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The TRIPS Agreement is an attempt to establish a functioning international consensus – or multilateral rule of law - about the extent to which countries should protect the intellectual property of other countries. Part of the background to the TRIPS Agreement was that the pre-existing international conventions were in some important respects no longer providing such a consensus, especially in the area of industrial property. Its absence was giving rise to increasing tensions in international trade relations, in a world where knowledge and other intangible elements protected by intellectual property were becoming increasingly important in the value of goods and services traded internationally and in the international competitive position of many countries.

The task in seeking such a consensus is not easy. Finding a proper balance in intellectual property regimes, notably between the long term social interest in promoting creativity and inventiveness and the shorter term interest in maximizing access to existing creations and inventions, is difficult enough at the national level. At the international level, involving countries with differing interests and at different stages of development, it becomes more difficult. The issue gets somewhat transmuted into a question of finding a proper balance between, on the one hand, the need in an interdependent world for countries to accept some commitments to protect the intellectual property of other countries and, on the other, their concern to preserve policy space to optimize the intellectual property system from a domestic perspective.

Of course, since the TRIPS Agreement was negotiated, there has continued to be great controversy about the proper balance in intellectual property systems. No doubt this is to some extent inevitable and even desirable given the need to make difficult trade-offs between sometimes conflicting objectives, as well as the need to adjust to changes in technology. However, there are reasons why the debate on the

balance in intellectual property protection has been particularly acute in recent years. Let me mention some of them:

- one has been the growth of doubts about the way globalization is currently managed, including on the part of increasingly influential civil society groups who tend to see intellectual property law as unduly reflecting the interests of big business;
- linked to some extent with this is the increasing debate, in developed as well as in developing countries, as to whether the strengthening of intellectual property protection has overshot the optimal point of balance, for example in relation to such matters as the term of protection for copyright, the quality and scope of patents, the availability and strength of injunctive relief, etc.;
- third, the digitization of information and the Internet have given rise to a roster of difficult intellectual property issues;
- finally, the growth of the HIV/AIDS crisis, especially in Africa, has focused much attention on how intellectual property rules affect access to medicines.

Much of the debate in recent years about the optimal balance in the intellectual property system has not taken place in the context of the WTO, because the issue has related to matters not regulated in detail in the TRIPS Agreement or to so-called TRIPS-plus matters. Examples include the debates about the intellectual property implications of the Internet, which at the international level have given rise to the WIPO Internet treaties and the WIPO Internet Domain Name processes; about the extension of the term of protection for copyright and the open source movement; and about the patentability of computer software and business methods and more generally the quality of patents granted.

At the international level, an increasing number of international organizations, in addition to the WTO and the WIPO, have taken up issues relating to the balance in

the intellectual property system, sometimes in the form of commenting on the TRIPS Agreement and the way it should be interpreted, applied or modified. These include the Convention on Biological Diversity, the FAO, UNCTAD, the World Health Organization, the UNDP, the UN Office of the High Commissioner for Human Rights and the World Bank.

Turning to the TRIPS Agreement itself, the balance struck has been approached in different ways:

- (i) On the one hand, there has been increasing emphasis in many circles, including those I have just mentioned, on the importance of the flexibilities recognized in the TRIPS Agreement that enable developing countries to fine-tune the balance in their intellectual property systems in the light of their developmental, health and other policy objectives. There have also been proposals presented by developing countries aimed at improving the balance in the TRIPS Agreement from their perspective. Each of the three major intellectual property initiatives that have been taken up in the WTO over the last decade has reflected in some measure concerns on the part of developing countries to rebalance the Agreement in their favour. These are TRIPS and public health; biotechnology/biodiversity/traditional knowledge; and, to some extent, geographical indications. I shall speak about these in more detail in a moment.
- (ii) On the other hand, the TRIPS Agreement has not been accepted by all as necessarily providing for adequate protection of intellectual property and there has been a continuing effort to get trading partners to agree to enhanced protection in some important respects, not so much in the context of the WTO or the TRIPS Agreement as in the context of bilateral and regional negotiations, especially on free trade area agreements.

Turning now to the three main initiatives in the WTO on intellectual property since the WTO came into force, perhaps the first point I should make is that

intellectual property issues are less central to the present Doha Round of multilateral trade negotiations - the main preoccupation of the WTO at present - than they were in the context of the Uruguay Round, which gave rise, *inter alia*, to the TRIPS Agreement. Nonetheless, the proponents of the issues of geographical indications and the relationship between the TRIPS Agreement and the Convention on Biological Diversity make the point that they view progress on these matters as being an important part of the balance to be found at the end of the Doha Round, in the former case in regard to the agriculture axis of the negotiations and in the latter case in regard to the development dimension of the negotiations.

As for the issue of TRIPS and public health, this has been explicitly kept separate from the Round by WTO Members. The heart of this issue has been a debate about whether the flexibility in the TRIPS Agreement is sufficient to ensure that it is supportive of public health, especially in permitting affordable access to existing medicines in poor countries while also promoting R&D into new ones. Different views were being expressed about the nature and scope of the flexibility in the TRIPS Agreement, for example in regard to compulsory licensing or parallel imports. Questions were being raised as to whether this flexibility would be interpreted by the WTO and its Members in a pro-public health way. And there was concern about the extent to which governments would feel free to use to the full this flexibility without the fear of coming under pressure from trading partners or industry.

In order to respond to these concerns, WTO Members adopted at Doha in November 2001 a Declaration on the TRIPS Agreement and Public Health. The Declaration emphasizes that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health and reaffirms the right of Members to use, to the full, the provisions of the TRIPS Agreement which provide flexibility for this purpose. The Declaration also makes it clear that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. These statements thus provide important guidance to both individual Members and, in the event of disputes, WTO dispute settlement bodies on how the TRIPS Agreement is to be interpreted and applied.

The Declaration also contains a number of important clarifications of some of the flexibilities contained in the TRIPS Agreement, while maintaining Members' commitments in the TRIPS Agreement, notably in regard to Members' rights to determine the grounds upon which compulsory licences are granted, to determine what constitutes a national emergency or other circumstances of extreme urgency (where an abbreviated procedure for the grant of a compulsory licence is permitted under TRIPS), and to establish their own regimes for the exhaustion of IPRs.

It should also be noted that, while emphasizing the scope in the TRIPS Agreement to take measures to promote access to medicines, the Declaration recognizes the importance of intellectual property protection for the development of new medicines and reaffirms the commitments of WTO Members in the TRIPS Agreement.

In regard to the least-developed country Members of the WTO, the Declaration contained an agreement to accord them an extension of their transition period, from 2006 until the beginning of 2016, in regard to the protection and enforcement of patents and rights in undisclosed information with respect to pharmaceutical products. I might also mention at this point that, at the end of 2005, the WTO Members agreed to extend the general transition period for least-developed countries until July 2013, without prejudice to the longer period earlier agreed in respect of pharmaceuticals.

WTO Members recognized in the Doha Declaration that there was one area where the TRIPS Agreement, as adopted, might not contain sufficient flexibility from a public health perspective. This concerned the ability of countries with no or limited manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing. It was not in dispute that Members can issue compulsory licences for importation as well as for domestic production. However, the concern was about whether sufficient sources of supply from generic producers in other countries to meet demand for such imports would be available, particularly in the light of the provision of Article 31(f) of the TRIPS Agreement which states that any compulsory licences granted to generic producers in those other countries shall be "predominantly for the supply of the domestic market of the Member" granting the

compulsory licence. Paragraph 6 of the Doha Declaration recognized this problem and called for an expeditious solution.

This was achieved through the adoption by WTO Members in August 2003 of a Decision waiving the restriction in Article 31(f) where this is necessary to enable production and export of pharmaceuticals under a compulsory licence to meet the public health problems recognized in the Doha Declaration of countries with inadequate domestic manufacturing capacity. The waiver is subject to a number of conditions to ensure transparency in its operation and to safeguard against the risk of diversion of the exports to unintended markets. Final consensus was reached on this Decision with the aid of a statement that the Chairman read out before its adoption, setting out a number of shared understandings, for example that the system should be used for public health and not for industrial or commercial policy purposes.

In adopting the Decision on the waiver, WTO Members agreed that the waiver should be replaced by a permanent solution in the form of an amendment to the TRIPS Agreement. This was agreed on 6 December 2005, when based on a recommendation from the TRIPS Council, the WTO General Council adopted a Protocol of Amendment to the TRIPS Agreement and opened it for acceptance by Members, the first amendment done of any WTO Agreement so far. Once again, this Decision was taken in the light of a Chairman's statement. The Protocol entails a transposition of the terms of the waiver Decision without substantive change, in the form of a new Article 31*bis* to be added to the TRIPS Agreement, setting out the key additional flexibilities to be built into that Article, and an annex to be added to the TRIPS Agreement setting out the more detailed provisions of the system. The amendment will become effective when the Protocol will have been accepted by two thirds of the WTO Membership. In the meantime, the waiver decision continues to operate. The present situation is that nine WTO Members, the United States, Switzerland, El Salvador, the Republic of Korea, Norway, India, the Philippines, Israel and Japan have deposited their instruments of acceptance of the amendment.

A second area where, as I mentioned earlier, many developing countries have sought to improve the balance of the TRIPS Agreement from their perspective is that of the three related issues of the protection of biotechnological inventions and plant

varieties, the relationship with biodiversity, and the protection of traditional knowledge and folklore.

The aspect of these three issues that is, at present, being most actively pursued by some developing countries in the WTO is the relation between the TRIPS Agreement and the Convention on Biological Diversity. Here there is a wide measure of common ground among WTO Members on the underlying objectives, namely the avoidance of erroneous patents entailing the use of genetic material and related traditional knowledge and securing compliance with national regimes for access to such genetic material and traditional knowledge and for the sharing of benefits derived from their use. But there are different views on how these objectives should be achieved. Some developing countries are seeking, as part of the results to the Doha Round of trade negotiations, an amendment of the TRIPS Agreement to require patent applicants to disclose, as a condition of patentability, information on the source and origin of biological material and associated traditional knowledge used in inventions, as well as evidence of having obtained prior informed consent for access to them and of having entered into fair and equitable benefit sharing arrangements. Some European Members are ready to envisage a more limited disclosure requirement relating to the origin or source of genetic material and related traditional knowledge, without consequences for patentability. Some other Members hold the view that the underlying objectives can best be achieved in other ways, without putting new requirements on the patent system, notably through more effective use of the existing mechanisms of the patent system to avoid erroneous patents and through national access and benefit-sharing regimes and contracts based on them. In addition to these diverging views on the merits of different courses of action, there are also differences on whether this matter forms part of the agreed negotiating package for the Round.

The third major area of debate in regard to the evolution of the balance in the TRIPS Agreement is on geographical indications, especially proposals for extending the higher level of protection, which presently only has to be given to GIs for wines and spirits, to other product areas – so-called GI extension. There is also an ongoing negotiation on the establishment of a multilateral registration system for geographical indications for wines and spirits. GIs protection is not a North-South issue but rather

one where strong differences of view can be found among both developed and developing countries. As I indicated earlier, the issue of GIs protection is better appreciated within the context of the dynamics of the negotiations on agriculture in the Doha Round. Differences of view on the merits of what should be done on both aspects of the GI negotiations remain profound – notably whether GI extension is a good idea at all and whether registrations under the GI register for wines and spirits should provide for legal effects that take the form of presumptions of validity. Moreover, as in the case of TRIPS/CBD, Members are also divided on whether or not the issue of GI extension was made part of the present Round of trade negotiations when they were launched at Doha.

Let me now turn to experience with the settlement of disputes between WTO Members under the TRIPS Agreement. As you know, one of the underlying aims of the TRIPS Agreement is to ensure that disputes about whether trading partners adequately protect intellectual property are resolved through multilateral procedures, and not through unilateral determinations and retaliatory measures or threats thereof. On the whole, it would seem that the TRIPS Agreement together with the WTO dispute settlement system, which explicitly prohibits unilateral determinations and retaliatory measures, have indeed contributed to this goal.

Moreover, the WTO dispute settlement system has shown itself, in a relatively low-key way, capable of resolving disputes in the intellectual property area, making State-to-State obligations contained not only in the new rules in the TRIPS Agreement but also in a large body of pre-existing international law incorporated in it by reference justiciable through a practicable multilateral dispute settlement mechanism for the first time. Twenty-six complaints relating to 21 separate matters have been lodged under the system in the TRIPS area. Panel reports and, where they have been appealed, Appellate Body reports have been adopted in nine cases. Nine of the other cases have been settled bilaterally between the parties to the dispute; the terms of these settlements are made public and can be important in influencing the way others implement the Agreement. As regards the rest, consultations are still pending or the case has become inactive. The main outstanding case is the complaint lodged in April this year by the United States against China in regard to the protection and enforcement of intellectual property

rights. Last week, the United States made a first request for the establishment of a dispute settlement panel to examine the TRIPS consistency of three aspects of the Chinese IPR system, namely thresholds for criminal procedures and penalties, measures for the disposal of infringing goods confiscated by customs, and copyright and related rights protection and enforcement in regard to works not authorized for publication or distribution within China. If the United States make a second request at the next meeting of the Dispute Settlement Body, scheduled for late September, the panel will be automatically established.

As regards the subject-matter of the 26 cases so far, a number have related in substantial part to the scope of allowable exceptions in the patent, copyright, trademark and geographical indications areas and therefore the balance found in the TRIPS Agreement. A number of others have concerned transitional matters, for example the so-called mailbox and exclusive marketing rights provisions in paragraphs 8 and 9 of Article 70, and the way in which the TRIPS rules apply to pre-existing subject-matter. A number have focused on enforcement, but none of these has been so far the subject of rulings, most having been settled bilaterally.

Some of the Panel and Appellate Body reports have had to interpret important provisions of WIPO Conventions incorporated into the TRIPS Agreement. Panels and the Appellate Body have sought to take care to interpret provisions of the TRIPS Agreement and of the WIPO conventions concerned in ways which reconcile them and avoid conflicts between them. Panels have invariably sought and obtained factual information from the International Bureau of the WIPO about drafting history and subsequent practice in regard to WIPO provisions that they have been called upon to interpret.

In general, Members' compliance with adverse rulings under the WTO dispute settlement system as a whole has been good. However, in two intellectual property cases, *US - Copyright Act* and *US - Section 211 (Havana Club)*, implementation is still pending. In the first of these, the United States initially agreed on arrangements to financially compensate the EC pending modification of its legislation; these arrangements have now expired.

One of the concerns of developing countries about making the GATT or WTO dispute settlement system applicable to the TRIPS Agreement was that they might be the subject of a large number of complaints and that, through so-called cross-retaliation, might put their market access rights in jeopardy if found in breach of their TRIPS commitments. What has been the experience so far? Most TRIPS complaints have been between developed countries, with only eight of the 26 directed at developing country respondents, of which two have so far involved the establishment of panels. While this concentration on complaints involving developed countries was not unexpected prior to the 2000 deadline for implementation by developing countries, we have not seen, so far, any large-scale recourse to dispute settlement against developing countries after this date. In fact, apart from the recent complaint against China, since 2000 there have only been two complaints filed concerning developing country implementation, both in 2000 and both settled bilaterally. It appears that developed countries have hitherto regarded bilateral discussion and technical cooperation as likely to be more fruitful in resolving any issues that they might have in regard to developing country TRIPS implementation.

Retaliation, or more properly "suspension of concessions or other obligations", can be authorized under the dispute settlement system as a last resort if a Member found to be nullifying or impairing benefits fails to implement recommendations and rulings within the period fixed or to offer acceptable compensation. To date, there has been no case of a Member obtaining authority to retaliate in response to the failure of another Member to comply with its TRIPS obligations. So-called cross-retaliation is possible if retaliation in the same sector of the WTO is not practicable or effective. There has been only one instance of authorized cross-retaliation so far under the whole dispute settlement system. This involved TRIPS, but in the sense of enabling a developing country to use authority to withdraw TRIPS obligations as a means of putting pressure on a developed country Member to comply with its GATT and GATS obligations. This was the authority given to Ecuador not to apply certain obligations on intellectual property matters relating to the protection of performers, producers of sound recordings, broadcasting organizations, industrial designs and geographical indications, in response to a failure of the European Communities to bring its banana regime into compliance with its GATT and GATS obligations. In the event, Ecuador did not find it necessary to actually carry out these retaliatory

measures. Two additional requests for authority to cross-retaliate in the TRIPS area have been lodged more recently. One is the request by Antigua and Barbuda in connection with its dispute with the United States in regard to the cross-border supply of gambling and betting services; this is presently the subject of arbitration proceedings to assess the appropriateness of Antigua and Barbuda's retaliation proposals. The other is a Brazilian request for authority to cross-retaliate in the TRIPS area against the United States in connection with the dispute on subsidies on upland cotton; this request is presently suspended pending a proceeding to determine whether the United States has complied with the earlier panel ruling on this matter.

This then is an attempt to update conference participants on the situation in the WTO regarding the TRIPS Agreement and to place it in the broader context of the ongoing international debate about the proper balance to be found in intellectual property regimes. I have sought in particular to set out briefly the state of work on each of the three main initiatives that have been taken by WTO Members in regard to the TRIPS Agreement, namely in relation to TRIPS and public health, the relationship between the TRIPS Agreement and the CBD and the protection of geographical indications. I have also briefly summarized experience with and the state of work on the settlement of disputes in the WTO in the intellectual property area.
