## THE FUTURE OF IPRS IN THE MULTILATERAL TRADING SYSTEM: RESPONDING TO COUNCIL FOR TRIPS ACTIVITIES, THE DOHA DEVELOPMENT AGENDA, AND THE EVOLVING WTO JURISPRUDENCE ON TRIPS

The note should, among others, address topics such as:

- Which issues should developing countries pay special attention to in the preparations for the forthcoming Mexico Ministerial Conference?
- Which lessons can developing countries draw from negotiations at the Council for TRIPS (e.g. on article 27.3.b) and from the evolving WTO -TRIPS jurisprudence?
- How should developing countries strategise to most effectively deal with the TRIPS review process?
- How to bridge the gap between demands for higher standards in the light of the insufficient or complete lack of data and evidence to support those demands

This note addresses the future work program of developing countries in the area of trade related aspects of intellectual property rights (TRIPS) with particular reference to activities within the framework of the World Trade Organization (WTO).

I. Issues for the Mexico Ministerial Conference

The first question to address is which issues developing countries should pay special attention to for the forthcoming Mexico Ministerial Conference (10-14 September 2002):

1. <u>Public Health</u>: The Council for TRIPS is instructed by Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health to report to the General Council before the end of 2002 regarding an expeditious solution to the problem of Members facing difficulty in using compulsory licensing because of insufficient or no manufacturing capacity for products in the pharmaceutical sector. At this time, there is uncertainty regarding (a) whether and when agreement on a proposal will be reached in the TRIPS Council, and (b) what the modality of such a proposal would be. Many developing Members consider that prospects for a favourable result are enhanced by seeking an "early harvest" agreement (preceding Cancun). The EC, however, has recently suggested that any recommendation to the General Council be put into a "single undertaking" basket to be adopted by Ministers. Assuming that the Paragraph 6 matter is not resolved before then, this is a matter to which developing countries should pay particular attention for the forthcoming Ministerial Conference.

I agree that it is preferable to aim for an early harvest agreement. If this matter is left for Mexico, developed Members will offer the solution as a major "concession" to developing Members for which reciprocal concessions will be demanded. This might have a significant impact on developing country interests both within and outside the TRIPS context.

2. <u>Non-Violation Causes of Action</u>: Developing countries have a substantial and immediate interest in resolving the question whether and under what conditions non-violation nullification or impairment (NVNI) causes of action may be initiated under the TRIPS

Agreement. Although developing Members might initiate NVNI actions, as a general proposition it seems more likely that developed Member IP interest holder groups will seek to expand the scope of TRIPS actions through this mechanism. If the *de facto* moratorium on NVNI actions is lifted, it may be very difficult to re-engage on limiting such actions. For this reason, it is important that the issue be addressed now, rather than as a longer term agenda item. (Matters such as the CBD relationship, for example, do not have the same short fuse.)

- 3. <u>Transfer of Technology</u>: Developing Members may press for concrete proposals on technology transfer from the developed countries. This would necessarily include commitment on funding. So far, assistance under the TRIPS Agreement has largely consisted of technical programs to implement IP laws. Developing Members might agree on one or two very specific proposals, rather than continuing to address this subject matter in the abstract.
- 4. <u>Convention on Biological Diversity and Article 27:3(b)</u>:
  - a. The relationship between the CBD and TRIPS Agreement assumed a concrete character during negotiations at the FAO on the International Treaty on Plant Genetic Resources for Food and Agriculture. The question was whether an obligation to pay a royalty imposed on inventors of patented agricultural products deriving from materials taken out of the Multilateral System would violate the Article 27:1, TRIPS Agreement, rule against discrimination as to field of technology. Without addressing the merits of that question, those who suggest that there is no conflict or potential conflict between the TRIPS Agreement and CBD might be referred to that incident.
  - b. The proposal that patent applicants be required to disclose the source of material from which genetic research (or related traditional medicine-based research) is conducted seems reasonable, and the arguments offered so far in opposition are weak.
  - c. Issues have been raised by certain developing countries regarding Article 27:3(b) and the patenting of life forms, including genetic material. This is argued to constitute "discovery" in contrast to "invention". It has been suggested that Article 27:3(b) might be amended to exclude such life forms from patenting. As an alternative, it might at least be made clear that such materials do not constitute "micro-organisms" and therefore are excludable.

In light of the EC's adoption of the Biotechnology Directive to cover this subject matter for internal market purposes (resolving debate over the meaning of Article 53(b) of the EPC), and U.S. jurisprudence so far on the subject, it will be very difficult to obtain an amendment to affirmatively exclude such subject matter (in its "non-natural" state). Even obtaining agreement on optional excludability might be very difficult given the centrality of this matter to the Pharma industry. This might be a case in which developing countries with an interest state a position on the record, and let the matter be put before a panel at some stage.

- d. Developed Members arguing that the 1991 version of UPOV is the only effective *sui generis* system of plant variety protection seem to have a very weak case. At the moment, there is considerable flexibility provided by Article 27:3(b) regarding this subject matter. The most appropriate tactic may be to resist further elaboration on this, leaving the matter to Member discretion.
- 5. <u>Geographical Indications of Origin</u>: This is a very difficult area for the developing countries because of the difficulties inherent in predicting whether there will be "net" advantage to them if greater general levels of GI protection are afforded. The basic problem is that the EC asserts extensive rights in geographical indications that developing countries might be required to recognize if more extensive protections are provided. This might affect developing country producers (being required to re-name their products) and

consumers (paying higher prices). This must be weighed against the analogous rights that developing countries will claim. Certainly there are some important areas where developing countries consider their interests are being neglected (*e.g.*, rice, tea, textiles). However, in some of these areas, there may be competing claims among developing countries that will need to be resolved before profitable advantage of strengthened GI protection can be taken.

Before the GI subject matter is given a priority, I would recommend waiting for further identification of specific developing country economic benefits.

6. <u>Traditional Knowledge and Folklore</u>: It may be useful to pursue rules against the "misuse" of traditional knowledge such as through foreign patent claiming based on publicly available information, prior to attempting to define "positive" ownership rights in traditional knowledge, which involves a far more complex set of issues.

From a TRIPS-economic standpoint, it seems doubtful that rights in traditional expression will have a "material" impact on development. While the protection of such expression is important on cultural grounds, and will have an impact in certain micro-economic settings, it may be preferable to pursue such protection at WIPO or another UN affiliate, where cross-concessions are less likely to be demanded.

- 7. <u>Pandora's Box</u>: The question inevitably arises whether opening the TRIPS Agreement to any amendment is opening a "Pandora's box" in that the developed countries have demands of their own that will be used to counter-balance any gains that developing countries may seek to achieve. There is certainly a risk that if the TRIPS Agreement is reopened, bilateral pressures will be applied toward achieving higher levels of protection. Two areas this is *less likely* to affect are (a) medicines, where the public interest is sufficiently high that a single purpose change might work and (b) non-violation causes of action that do not involve a reopening as such.
- II. Lessons Drawn from TRIPS Council Negotiations and WTO-TRIPS Jurisprudence
  - A. Lessons from Success

The most successful negotiations in the TRIPS Council up until now from the standpoint of the developing countries involve access to medicines, and there are some important lessons that may derived from that.

There were several distinctive elements to the negotiations leading up to the Doha Declaration on the TRIPS Agreement and Public Health:

- 1. The developing countries shared not only a common interest, but also a compelling public interest. The strong element of common interest facilitated the establishment of a common negotiating position.
- 2. The developing countries *led* the pre-Doha negotiations. The Ambassador of Zimbabwe chaired the TRIPS Council, and focused the attention of the Council on access to medicines. The developing countries formulated a number of cohesive policy papers that were circulated to the TRIPS Council. The developing countries submitted the first fully articulated draft of a declaration to the Council. There was a sense of commitment among the developing countries not to "break ranks" when the final negotiations took place in Doha.
  - a. These elements combined to place the developed countries in a defensive posture.

- 3. Public pressures were generated by two major external forces:
  - a. Major NGOs (such as MSF and Oxfam) geared up highly visible public relations campaigns in support of the developing country position. This placed considerable pressure on trade negotiators in terms of home constituencies.
  - b. The events of September 11, 2001, led to a negotiating vulnerability on the part of the United States, which came into the Doha negotiations with a compelling national interest not to repeat the Seattle fiasco. There was significant pressure to successfully conclude a Doha deal, with the terms of the deal having assumed a secondary role.
- 4. On the "risks" side, it should be recalled that a number of the developing country Geneva TRIPS Council delegates were in more subordinate diplomatic positions when the end game negotiations took place in Doha. More senior diplomats from the home capitals were not always as conversant with the issues as the TRIPS Council delegates, and were placed under a new set of pressures from developed country diplomats. A lesson to be derived from this "risk factor" is that close attention should be paid to briefing senior diplomats prior to the Ministerial Conferences. It may be more difficult to control for the risk factor of developed country diplomatic pressures that may come from outside the TRIPS arena (relating, for example, to IMF or World Bank funding).
  - B. Replicating the Conditions of Success

Distinctive elements of the Doha Declaration success may be subject to replication in certain contexts, but not in others.

- 1. Developing countries do not always share common interests in TRIPS matters.
- 2. Most issues are not as publicly compelling as access to medicines issues.
- 3. NGOs may not build public support on technical IP issues. This will vary depending on context.
- 4. Trade negotiating vulnerability cannot be anticipated as a recurring feature of negotiations.

This may suggest that developing countries would benefit by attempting to make calculations in advance concerning the extent to which elements more likely to lead to success will be present. Developing countries may find that their interests are better served by prioritizing negotiations in areas where they are able to identify strong common interests, public resonance and NGO participation. While developed country vulnerability in the sense of the Doha negotiations cannot be anticipated, a substitute for that kind of vulnerability may be a careful analysis of the concessions that developed countries are expected to pursue from the developing countries.

C. TRIPS Jurisprudence

The evolved jurisprudence on TRIPS has not yielded many surprises. In the *India-Mailbox* case the Appellate Body (AB) emphasized the importance of the express language of the TRIPS text, in contrast to "legitimate expectations". This has generally been interpreted as favourable to developing country interests because it dampens the prospects that developed country interest groups will be able to secure TRIPS-plus interpretations of the agreement. Nonetheless, the AB did not give India free reign to self-interpret and apply the agreement, signalling that national legislation would be reviewed for compliance with the express text.

The most important TRIPS decision is the panel report in *Canada – Generic Pharmaceuticals*. This decision has elements both favourable and unfavourable to likely developing country interests. On the less favourable side, the panel articulated a fairly narrow interpretation of the literal language of Article 30. On the positive side, the panel identified "discrimination" as the key term of Article 27:1,

and defined it in a way that should allow substantial flexibility in adopting *bona fide* differential treatment.

The panel report in *U.S. – Homestyle Exemption* reiterated a narrow approach on express language for exceptions. This case involved a fairly aggressive claim to exemption by the United States, one that the U.S. IP/copyright industries in fact opposed.

The AB's decision in *Canada – Patent Term* reinforced the line of decision in *India – Mailbox* concerning the centrality of express language.

The most unusual case is U.S. - Havana Club. The EC came in with a very poor legal position, arguing against a widely accepted view of the proper interpretation of the Paris Convention. Understandably, the EC's claims were rejected by the panel and AB. There were, however, two elements of importance to developing countries, one positive, one perhaps negative.

On the positive side, the AB affirmed that the United States had the right to make determinations regarding the ownership of IP interests (in this case trademarks) based on public policy considerations. That is, because Cuba had failed to compensate the original trademark holders (its own nationals), the U.S. could choose to de-legitimize Cuba's claim of successor ownership.

On the negative side, the AB found national treatment and MFN inconsistencies against the United States based on a highly improbable set of hypothetical circumstances that might result in discrimination under the literal language of the U.S. statutory and regulatory scheme. If the AB pursues such a rigorous interpretation of the national treatment and MFN rules in other contexts, there may be very little flexibility for differential treatment in favour of more localized developing country interests.

Dispute settlement decisions under the TRIPS Agreement must of course be read in light of decisions in other WTO areas. The most important from the developing country context may be (a) the *Shrimp-Turtles* decision and (b) the EC – Asbestos decision. In both these decisions the AB signalled some interest in considering the normative or policy context of its ruling, including in the *Shrimp-Turtles* decision the relevance of non-WTO agreements. The latter is relevant to the relationship between the TRIPS Agreement and CBD.

One point that may be extracted from the totality of AB decisions in the TRIPS and other socially relevant contexts is that the AB is not isolated from its political/public context. In a case involving a compelling public interest, such as access to medicines, the AB may be sympathetic to policy claims. However, attempting to predict the responses of a quasi-judicial body *in ambiguous cases* may be a "fool's errand". In respect to the AB, for example, the outcome might well be influenced by which three panellists are selected to decide the case. The *lesson* may be that, given a choice, it is preferable that agreement be obtained by diplomatic means, rather than leaving matters to the discretion of the judiciary.

## III. Strategising to Deal Effectively with the TRIPS Review Process

This may be the most important issue for purposes of medium to long term planning regarding the TRIPS Agreement. It involves the question of *process* in contrast to matters of *substance*.

Each developing country may have analyzed and determined its national interest in a particular TRIPS subject matter prior to engaging in the multilateral context. This would appear to be desirable from the standpoint of multilateral negotiations since this would reduce the possibility that the Geneva negotiator will eventually be undercut by his or her home constituency. However, developing

countries may have different capacities in respect to effectively analyzing TRIPS issues, and in this context the availability of external analytical assistance will be important from the outset. The development of internal-domestic capacity to analyze TRIPS issues from a local standpoint is a matter addressed by others in this program.

Over the past 50 years, there have been a number of efforts to achieve solidarity or common positions among developing countries in international forums. At the broad multilateral level there was (and are) the Group of 77, and the movement for a New International Economic Order. At the regional level, the Andean Pact in the early 1970s developed a rather sophisticated common plan to address technology and IP issues (*i.e.*, Decisions 84 and 85). Yet these efforts were largely unsuccessful in shifting the balance of negotiating leverage away from developed countries. In fact, developing country common efforts to reform the Paris Convention in the late 1970s and early 1980s are routinely cited as the triggering event for movement of intellectual property negotiations to the GATT.

This history is recalled for two reasons: (1) it is useful to be reminded that we are not the first to consider whether the developing countries might be more successful in achieving common objectives with coordinated strategies, and (2) that solutions based on "better or more sophisticated policy analysis" of developing country interests may yet run into a wall of "countervailing power" on the developed country side. This suggests that any strategy for effectively negotiating in the TRIPS Council should include components relating both to effectively determining what the optimal positions are *and* how negotiations might be conducted such that enough diplomatic pressure is brought to bear to achieve desired outcomes.

## A. Formulating Positions

The formulation of common negotiating positions is an inherently problematic exercise. Developing countries do not share uniform characteristics in terms of (1) level of overall economic development (2) technology infrastructure (3) trained research and development personnel, and so forth. Nor do developing countries necessarily confront the same problems. The U.S., EC, Japan and Switzerland differ with each other on TRIPS negotiating objectives, and developing countries at least arguably face even more disparate characteristics than these highly developed countries.

This suggests that an attempt might initially be made to identify developing countries that share characteristics from the standpoint of IP, and perhaps consider policy options, initially at least, within *subgroups of countries*.

It would seem highly desirable that a relatively *stable policy analysis group* be established on a subgroup or issue level. A problem confronting developing countries in Geneva is the rotating nature of diplomatic positions. At the point when a diplomat has spent a number of years on a particular subject matter and become adept with it, he or she may be transferred to a different negotiating arena. For the EU and U.S., which have a number of delegates dealing with the same sets of issues, and with large policy groups in the home capital, rotation is less of a problem.

Another problem is that developing countries are in *economic competition with each other*, and each may perceive that its advantage would lie in accepting incentives from developed countries (including making itself more attractive to investors in relation to other developing countries), rather than working on a common position. This was very likely the context that doomed the Andean Pact's otherwise well developed technology strategy – that is, developed country investors had other places to invest, so were more or less free to reject the strict Andean Pact's conditions.

The foregoing suggests that effectively strategising for TRIPS Council review and negotiations may involve: (1) building toward a developing country common position through stages that first identify the interests of subgroups, then attempting to reconcile potentially competing interests (2) creating a stable policy analysis group with a longer term memory, and (3) overcoming the desire to maximize individual gains at the potential expense of a common objective.

## B. Addressing the Wall of Countervailing Power

Developing countries face an enormous disadvantage in any trade negotiations with the developed countries. First, the developing countries are not able to offer comparable concessions (or the threat of withdrawing existing concessions). Second, the developing countries are highly dependent on the developed countries as the source of capital, whether it is provided through the IMF or World Bank, or through investment bankers and securities exchanges. In the TRIPS arena, developing countries are heavy net importers of technology, and dependent on continued developed country supply of technology.

TRIPS negotiations do not take place in isolation from other trade and finance negotiations. In this sense, no matter how reasonable from a public welfare policy standpoint a developing country negotiating demand is, the demand may not be accepted unless (a) the developed countries do not perceive their interests as adversely affected, or (b) the developing countries amass a sufficient amount of leverage to overcome resistance.

The "easiest" way to achieve negotiating objectives would be to identify positions that are aligned with developed country interests. This is plausible in some cases. For example, the developing countries may find that they have common cause with the EC on the issue of non-violation nullification or impairment, and (perhaps) on GIs.

A second but more costly way to achieve objectives is by offering reciprocal concessions. In some cases, for example, competition negotiations, the developing countries may decide that they would not be adversely affected. This may facilitate pursuing common cause (for example, with the EC on the competition issue).

A third way is through public relations offensive, perhaps in common cause with NGOs.

Whether the developing countries could plausibly threaten a general market access boycott in a way comparable to a U.S. Section 301 threat of market access restriction is debatable, but at least worth considering at some level. The central problem is one of establishing a disincentive for breaking ranks, and overcoming the problem faced by the Andean Pact in the availability of multiple potential sites for investment and exports. One alternative to a general developing – developed country market access restriction strategy would be to offer favourable treatment to one developed country or region over another based on favourable treatment in TRIPS negotiations. Developing and implementing a strategy of this nature would be highly complex.

IV. Demands for Higher Standards in Light of the Insufficient or Complete Lack of Data and Evidence to Support those Demands

The problem of indeterminacy in the economic analysis of TRIPS-related issues arising, *inter alia*, from the lack of adequate objective data is likely to persist for the foreseeable future. However, while the tools of economic analysis may not provide concrete answers to questions facing TRIPS negotiators, these tools are useful in identifying factors that may play a role in determining whether the introduction of new and higher standards of IP protection will benefit or harm consumers and producers in developing countries.

The problem of indeterminacy might be addressed by framing the matter as a "burden of proof" issue. That is, demanding empirical proof of a positive effect of the introduction of higher levels of IP in the particular contexts faced by developing countries (at different stages of development, and so forth).

I would not place too much emphasis, however, on this. Developed country policy researchers are adept at manipulating information, including data and statistics, to suit their objectives.

From the outset of negotiations in 1986, TRIPS demands have not been based on serious claims that developing countries will benefit from introducing higher standards of protection. They have, instead, been a matter of "protecting First World IP assets". Recall that in recent medicines negotiations, the U.S. argued that the price of medicines is but one of several factors preventing developing countries from addressing public health needs, and this was used as the basis for denying the relevance of patent protection. If the trade representative of the leading industrial power can argue that the price of goods is irrelevant to consumer welfare, this suggests that improvements in economic argumentation may not be the answer to claims for higher levels of protection.

Each developing country must decide for itself whether and in what contexts the introduction of IP protection will be beneficial for national welfare. Resistance to demands for higher levels of protection might be based on concepts of good governance and political responsibility towards citizens.