GENERAL TRENDS IN THE FIELD OF INTELLECTUAL PROPERTY: ISSUES AND CHALLENGES FOR THE ESTABLISHMENT OF A DEVELOPMENT-ORIENTED FRAMEWORK

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I. INTRODUCTION

This year marks the tenth anniversary of the coming into being of the World Trade Organization (WTO) and the adoption of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).¹ It is now widely accepted that the adoption and entry into force of the TRIPS Agreement significantly changed the international intellectual property regime in both institutional and conceptual terms. By introducing the principle of minimum intellectual property standards, the TRIPS Agreement became the *de-facto* conceptual and strategic basis for subsequent multilateral and bilateral intellectual property agreement negotiated subsequent to TRIPS and covering the same subject matter among and/or involving WTO members could only create higher standards. The TRIPS Agreement also ushered in the era where higher standards for intellectual property protection could be directly obtained in exchange for concessions in core trade areas such as agriculture and textiles and where trade measures could be used as an internationally accepted avenue to enforce intellectual property standards abroad.

Institutionally, the adoption of the TRIPS Agreement under the auspices of the WTO meant that the World Intellectual Property Organization (WIPO) ceased to have its 'exclusive competence' on intellectual property matters. The TRIPS Agreement also marked the beginning of a significant high profile debate on the costs and benefits of intellectual property for developing countries, a debate that has led to unprecedented levels of attention to be given by civil society, academic and other groups to intellectual property matters with important implications for the institutional dynamics in this area. In particular, the debate on the benefits and costs of intellectual property for developing countries has culminated into a number of important international developments including significant levels of funding for public interest issues relating to intellectual property from both philanthropic foundations and development agencies of developed countries; the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in November 2001 and a number of follow-up decisions in the WTO²; the establishment of the United Kingdom (UK) Commission on intellectual Property (IPR Commission) and the

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¹ The Final Act of the Uruguay Round of trade negotiations and the Agreement establishing the WTO were signed in Marrakesh, Morocco, in April 1994. The TRIPS Agreement was adopted as part of the Final Act. For the full text of the TRIPS Agreement see WTO, *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations*" Cambridge University Press, Cambridge, 1999.

² The Declaration is contained in WTO document WT/MIN(01)/DEC/2. See also the TRIPS Council Decision extending the transition period for least-developed countries (LDCs) with respect to pharmaceutical patents to 2016 (WTO document IP/C/25) and the General Council Decision waiving the obligations of LDCs under article 70.9 of the TRIPS Agreement with respect to pharmaceutical patents (WTO document WT/L/478) and the General Council Decision implementing paragraph 6 of the Declaration (WTO document WT/L/540).

publication of its influential report in September 2002³; and the establishment of the World Health Organization's (WHO) Commission on Intellectual Property, Innovation and Public Health (CIPIH) in 2004⁴, among others.

By examining these and other important developments, a number of emerging general trends in the field of intellectual property are discernible. These range from trends towards the upward harmonisation of intellectual property standards both at the international and bilateral level to increasing academic and policy work examining the role of intellectual property in development. This paper reviews some of the main trends in the field of intellectual property and the issues and challenges that arise for the establishment of a development-oriented international intellectual property framework. The paper is divided into four main parts. Following the introduction, part II discusses some of the main institutional and issue-specific trends in the field of intellectual property at the international, regional and bilateral level. Part III then examines the issues and challenges that arise, in the context of these trends, for the efforts currently underway in various forms to establish a development-oriented intellectual property framework. Part IV concludes the paper with some final remarks.

II. GENERAL TRENDS IN THE FIELD OF INTELLECTUAL PROPERTY

Over the last several years, a number of important trends have been emerging in the field of intellectual property. These general trends relate both to institutional developments and to issue-specific developments. It is important to note, however, that the various developments are intrinsically linked and it is not possible to draw a fine line between institutional and issue-specific trends. For our purposes, institutional trends refers to a pattern of developments relating to activities within the various institutions and outside which influence their overall approach or level of engagement with intellectual property issues. On the other hand, issue-specific trends refer to a pattern of developments on specific issues across fora and in different processes. Finally, it is also worth noting that this framework of analysis leaves out a few important trends such as the increase of developing country intellectual property experts and the increase in the number of universities and academic institutions in the South offering courses on intellectual property and other trade subjects including competition policy and investment.

II.1 Institutional and Process-related Trends

There is a significant number of institutions and processes that provide the fora for intellectual property negotiations and discussions. The main institutions and processes in this context include:

³ See IPR Commission, *Integrating Intellectual Property Rights and Development Policy*, IPR Commission, London, 2002. The Commission was set up in May 2001 by the then UK Secretary of State for International Development, Clare Short, to consider how intellectual property could work better for developing countries and for poor people. The Commission published its final report in September 2002 in which, among other things, it concluded that for most developing countries any beneficial trade and investment effects of intellectual property are unlikely to outweigh the costs at least in the short to the medium term.

⁴ For more information see <u>http://www.who.int/intellectualproperty/en/.</u> The CIPIH was established in early 2004 following the adoption by the World Health Assembly (WHA) at its 57 Session in 2003 of a resolution on intellectual property, innovation and public health which mandated the creation of the Commission. See WHO document WHA56/27. The CIPIH's mandate is 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.

the WTO; the United Nations (UN) and its specialised agencies including WIPO; and regional and bilateral processes. There are various trends that are discernible in terms of institutional processes and developments that warrant attention.

II.1.1 The World Trade Organization

In the last couple of years activities in the WTO Council for TRIPS have been fairly subdued, save for the negotiations relating to the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The TRIPS Council has therefore progressively become a routine gathering. For example, while in previous years the TRIPS Council generally met for up to three days with some sessions running into the late night, the TRIPS Council meeting in March 2004 lasted for barely a day.⁵ This low level of activity in the Council for TRIPS is, in part, attributable to the fact that most energy and political importance in the WTO has been dedicated to the main planks of work in the Doha Work Programme, namely, agriculture, non-agricultural market access (NAMA) and Singapore issues.

The result has been that most of the development-related TRIPS issues which fall under the category of implementation-related issues and concerns and special and differential treatment have received little attention. Although there have been some discussions on the relationship between the Convention on Biological Diversity (CBD) and the TRIPS Agreement and related issues under the review of article 27.3b, it is fairly clear that less effort is being dedicated to these issues as compared, for example, to the 1999 to 2001 period. It is also noteworthy, that there has been virtually no discussion relating to the review of the TRIPS Agreement under article 71.1 over the last three or so years. This is a particularly significant development since this review had previously been billed as the avenue through which developing countries could push for the substantive revision of the TRIPS Agreement so as to take into account the development dimension.

There are at least two other relevant developments that underlie this low level activity trend in the WTO. The first relates to the increased intensity and political profile of negotiations at WIPO. Following the launch of the WIPO Patent Agenda and the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2001, coupled with a number of critical reviews of these processes, most notably in the IPR Commission's report and the South Centre T.R.A.D.E Working Papers 12⁶, there has been a growing attention devoted to WIPO including by developing country negotiators and policy makers and civil society organizations around the world. This has led to reduced political visibility of TRIPS issues. At the same time, the major proponents of higher intellectual property, most notably the United States and the European Union (EU) have strategically shifted their focus to WIPO activities. The second development relates to the increasing number of new negotiations on free trade agreements which contain intellectual property components. Consequently, the United States, in particular, as well as other major developed countries appear to have as their main interest the maintenance of the status quo at the Council for TRIPS.

⁵ For a review of the current issues under discussion in the TRIPS Council see South Centre and CIEL, "Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral and Bilateral Fora", *South Centre/CIEL IP Quarterly*, First Quarter 2004, 2004.

⁶ Correa, C., and S. Musungu, "The WIPO Patent Agenda: The Risks for Developing Countries", *T.R.A.D.E Working Papers 12*, South Centre, Geneva, 2002.

II.1.2 The United Nations and its Specialised and other Agencies

On the other hand, there has been a considerable increase in the number of activities in important UN agencies relating to intellectual property in the last couple of years as compared to the period leading to and after the adoption of the TRIPS Agreement. While most of the activities and processes in the UN are concentrated at WIPO, there are also significant developments in other agencies including developments at the CBD, the Food and Agriculture Organization (FAO), WHO, the United Nations Conference on Trade and Development (UNCTAD) and in the UN human rights bodies and committees. While there are notable activities at other agencies such as the United Nations Educational, Scientific and Cultural Organization (UNESCO) and through processes such as the World Summit on Information Society (WSIS), the discussion here will concentrate on the former agencies and processes.⁷

A. The World Intellectual Property Organization

The advent of TRIPS created significant strategic and institutional challenges for WIPO.⁸ As already noted, WIPO had to share its hitherto 'exclusive competence' on intellectual property matters with the WTO. WIPO responded to the challenges occasioned by TRIPS at two basic levels. At the first level, WIPO moved to establish its relevance in the new scenario by quickly adopting a resolution in 1994 mandating the International Bureau to provide technical assistance to WIPO Members on TRIPS related issues followed by a second resolution in 1995 to enter into a cooperation agreement with the WTO for WIPO to provide technical assistance to developing country Members of the WTO irrespective of their membership in WIPO.

These responses were helped by the understanding by the proponents of the TRIPS Agreement that although lacking in enforcement, the standards established under WIPO treaties and the technical expertise that existed in the organization were indispensable in ensuring the success of the TRIPS project. At the second level, WIPO clearly realising that the circumstances leading to the adoption of the TRIPS Agreement in the WTO meant that for it to remain the main forum on intellectual property matters it had to show that it can deliver new standards faster and more efficiently, has embarked on a number of initiatives ranging from the patent agenda to the digital agenda which underlie its post TRIPS agenda. Consequently, WIPO has had a busy schedule in the past couple of years. Intense negotiations and/or discussions have characterised the various committees and assemblies of the organization during this period.

Under the patent agenda, negotiations on a draft Substantive Patent Law Treaty (SPLT) in the Standing Committee on the Law of Patents (SCP) and the reform of the Patent Cooperation Treaty (PCT) in the Working Group on the Reform of the PCT, have evidenced trends towards upward patent law harmonisation although these processes have also evidenced a trend towards renewed and growing interest in WIPO discussions from developing countries and civil society groups. This interest has seen; in particular, the strong participation in the SPLT negotiations by

⁷ For example, in August 2003, UNESCO adopted the "International Convention for the Safeguarding of Intangible Cultural Heritage", a legal instrument which aims to safeguard oral traditions and expressions. At WSIS there have been discussions relating to how intellectual property affects access to information.

⁸ For further discussions on the challenges that TRIPS brought about for WIPO and related discussions see Correa and Musungu, *supra*, note 6 and Musungu, S., and G. Dutfield, "Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organization (WIPO)", *TRIPS Issues Papers 3*, QUNO-Geneva and QIAP-Ottawa, 2003.

developing countries which has led to calls by the trilateral group of patents offices (The United States Patents and Trademarks Office (USPTO), the European Patent Office (EPO) and the Japanese Patent Office) and industry associations for the scaling down of the ambitions in this process. Another trend that is discernible in these negotiations and other discussions in WIPO is the activism of the WIPO Secretariat. There is, at least, anecdotal evidence that the Secretariat does not always act as the servant of its membership as a whole but as a free agent with its own agenda. That agenda seems more closely linked to the interests and demands of some member states than to others, and more to pro-strong intellectual property protection than to the preservation of policy flexibilities for developing countries.

The other subject on which there have been high profile discussions is the relationship between intellectual property and genetic resources, traditional knowledge and folklore. Although no significant outcomes have resulted in the IGC's work, its existence has had a high political profile both within governments and civil society organisations.⁹ The WIPO General Assembly in September/October 2003 extended and modified the IGC's mandate for another two years. Finally, there have also been important processes and discussions on copyright and related issues including encouraging WIPO member states to sign up to the 1996 WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) in addition to on-going negotiations concerning a possible convention to protect the rights of broadcasters outside the Rome Convention framework.

At the same time, WIPO's technical and legal assistance activities have come in for serious criticism for a variety of reasons in the recent past. The organisation's activities under the Cooperation for Development Programme which include courses, seminars and legislative services,¹⁰ have been criticised, in particular, because they are geared to 'facilitate the implementation' of TRIPS and other Agreements meaning that the emphasis of the programmes is on performance of the obligations in the Agreements by the developing countries and least-developed countries. This technical assistance is unlikely to help developing countries tailor their intellectual property laws to meet their development objectives.

Two main concerns underlie the various criticisms levelled at WIPO's technical assistance.¹¹ The first is that the International Bureau's work especially with relation to legal technical assistance has over-emphasised the benefits of intellectual property while giving very little attention to its costs¹². Other critics have pointed out that the International Bureau is partisan in its approach to the debate about intellectual property and development and that it is not giving developing countries the best advice¹³. The second concern is that because of the nature of activities under the technical assistance programmes; legal technical assistance, automation of offices and

⁹ For a review of the work of the IGC as well as issues that arise with respect to its renewed mandate, see Lettington, R., and K. Nnadozie, "A Review of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore at WIPO", *T.R.A.D.E Occasional Papers 12*, South Centre, Geneva, 2003.

¹⁰ WIPO Annual Report for 2002. Available at http://www.wipo.int.

¹¹ For further discussion regarding WIPO's technical assistance see the IPR Commission, *supra*, note 3 and Musungu and Dutfield, *supra*, note 7.

¹² See, e.g., IPR Commission, *supra*, note 3.

¹³ See *Medicines Sans Frontieres (MSF)*, "Doha Derailed: Technical 'Assistance' A Case of Malpractice?", MSF, 2003. Available at http://www.msf.org.

provision of software, training etc., the International Bureau may exercise undue influence on developing countries which may affect the stances of these countries in WIPO negotiations. Despite these criticisms, however, there has been no discernible reorientation of design and delivery of WIPO's technical assistance.

Overall therefore, there are a number of general trends that emerge with respect to WIPO as an institution. First, there has been, in general, an overall stepping up of standard setting activities at WIPO with respect to various categories of intellectual property ranging from patents to copyright and related rights. Second, there is a drive from within WIPO backed by the major intellectual property offices towards the upward harmonisation of patent law standards as well as the creation of new standards in other areas such as in the area of webcasting. Third, the processes linked to genetic resources, traditional knowledge and folklore continue to be characterised by a high profile political dialogue with no significant concrete outcomes so far. Fourth, despite the criticisms that have been levelled against WIPO's technical assistance, the trends in its technical assistance programme continue to be biased towards stronger intellectual property protection as opposed to preservation of policy flexibilities for developing countries. Finally, there is increasing critical participation by developing countries and civil society groups in WIPO activities which is putting continuing pressure on WIPO to integrate the development dimension in its work.

B. The Convention on Biological Diversity

The CBD through various COPs including COP-7 which took place in Malaysia in February 2004 has been discussing various issues relating to intellectual property.¹⁴ It is in this context that the Bonn Guidelines on Access and Benefit Sharing were developed and on the basis of which the Working Group (WG) on Access to Genetic Resources and Benefit-sharing (ABS) has been mandated to elaborate and negotiate an international regime on ABS. The WG on ABS is expected to carry out its work in collaboration with the WG on Article 8(j), which deals with indigenous communities' issues. In this context, there has been a clear trend at the CBD to elaborate and consolidate an ABS regime as well as to develop elements for *sui generis* systems for the protection of traditional knowledge and to explore the conditions under which the use of existing intellectual property rights can contribute to reaching the objectives of the CBD.

Another important trend at the CBD, which has become particularly controversial, relates to a situation where the CBD Secretariat has been moving towards 'sub-contracting' issues relating to the relationship between intellectual property and genetic resources and associated traditional knowledge to WIPO. Although the latest decision from COP-7 ostensibly invites several international organisations to cooperate with the WG in elaborating the international regime on ABS, the underlying idea appears to have been to progressively increase the substantive role of WIPO in the debate about intellectual property and genetic resources in the CBD context. Inspite of the significant number of developing countries which have expressed their reservations about this approach both at the CBD and at WIPO, the trend appears to be the continued push for the delegation of matters relating to intellectual property and genetic resources and associated traditional knowledge to WIPO.

¹⁴ For an overview of the most recent intellectual property developments at the CBD see South Centre and CIEL, *supra*, note 5.

C. The Food and Agriculture Organization

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)¹⁵ is set to enter into force on 29 June 2004, 90 days after the ratifications and or accessions by 40 countries.¹⁶ This means that the ITPGRFA has come into force in a fairly short time (just over two and a half years following its adoption) considering the relatively high number of ratifications and or accessions that were required for its entry into force.¹⁷ Once the treaty comes into force, a governing body, composed of all Contracting Parties, will be established with the responsibility for the full implementation of the Treaty. The Treaty establishes a framework for the conservation and sustainable use of plant genetic resources for food and agriculture and, in particular, provides for a multilateral system for facilitated access and benefit sharing for selected plant genetic resources.

It is likely that among of the most contentious issues that will come up in the initial meetings of the governing body and probably on an on-going basis thereafter, will relate to intellectual property issues including conditions relating to access to the crops in the multilateral system and the terms of the material transfer agreements (MTA). While it is too early to discern any particular institutional trends with respect to the ITPGRFA and, in particular, on how the issues relating to intellectual property will develop, it is clear that important developments are likely occur at FAO with various implications for the profile of intellectual property issues at the organization. The speed with which the Treaty has come into force demonstrates the large interest by countries in the issues covered and would suggest a likely trend towards increasing discussions on intellectual property issues at FAO, considering the importance attached to facilitated access and the MTA.

D. The World Health Organization

The WHO has been working on issues of TRIPS and public health from quite early on and actively participated in the debates leading to the Doha Declaration on TRIPS and public health as well as the follow-up processes and negotiations. The organisation has also been involved in a significant amount of work at the regional and country level including the provision of technical assistance on matters on intellectual property and public health. However, most of these work was concentrated in the Department of Essential Drugs and Medicines Policy (EDM) and it was never clear that this represented a fully thought through organisation-wide policy on these matters. This situation has been changing in the last couple of years towards discussions and processes at the highest level in WHO on intellectual property and public health matters.¹⁸

¹⁵ The FAO Conference, at its Thirty-first Session (November 2001) adopted the Treaty through Resolution 3/2001. For further information on the treaty as well as the status of ratification, approval, acceptance and accession see http://www.fao.org/Legal/TREATIES/033s-e.htm.

¹⁶ See article 28 of the Treaty.

¹⁷ Compare this with the Patent Law Treaty (PLT) at WIPO which required only ten ratifications and or accessions to come into force but which is not yet in force and has only eight ratifications/accessions so far 4 years after its adoption. The PLT was adopted on 1 June 2000.

¹⁸ At the 57th WHA which took place in May 2004 apart from a resolution regarding the report on genomics and world health which among other things authorises the Director-General to help Member States frame appropriate national policies to benefit from advances in genomics which would include intellectual property (See WHA57.13), adopted a resolution on HIV/AIDS (See WHA57.14) which specifically recalled the Doha Declaration on TRIPS and public health and urged Members "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights" (para. 2(4) and "to encourage that

There have been significant discussions on TRIPS and public health issues in the last three or so World Health Assemblies (WHA) which culminated in 2003 with the WHA Resolution on Intellectual Property, Innovation and Public Health which mandated the formation of the CIPIH. There is also important work that is being undertaken under the Human Genetics Programme on the impact of gene patents on access to genetic technologies in developing countries as a follow-up to the Genomic and World Health report which identified intellectual property as a factor affecting the accessibility of the results of genomic research.¹⁹

While the work of the CIPIH will complement WHO's work on intellectual property and access to essential medicines in the EDM and the work on gene patents in the Human Genetics Programme as well as other related work in other WHO departments, the establishment of the CIPIH confirms a trend within WHO towards some form of organisation-wide approach on intellectual property and public health as opposed to the previous department based and ad hoc approach. Further, the trend which has emerged over the last few years where the WHA has addressed intellectual property issues in various contexts of WHO's work is likely to continue.

E. The United Nations Conference on Trade and Development

UNCTAD has, over the years, played a key role in international intellectual property matters and has, in particular, conducted fundamental work relating to intellectual property and development including the relationship between intellectual property and technology transfer as well as competition policy. It is also noteworthy that UNCTAD played an important role during the negotiations between the UN and WIPO for WIPO to become a specialized agency of the UN. In the period leading to the adoption of the TRIPS Agreement and in many respects thereafter, UNCTAD's work on intellectual property has been somewhat limited. This trend has been attributed to the fact that there was a deliberate effort by key players to sideline UNCTAD on these issues because UNCTAD had served as an important forum for developing countries to develop strategies and analytical work which demonstrated the serious negative consequences for technology development and related objectives that arose from the existing intellectual property regimes.²⁰

That said, however, although there is no single major programme in UNCTAD on intellectual property, UNCTAD has continued to be involved in intellectual property work in the context of other policy areas and/or in collaboration with other organisations. In this context, there is significant work focusing on traditional knowledge as well as the continuing work on transfer of technology and the work on E-Commerce in relation to open source software and related issues. On the collaboration side, UNCTAD has over the last few years conducted a quite successful joint capacity building project on intellectual property rights and sustainable development with the International Centre for Trade and Sustainable Development (ICTSD). This project has been responsible for a large number of research works on intellectual property and development as well as meetings and conferences.²¹

bilateral agreements take into account the flexibilities contained in the WTO TRIPS Agreement..." (para. 2(6). ¹⁹ The Advisory Committee on Health Research, WHO, *Genomics and World Health*, WHO, Geneva,

¹⁹ The Advisory Committee on Health Research, WHO, *Genomics and World Health*, WHO, Geneva, 2002.

²⁰ See, e.g. Braithwaite, J., and P. Drahos, *Global Business Regulation*, Cambridge University Press, Cambridge, 2000, p. 68.

²¹ Among the publications that have been produced under this project are the "The Resource Book on TRIPS and Development" and the policy discussion paper on "Intellectual Property Rights: Implications

Finally, it has emerged in the context of the preparations for UNCTAD XI, that the trend where developing countries make efforts to increase the work of UNCTAD on intellectual property and to have UNCTAD undertake analysis on strengthening the development dimension in international intellectual property rule-making, including effective transfer of technology to developing countries; protection of traditional knowledge, genetic resources, and folklore will continue. On the other hand, it is also clear that the opposition by the United States and other developed countries to the inclusion of intellectual property in the mandate of UNCTAD will continue.

F. The United Nations Human Rights Bodies and Committees

Over the last four or so years, there has been a clearly discernible trend for the human rights community and various UN bodies especially the various human rights bodies and committees to examine and explore the implications of intellectual property for the protection and promotion of human rights. For example, the Sub-Commission on Human Rights adopted resolutions on intellectual property and human rights at both its session in 2000 and in 2001²² in addition to a report by the High Commissioner for Human Rights in 2001 on the 'Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on the Protection of Human Rights'²³. The reports of the Special Rapporteurs on globalisation and human rights also addressed the issue of intellectual property and human rights.²⁴ More recently, the Committee on Economic, Social and Cultural Rights (CESCR) has been working on a General Comment on article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which deals with the enjoyment of the benefits of scientific progress and its applications; and the concept of benefiting from the protection of the moral and material interests resulting from scientific, literary or artistic productions.

More interesting, the Human Rights Committee at its 80th Session this year in its concluding observations on the report submitted by Uganda with respect to the International Covenant on Civil and Political Rights (ICCPR), urged Uganda to adopt comprehensive measures to allow a greater number of persons suffering from HIV/AIDS to obtain adequate treatment. Although not specifically mentioned, it is considered that this meant the adoption, among others, of appropriate intellectual property rules and the use of TRIPS flexibilities. Finally, there has also been increasing activities by civil society groups in this area and organisations such as 3D and the Ethical Globalisation initiative have been developing significant programmes in this area.

II.1.3 Bilateral and Regional Trade Agreements

The most active fora with respect of intellectual property standard setting today is the bilateral and regional fora in the context of free trade agreements and there is a clear trend that this will continue to be the favourite fora for, at least the United States, in the short to the medium term. In just a couple of years the United States has negotiated and or is negotiating free trade agreements with intellectual property components with all Latin and Central American and Caribbean countries individually, in groups or collectively and with Australia, Morocco, the Southern Africa

for Development". This is in addition a significant number of issue specific research papers. For full information about the outputs of this project see http://www.iprsonline.org/unctadictsd/projectoutputs.htm. ²² See Resolutions 2000/7 and 2001/21.Both available at http://www.unhchr.ch.

²³ See document E/CN.4/Sub.2/2001/13. Available at http://www.unhchr.ch.

²⁴ See e.g., Oloka-Onyango, J., and D. Udagama "Globalisation and its Impact on the Full Enjoyment of Human Rights" document E/CN.4/Sub.2/2000/13.

Customs Union (SACU) countries, Singapore and Thailand. The EU has also been negotiating a free trade area with MERCOSUR countries where intellectual property has featured. There are also signs that Japan is getting more aggressive with free trade agreements, at least in Asia, and it is likely that there will be attempts to include intellectual property issues in these negotiations. These free trade agreements replicate the TRIPS approach where higher standards for intellectual property protection are directly obtained in exchange for concessions in core trade areas such as agriculture and other market access preferences and where trade measures are used as an agreed avenue to enforce intellectual property standards abroad.

Another important trend in the bilateral approach to intellectual property negotiations has been the requirement that the parties to the free trade agreement ratify or accede to a host of, mainly, WIPO treaties. For example, article 15 of the United States and Morocco free trade agreement requires the parties to ratify or accede to eight WIPO treaties in addition to making best efforts to ratify or accede to two others. This trend, although having its origin in the approach taken in the negotiations of the TRIPS Agreement where the TRIPS Agreement incorporated, by reference, a number of substantive provisions of WIPO treaties, is more expansive as it requires not just adherence to selected provisions of particular treaties but adherence to whole treaties.

II.2 Issue-Specific Trends

Apart from the institutional trends described above, there are a number of important issue-specific trends that are emerging in the field of intellectual property. These include trends relating to intellectual property and public health, intellectual property and genetic resources and traditional knowledge, patent law harmonisation, copyright and related rights, intellectual property and transfer of technology and dispute settlement and enforcement of intellectual property, among others.

II.2.1 Intellectual Property and Public Health

The relationship between intellectual property and access to essential medicines and public health more generally, has dominated the discussions on intellectual property and development for the last four years or more. The result has been a number of high profile events and processes including the adoption of the Doha Declaration on TRIPS and public health, the WHA Resolution on Intellectual Property, Innovation and Public Health and the adoption of the 30 August 2003 Decision by the WTO General Council implementing paragraph 6 of the Doha Declaration on TRIPS and public health. There are, however, a number of new emerging trends regarding this issue. First, while there continue to be discussions on this subject at the WTO in the context of paragraph 11 of 30 August Decision, the energy as well as the massive international coalition between developing countries and civil society groups that characterised the earlier Doha processes has been dissipating progressively across the board.²⁵

This trend can be explained by a variety of factors which include, among others, the deadlock in agricultural and other negotiations in the Doha Work Programme; the high political costs that have been associated with the efforts on TRIPS and public health for developing countries; the increasing view that the United States is unlikely to relent on its position on paragraph 6; and the shift in focus by major civil society groups such as MSF and Oxfam and policy analysts to bilateral and regional

²⁵ Paragraph 11 provides that the TRIPS Council shall initiate work by the end of 2003 on the preparation of the amendment with a view to its adoption within six months.

free trade agreements and national level processes. The second trend is that while the debate continues at the bilateral and regional level, the focus of the debate has shifted from the basic TRIPS flexibilities such as compulsory licensing and parallel importation to less understood areas, in particular, test data protection and the linkage of patent status to regulatory approval for generic medicines.²⁶ The free trade agreement between the United States and Australia has even gone further and made Australia's medicines benefits scheme subject to intellectual property considerations.²⁷

The third major trend on the issue of intellectual property and public health has been the considerable shift of emphasise particularly by civil society groups and development friendly intellectual property technical assistance providers from international negotiations to national and regional implementation, as well as a general progressive trend towards evidence based approach to the debate on intellectual property and public health. The evidence based approach is confirmed by such processes as the IPR Commission and the CIPIH as well as important national developments such as the Nuffield Council on Bioethics' report²⁸ and the report of the United States Federal Trade Commission (FTC) on the promotion of innovation²⁹.

II.2.2 Intellectual Property and Genetic Resources and Traditional Knowledge

While the question of the relationship between intellectual property and genetic resources and associated traditional knowledge has been internationally discussed since the adoption of the CBD in the early 90s, the debate on this issue received a significant boost to its political profile starting with the review of article 27.3b of the TRIPS Agreement and the events leading to and at the WTO Seattle Ministerial Conference in 1999. Around the same time, the issue gained prominence in WIPO in the context of the PLT diplomatic conference which resulted into the eventual creation of the IGC. Since then, the issue has been discussed in many fora and there are a number of important processes underway to deal with this question ranging from the WTO discussion on TRIPS and CBD and issues around disclosure, prior informed consent and benefit sharing to the IGC and to the CBD ABS discussions. In these processes and discussions a number of trends have emerged.

First, while the WTO debate has continued, the focus on this issue has narrowed to more specific discussions for a framework for disclosure, prior informed consent and benefit sharing as opposed to the earlier debate where these issues were discussed as part of a larger cluster of issues under the review of article 27.3b of TRIPS and the review under article 71.1 of TRIPS. Since the Doha Ministerial conference, the CBD TRIPS issue has acquired its own separate momentum and dynamics and has moved progressively forward. The second trend relates to the position of various players on this issue. In the WTO as in WIPO, the United States has continued with its insistence that these issues are not patent law issues and should be dealt with outside the intellectual property regime.

²⁶ For further discussion see e.g., South Centre and CIEL, *supra*, note 5 and Abbott, F., "The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements", *Occasional Paper 14*, QUNO, Geneva, 2004. Available at http://www.geneva.quno.info/.

 $^{^{27}}$ For a discussion of the effects of the free trade agreement on Australia's medicines policy see Drahos P., *et al*, "The FTA and the PBS", mimeo, 2004.

²⁸ See, Nuffield Council on Bioethics, "The Ethics of Patenting DNA, A Discussion Paper", Nuffield Council on Bioethics, London, 2002.

²⁹ See FTC, "To Promote Innovation: The Proper Balance of Competition and Patent Law Policy", FTC, Washington D.C, 2003. Note, however, that this report is not dedicated on intellectual property and public issues but is a more general commentary on innovation.

On the other hand the EU, while agreeing that there are issues to discuss has pushed the line that these issues can only be discussed in terms of standard setting after the IGC has completed its work. Some other countries such as Switzerland while acknowledging that this is an issue to be dealt with in the patent system and that the IGC is not the only fora to discuss the issue, have proposed voluntary schemes as opposed to mandatory disclosure, for example.³⁰ Most developing countries on the other hand have continued to argue that this is an issue to be dealt with in patent law standard setting; that the IGC is not the exclusive fora for these issues; and that a mandatory international regime is the solution to the problem.

The third trend, which flows from the second trend, is that there continues to be very little tangible results on this issue. The happenings at the CBD, the lack of any tangible results from the IGC process and its designation as 'the dumping ground' by some players such as the United States and the EU as well as the scaling down of the developing countries' agenda in the WTO and the difficulties in achieving results even on this smaller agenda illustrate this trend. Finally, is that the trend where the issue has been discussed in different fora continues with various implications including the pursuance of uncoordinated agendas by many developing countries.

II.2.3 Patent Law Harmonisation

The process of patent law harmonisation has mainly taken place at WIPO in the context of its patent agenda and related activities. While the negotiations on the draft SPLT continue at the SCP and the so-called first phase of the PCT reform has virtually been completed³¹, fortunes are changing for these processes and there is a clear trend in WIPO as well as outside WIPO towards scaling down the ambitions in these processes, at least, in the short term. This trend is a fairly direct result of another trend on this issue. While the earlier sessions of the SCP and the PCT Reform Working Group evidenced an asymmetrical participation of developing countries in relation to developed countries, the past few meetings have been characterised by increasing developing country involvement and influence.

That said, however, the trend where the WIPO Secretariat and the major patent offices and industry and patent lawyers association have proceeded with these processes as if developing countries do not exist in the organization continues. The attitude that the issues under discussion in the patent harmonisation processes relate to matters that need to be sorted out between the United States and the EU and occasionally Japan, Australia and Canada continues unabated. Any significant developing country participation on this issue continues to be received with irritation and labelled 'controversial', 'politically sensitive' or 'misplaced'. For example, at the tenth session of the SCP held in May 2004, the USPTO, EPO and Japan actively supported by the WIPO Secretariat and industry and lawyers' associations sought to introduce a new framework (a reduced package of issues) for the SPLT negotiations on the basis that, among others:

• the debate in the SCP about the benefits of harmonisation, the balance between rightholders and the public interests and the relationship between the patent system and other policy and regulatory issues such as public health, "suggests that the original objective of

³⁰ Switzerland has proposed for example the amendment of PCT Regulations to allow countries to require disclosure of origin of genetic materials and associated traditional knowledge used in inventions in patent applications. See WIPO documents PCT/R/WG/4/13, PCT/R/WG//11 and PCT/R/WG/6/11.

³¹ This phase was aimed at making changes to the PCT Regulations with regard to the international search and examination procedures under system. The second phase is supposed to entail a more fundamental overhaul involving the amendment and changes in the treaty itself.

the SCP to achieve broad and deep harmonisation of patent laws might be too ambitious and not easily achieved"³²; and,

• while a good deal of progress has been achieved thus far, recent discussions in the SCP suggest that the current model for discussion is not as productive as it could be and should be because of the sheer volume and complexity of the issues and because several provisions of the draft treaty have been extremely controversial and of high political sensitivity and much of the debate has focused on these issues which has hampered the achievement of the desired results.³³

Finally, although the trends in WIPO on this issue reflect a slowing pace there is also a trend for upward harmonisation through bilateral and regional free trade arrangements. This trend continues apace and there are no signs of near term changes in the approach. In this context, it is important to note that, except in the negotiations on a free trade area in the Americas (FTAA), there has been no substantial developing country resistance at the bilateral/regional level to the pressure for upward harmonisation including in such politically high profile areas as public health. In addition, other development concerns such as the protection of genetic resources and traditional knowledge and transfer of technology which have prominently featured on the international scene have not featured significantly in the patent negotiations at this level except for a few notable exceptions such as the FTAA and the EU-MERCOSUR negotiations.

II.2.4 Copyright and Related Rights

Although the WIPO digital Agenda was initiated in 1999 with the aim of, *inter alia*, modifying the international legislative framework by adapting broadcasters' rights to the digital era and extending the principles of the WIPO Performers and Phonograms Treaty to audiovisual performances, there has been a recent trend both in WIPO and outside towards increased focus on copyright and related issues. For example, the Standing Committee on Copyright and Related Rights (SCCR) is currently discussing the possibility of a new treaty to deal with the rights of broadcasting organizations outside of the Rome Convention framework and there is a growing push for the holding of a diplomatic conference on this issue in the near future. The proposed treaty would create a system of ownership for material transmitted over wireless means such as television, radio and satellite, as well as wired communications over cable networks, and also over Internet computer networks. The push for this treaty has been accompanied by the renewal of discussions about updating the rights of performers in their audiovisual performances, an issue left unresolved by the 2001 diplomatic conference on the protection of audiovisual performances.

On the other hand, mostly outside WIPO, there has been a growing movement on the issue of open source software and related concepts. Open access initiatives which are considered appropriate in fields where decentralised creation is efficient such as in academic research and software development, offers an alternative to the exclusive intellectual property rights model. Although WIPO has so far refused to discuss this issue, open source software has gained increasingly significant currency in copyright discussions outside WIPO including at the WSIS and in public procurement discussions in many governments including the United States and EU governments. In WIPO, though the resistance continues, civil society groups such as the Civil

³² See the Memorandum of the International Bureau titled "Information on Certain Recent Developments in Relation to the Draft Substantive Patent Law Treaty (SPLT)", WIPO Document SCP/10/1, 17 March 2004, para. 2.

para. 2. ³³ See the Proposal by the United States of America, Japan and the EPO Regarding the Substantive Patent Law Treaty (SPLT); WIPO document SCP/10/9, 22 April 2004.

Society Coalition (CSC) continue to raise issues related to open source software and copyright from the observer benches.

II.2.5 Intellectual Property and Transfer of Technology

In general, transfer of technology discussions in the context of the intellectual property and development debate continue to be just that -discussions with no concrete change in the situation despite the adoption on February 2003 Decision on a new framework for the monitoring and full implementation of article 66.2 of the TRIPS Agreement.³⁴ Although there have been some improvements in the reporting under this new system, the trend continues to be the recital of overseas development aid as the incentives for the transfer of technology. At the same time, the WTO Working Group on Trade and Transfer of Technology (WGTTT) continues to totter on the brink of disappearing into oblivion.

II.2.6 Dispute Settlement and Enforcement of Intellectual Property Rights

It has already been noted that it is now generally accepted that trade measures are legitimate means for enforcing intellectual property abroad. However, there has yet been no agreement with respect to the application of non-violation and situation complaints to intellectual property in the WTO. The discussions in the WTO have been going on for over fours years with very little change in the countries positions nor any significant movement towards the resolution of this issue. Another trend on this issue in the WTO is a movement towards putting the issue on the back burner and maintaining the status quo. No country has presented any new proposal since September 2002 and no specific recommendations were forwarded to the Cancun Ministerial Conference on the subject. Further, although the issue was not placed on the TRIPS Council agenda in the December 2003 and in the March 2004 meetings, no country appeared to see any problem with that.

There is however, an opposite trend on this issue in the bilateral and regional fora. Bilateral agreements such as the recently concluded US-Chile, Central American Free Trade Agreement (CAFTA), and US-Australia, for instance, explicitly place intellectual property within the scope of non-violation complaints. The FTAA Discussions may also result in the applicability of non-violation complaints in the field intellectual property.³⁵ The bilateral agreements not only apply non-violation complaints to their intellectual property provisions, but the application is, in many cases, agreed to without any debate.³⁶ One of the reasons for this may be that non-violation complaints are not dealt with in the intellectual property chapters of these agreements but, rather, in the dispute settlement chapters.³⁷

On enforcement although WIPO has so far failed to get a mandate from the members to engage in norm setting in this area, the work of its Advisory Committee on Enforcement (ACE) continues to be geared towards establishing some form of soft law.³⁸ The technical assistance in this area also continues to be fairly biased. On the bilateral and regional front there are more aggressive enforcement procedures that are emerging from the free trade agreements.

³⁴ See WTO document IP/C/28.

³⁵ For further discussions about this trend and the challenges in the bilateral and regional trade agreements see South Centre and CIEL, *supra*, note 5.

³⁶ South Centre and CIEL, *supra*, note 5, p.3.

³⁷ See e.g., Annex 22.2 of the US-Chile FTA, Annex 20.2 of CAFTA.

³⁸ For more information about the ACE and its discussions, see http://www.wipo.int/documents/en/meetings/2004/ace/index_2.htm.

III. TRENDS IN INTELLECTUAL PROPERTY: ISSUES AND CHALLENGES FOR THE ESTABLISHMENT OF A DEVELOPMENT ORIENTED FRAMEWORK

In the context of the emerging trends in the field of intellectual property, developing countries and other proponents of a development-oriented framework face complex challenges in not only coordinating their strategies and positions across fora but also in addressing the various substantive issues that are under negotiation and/or discussion. Throughout the ten years of the existence of the TRIPS Agreement, the extent and effectiveness of developing countries' participation in various fora and processes has varied.³⁹ What is true though is that to a large extent most developing countries have argued consistently during this period that international rules on intellectual property can only promote development if they facilitate the transfer and diffusion of technology and contain enough flexibility to allow these countries take into account their development objectives in designing their intellectual property regimes. However, as is clear from both the institutional and issue-specific trends discussed above, there is a long way to go to achieve this objective and in fact some of the trends show that the situation is getting worse.

The question that arises therefore is to how the advocates of the development-oriented intellectual property framework and developing countries, in particular, have been affected and/or are responding to the various general trends in the field of intellectual property. While there are some clear responses such as the shift by some countries and civil society groups to bilateral and regional level and to WIPO work, it is quite difficult to clearly map at the current time the effects and responses to the broad trends identified in this paper. However, a number of general conclusions can be drawn about what these trends mean for these countries and other groups.

First, trends towards decreased activities at the WTO and an increase of activities at WIPO, in other UN agencies and at the bilateral level means that developing countries will have to significantly improve their policy coordination on intellectual property matters both in terms of national policy formulation and participation in negotiations in various fora. While it is true that some developing countries have followed the United Sates on its forum shifting journey and are equally engaged in the various fora many others are simply not engaged even at WIPO. Except for a few notable examples such as Egypt, for example, Africa countries including Kenya, Zimbabwe and South Africa which have been very active in the TRIPS Council have not demonstrated any serious engagement in WIPO and in other fora such as at WHO and at the CBD. This means that one can not necessarily argue that the subdued activities in WTO clearly reflect a thought through shift of focus by developing countries to other international processes and to bilateral negotiations.

Second, these trends also suggest that the success stories such as those in the WTO on intellectual property issues may not be easily replicated in the new scenario. In addition, the changing nature of the alliances that had developed in the WTO between developing countries and civil society organizations and the change in the technical issues that need to be addressed means that assumptions can not be made about the readiness and ability of developing countries to respond effectively to the emerging trends. For example, the issues that will arise at the FAO, in the

³⁹ For a detailed analysis of developing countries participation in WIPO see Musungu and Dutfield, *supra*, note 7.

context of the CIPIH work and with respect in bilaterals such as test data protection do not neatly fall into the well known TRIPS flexibilities with the result that the expertise and experience that has been gained through the TRIPS Council and WTO processes may not be sufficient or even available in these other processes. In this regard, the continued need for capacity building should be appreciated. More strategic thinking will also have to go into managing and nurturing the developing countries, civil society and academics alliance and into the need for and suitability of new alliances.

Third, the shift of these issues to the national and regional context means that the role of national and regional institutions including regional economic organizations, regional patent organizations and national courts and institutions such as the competition authorities need to be more seriously examined. Finally, the trend towards bilaterals and the shift of activities to other fora also means that the solidarity of developing countries on intellectual property issues will progressively be eroded

But the above can only be preliminary conclusions. Many questions remain regarding the effect of these various trends in the field of intellectual property on the efforts to establish a development-oriented intellectual framework and regarding the responses of the proponents of this model. More research is needed to fully map the effects of the general trends in the field of intellectual property and the appropriate responses to them. Some of the questions that need to be more comprehensively answered include the following:

- To what extent can developing countries and other advocates of the developmentoriented intellectual property framework dedicate significant resources and attention to TRIPS issues in the context of the on-going difficulties in the main areas of the Doha Work Programme, namely, agriculture and non-agricultural market access issues?
- Considering that the major intellectual property players have shifted their focus to WIPO and bilateral activities, in part, because of the effectiveness of developing countries at the WTO, should developing countries and their partners simply shift focus to WIPO and bilaterals or should they seek to develop a strategy to try and make gains in the WTO? In other words, should developing countries also adopt a strategy of 'maintaining the status quo' in the TRIPS Council?
- How should developing countries and civil society groups effectively engage in the various WIPO negotiations? For example, (a) in the patent harmonisation process should they simply seek flexibilities based on the TRIPS flexibilities? (b) Considering the lack of progress on genetic resources and traditional knowledge issues in both WIPO and WTO and the 'sub-contracting approach by the CBD' what should be the strategy on these issues both in institutional and substantive terms? (c) what needs to be done to push WIPO towards providing development-friendly technical assistance and increasing the critical participation of developing countries and civil society groups in its processes?
- How should developing countries approach the new processes and developments, in particular, the entry into force of the ITPGRFA, the work of the CIPIH, open access initiatives, enforcement and human rights?

- There has been a significant increase in the number of works and materials on intellectual property and development as well as the number of experts on these issues, how should this be harnessed and channelled?
- What needs to be done with respect to bilateral trade agreements and their TRIPS-plus approach considering that there are no signs that the speed with which these are being entered into is not reducing and the fact that it is not necessarily true that the United States is the main demandeur for all these bilaterals in the first place?
- With respect to such an issue as TRIPS and public health is there still value for expending political and other efforts at the WTO or should the processes move to the national and regional level? In this regard, what needs to be done to maintain or at least manage the changing relationship between developing countries and civil society groups on TRIPS and public health as well as on other intellectual property and development issues?
- Is there anything that can realistically be done on intellectual property and transfer of technology at the international level?

IV. FINAL REMARKS

There are a variety of general trends that are discernible in the field of intellectual property which can be broadly categorised into institutional trends and issue-specific trends. These trends have important implications for the efforts to establish a development-oriented intellectual property framework both in the short and the long term. Although it is possible to identify some of the effects and responses to these trends by developing countries and other advocates of a development-oriented intellectual property regime, it is difficult and beyond the scope of this paper to clearly map the various responses and effects although some general conclusions can be drawn. What is clear, however, is that these trends raise a number of important issues and significant challenges for developing countries and other proponents on a development-friendly intellectual property regime. These issues and challenges need to be examined and discussed with a view to developing a clear view of the effects of the various trends and the appropriate responses to these trends.