶ See article "US will not abandon WTO Talks despite Failure in Geneva", available <http://usinfo.state.gov/xarchives/display.html?p=washfile-eng->

http://www.bilaterals.org/article.php3?id_article=4868

⁴⁷ The beneficiary countries include: Argentina, Brazil, Croatia, India, Indonesia, Kazakhstan, Philippines, Romania, Russia, South Africa, Thailand, Turkey, and Venezuela.

fact that the International Trade Commission has yet to complete its analysis of the FTA on the United States economy, it is unlikely that the FTA will be presented and debated before Congress until after the United States November Congressional elections. The FTA with Colombia is the second, after the Peru FTA in the Andean region to be concluded. Currently, negotiations with Ecuador have been suspended. It is still unlikely at this time that FTA negotiations with Bolivia will be launched, as had been expected earlier this year.

Middle East

The United States has ratified the FTA with Oman. The agreement builds on FTAs already concluded with Israel, Jordan, Morocco, and Bahrain and are part of a larger United States' Middle East strategic policy. It is unlikely that the United States - United Arab Emirates FTA negotiations will be completed in time to be considered under current Trade Promotion Authority (TPA) mandate set to expire at the end of June 2007. The fifth round of trade negotiations was suspended earlier this year, due to political controversy over the investment of Dubai Ports in a British company running logistics at terminals in six major United States' ports.⁴⁸

Asia

The Third round of FTA talks between Malaysia and the United States has been rescheduled to take place in October 2006. Reports state that the postponement of trade talks was at the request of Malaysia because its chief FTA negotiator had been promoted to a new position and time was needed to allow his replacement to prepare.⁴⁹ FTA negotiations with Thailand continue to be stalled, and are likely to continue to be so as long as the present military rule persists.

A Congressional vote on a bill granting Vietnam permanent Most-Favoured-Nation status will take place after the November elections.

⁴⁸ Bahrain Tribune, « No Political price for FTA, says UAE », | 4 June 2006, cited at http://www.bilaterals.org/article.php3?id_article=4868

⁴⁹ See, World Trade Online, Inside U.S. Trade Vol 24, NO.38- September, 2006, available at <http://www.insidetrade.com/>.

Africa

The United States - Southern African Customs Union (SACU) FTA negotiations, launched in 2003, is looking increasingly unlikely. The countries that make up the SACU are Botswana, Lesotho, Namibia, South Africa and Swaziland. Differences remain on the core issues, including the impact of the FTA on access to medicines.

Other US FTA negotiations

It is unlikely that United States - Panama FTA negotiations will be completed in time to be considered under the TPA. Progress appears to be stalled by disagreements in agriculture and procurement issues.

Free Trade Agreements involving the European Union

The suspension of the Doha Round appears to have prompted the European Union (EU) to reconsider its trade policy strategy. The European Union Trade Commissioner, Peter Mandelson, has announced the adoption of a new trade policy strategy for the EU, which aims at "opening new markets abroad for EU companies to trade and ensuring that European companies are able to compete fairly in those markets."⁵⁰ The strategy includes the launching of the next phase of the EU's global strategy for protecting intellectual property rights; the proposal of new generation bilateral free trade agreements "with key partners to build on WTO rules by tackling issues which are not ready for multilateral discussion and by preparing the ground for the next level of multilateral liberalisation"; and the mapping out of a comprehensive new strategy on China at the end of October 2006.

Reports indicate continued progress of trade talks between the EU and the Gulf Cooperation Council (GCC), with parties expecting to sign an FTA before the end of 2006. Likewise, EU-Mercosur FTA trade talks have also resumed following their

suspension in 2005. The parties are scheduled to meet in November 2006.⁵¹

European Partnership Agreements

Various activities took place during the third quarter of 2006, with respect to the EU-African, Caribbean and Pacific Group of States (ACP) Economic Partnership Agreements. These included an agreement between ACP and EU on modalities and terms of references for Review of Economic Partnership Agreements (EPAs), stipulated in Article 37.4 of the Cotonou Agreement; the beginning of second phase of negotiations on EPAs, for the Economic Community Of West African States (ECOWAS) and EU; and a meeting in Mombassa between the European Community and Eastern and South African countries' (ESA) trade representatives to discuss the response by the EC to the draft text prepared by ESA. However, divergences continue to exist between the EU and ESA on how to ensure that EPAs deliver on their development objectives. Furthermore, Joint Technical Negotiations sessions have been held between the EC and the Caribbean Forum of African, Caribbean and Pacific States (CARIFORUM) and Pacific Forum, respectively.⁵²

⁵⁰ See European Commission, "Global Europe: competing in the world", Speaking points by Commissioner Mandelson, 4 October 2006 available at http://ec.europa.eu/commission_barroso/mandelson/speeches_articles/sppm117_en.htm

⁵¹ "EU/Mercosur meeting postponed for November", available at

http://www.bilaterals.org/article.php3?id_article=6051

⁵² See Melissa Julian and David Makhan, "EPA Negotiations Update", in Trade Negotiations Insights, Vol. 5, No. 5 September-October 2006, ECDPM –ICTSD, available at

http://www.ictsd.org/tni/tni_english/TNI_EN_5-5.pdf.

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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