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Trade Diplomacy, the Rule of Law and the Problem of Asymmetric Risks in TRIPS

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The WTO has just finished two and one half years of negotiations on the TRIPS Agreement and Public Health, with an additional tranche of negotiations scheduled to commence soon. These negotiations have been extraordinarily instructive on the subject of trade diplomacy and the means by which ends are achieved at the WTO. In my view, over this period developing countries have made significant strides in efforts to integrate and co-ordinate their trade negotiating positions. Moreover, the collective urgency of the public health negotiations created a dynamic that even today is spilling over and informing the agriculture negotiations, where a well organised group of developing Members is using their combined strength in the face of entrenched economic powers.

The processes by which the Doha Declaration was adopted and the Paragraph 6 waiver decided were ugly. This was the part of trade diplomacy that we can characterise as the negotiation phase. It is a phase in which the powerful actors bargain from a position of strength, and in which the single most powerful actor has the capacity to disable the WTO and all other Members. It is a process in which the powerful have the capacity to visit individual national capitals and circumvent the Geneva processes at their will. A process in which individual developing country delegates can be singled out as disruptive actors and manoeuvred out of the negotiating process. It is a process in which nations and regions can be pitted against each other in attempts to fragment coalitions. It is, frankly speaking, a sobering and depressing spectacle. Yet in the face of this power economics diplomacy, developing countries stuck together better than the average family, and in the end resisted the harshest demands placed on them. I believe the developing country negotiators involved in the TRIPS and Health negotiations did well in the face of powerful opposition, and that the overall results are a net positive.

Because of time limitations I do not want to dwell today on the process of negotiation, a topic of strategic developmental interest of the utmost importance. I presented a PowerPoint history of the negotiations at the World Bank in February, and am working now on a detailed history of the Paragraph 6 negotiations that will continue through the recent waiver end-game. I would only again briefly observe at this stage that among the most hopeful signs of strengthening developing country response to aggressive unilateral and bilateral pressures is the co-ordinated actions of the Group of 21. While the Group may not here achieve a positive result in the face of co-ordinated and locked in EU-U.S. positions, it may at the least avoid a negative result. Also, there have in recent months been several instances of somewhat less publicly visible developing country coalition-building in terms of agreement to co-ordinate strategic action on economic issues. These are all positive signs, though I do not for a moment propose to discount the continuing large scale problem posed by asymmetric political and economic power. However, here I want to focus on the next phase in WTO trade diplomacy, that is, the process of implementation.

This is where even greater threats and risks await, and where the WTO as an institution must ultimately be held to account. I want to stress at the outset that Director General Supachai, the head of the WTO, has publicly stated that "This is a historic agreement for the WTO ... allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules ... prov[ing] once and for all that the organisation can handle humanitarian as well as trade concerns." Ambassador

^{*} This paper was presented at a symposium held in connection with the WTO Fifth (Cancun) Ministerial Conference. It has been revised to take into account comments received at the symposium and shortly afterwards. Most of those revisions are in the form of footnotes that respond to the comments.

¹ The political and economic pressure applied during these negotiations is largely a matter of public record. For example, there was little attempt to disguise efforts to convince prospective importing Members that their interests were at odds with those of prospective exporting Members. While those involved in the negotiations are familiar with the pressures applied with respect to individual delegates, the interests of those affected would not be served by recounting details here.

² Frederick M. Abbott, Negotiations in the WTO TRIPS Council pursuant to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health, World Bank Seminar, Washington, DC, Feb. 3, 2003 (available at http://www.worldbank.org/wbi/B-SPAN/sub_patents_medicines.htm).

³ Intellectual Property, Decision removes final patent obstacle to cheap drug imports, WTO Press Release, Press/350, 30 Aug. 2003 (03-4558).

Linnet Deily of the United States has publicly stated that "The decision will ensure that patent rules do not prevent a country that lacks capacity to produce medicines for itself from obtaining them from abroad." At the opening ceremony of the Fifth Ministerial, Director General Supachai reiterated the historic significance of the agreement on TRIPS and public health, saying that "This is evidence that the WTO system is working and can produce important results on critical issues of particular interest to developing countries". The EC Commissioner for Trade, Pascal Lamy, said the "deal on access to medicines [is] vital if we are to show that the WTO and the multilateral system is not just about mindless liberalisation, or kow-towing to globalisation. Of course, we have much more work to do to ensure delivery in practice, on the ground. But the deal, however long we waited for it, shows that the WTO can and will put people before markets." This time around, these statements must be more than the mere rhetorical flourishes that accompanied the close of the Uruguay Round and the adoption of TRIPS, but must instead be understood as commitments on behalf of the WTO as an institution to defend the interests of its weaker Members. The institution must absolutely be held to account for its promises. It is here that a detour into the past will bring us to the road ahead.

What brought us here?

Why did the Doha Declaration on the TRIPS Agreement and Public Health come about? South Africa accepted to implement the TRIPS Agreement as a developed Member of the WTO. It brought its national intellectual property legislation into compliance. It also adopted a National Drug Policy (1996) and legislation to implement it, the Medicines and Related Substances Control Amendments Act of 1997. And what did that Act do? It authorised the Health Minister to prescribe rules for the parallel importation of patented medicines, it introduced rules to promote competition and price reductions through generic substitution, and it allowed for the development of a single exit price mechanism for private sector drugs to discourage discrimination against the poor. This legislation was subject to vehement attack from the United States, and later the European Union, for being inconsistent with South Africa's TRIPS obligations. But there was nothing inconsistent with TRIPS in this legislation, a fact readily apparent to anyone familiar with the subject, including the United States and EU trade authorities. These governmental attacks were accompanied by large-scale litigation by 39 pharmaceutical companies seeking to prevent the government from implementing a progressive health care plan to benefit the poor.

During the course of the South Africa dispute, I approached members of the WTO Secretariat to ask why, if the U.S., EU and pharmaceutical industry were threatening South Africa on the basis of claims that clearly were not supported by the TRIPS Agreement, the WTO was not speaking out? The answer I received was that the WTO is a Member-driven organisation, and it is not the role of the Secretariat to speak on behalf of its Members. Yet the credibility of the WTO as a multilateral institution was under attack, and if the Director General was unable or unwilling to defend the rights of the less powerful Members, where would this defence come from? The WTO as an institution did not stand up for a less powerful Member.

In this case, the pressure came from NGOs that embarrassed a U.S. presidential candidate into retreating from his own hard line against South Africa. The U.S. withdrew its economic battleships, and the pharmaceutical companies after a period of public and legal pounding, withdrew their litigation and paid the South African government's legal fees, the ordinary lot of the loosing party in litigation in that country.

What was at issue in the South Africa case was implementation of the flexibilities in the TRIPS Agreement. The government came under attack for doing what it was clearly permitted to do. There was a powerful message inherent in that attack: You do not need to care about the rules if you are sufficiently powerful. We can agree to TRIPS but reserve the right to breach our commitment. And I would not have the bad taste to mention it except that we are once again facing the implementation of

⁴ Statement of Ambassador Linnet F. Deily, Permanent Representative to the World Trade Organisation and Deputy U.S. Trade Representative, Following Agreement in WTO on Access to Medicines, Office of USTR, 30 Aug. 2003.

⁵ Stating, "Just two weeks ago, we concluded a historic and significant agreement on TRIPS and Public Health". Address by Dr. Supachai Panitchpakdi, Director General, WTO Ministerial Conference (Cancun), Fifth Session, 10 Sept. 2003, WT/MIN(03)/10.

⁶ *Id.*, and adding "The added confidence and vigour that we have all drawn from this agreement must now be applied to the challenges we face in the negotiations."

⁷ Statement by Mr. Pascal Lamy, Commissioner for Trade, European Communities Commission, WTO Ministerial Conference (Cancun), Fifth Session, 10 Sept. 2003, WT/MIN(03)/ST/5.

TRIPS flexibilities in national law and with grave concern that the lessons have not been learned, that the new rules will stand as window dressing, and that the strong will not be barred from preying upon the weak.

For example, nothing could be clearer than the text of Paragraph 7 of the Doha Declaration. Least developed Members of the WTO need not adopt patent protection for pharmaceutical products, and they need not enforce pharmaceutical patent rights. Least developed countries are in the process of procuring HIV-AIDS medicines. They are being subsidised by various donor programmes. There is absolutely no question and no room for contrary interpretation – as a matter of TRIPS law, least developed Members of the WTO may ignore patents. Yet when asked to confirm this TRIPS implementing rule, the WTO Secretariat advised a prominent NGO that it could not do that because it does not have the authority to interpret WTO legal instruments, despite the fact that the WTO Secretariat routinely participates in training seminars on TRIPS Agreement implementation and as a matter of course provides guidance regarding the meaning of its provisions.

Concerns on implementation

A number of developing country Members of the WTO have expressed concern over the Decision on Implementation of Paragraph 6 because it includes procedural requirements involving provision of information to the TRIPS Council, and the issuance of licenses. From a legal standpoint, the obligation to provide information is a formality that should add virtually nothing to the transaction cost of using the mechanism. But why are these countries worried? Is this some form of governmental paranoia? No. It is a deadly serious concern that the powerful actors will use the information as reason for a visit to the national capital to explain that the rules are not actually intended to be used, and that their use may regrettably lead to the loss of market access or denial of IMF loans.

But here is the problem that is so difficult to address. The problem is not the rule itself. The problem is that to the powerful actors the rules do not appear to apply. Developing Members are accorded rights, but are threatened if they attempt to use them. A new set of rules spells out in detail the steps that importing and exporting Members should take in order to secure a supply of low-cost medicines. These may not be the easiest set of rules to follow, but neither are they the hardest. They call for fairly routine administrative processes. Based on the historical record, the problem is that the powerful actors will not live by the rules they have agreed to. They will not allow developing countries to make effective use of the mechanism. They will threaten them for contemplating to do so.

Let me frame it another way because this is such a critical point. If the concern is that developed Members will threaten developing Members on the basis of agreed-upon rules, no set of rules will be adequate. And because commercial actors and governments are very wary of acting in the absence of agreed-upon rules, the solution is not the absence of rules. The absence of rules will not act as a deterrent to pressure and threats, and will not create an environment conducive to addressing public health needs.

Possible responses

There are a number of ways that the problem of threats might be addressed, some already ongoing.

First is leadership by the economically and politically stronger of the developing Members, coupled with collective political support from other developing and developed Members. Brazil has taken on

⁸ Exchange of correspondence between Ellen 't Hoen, Campaign For Access to Essential Medicines, Medecins Sans Frontieres and Jayashree Watal, Counsellor, Intellectual Property Division, WTO, posted to IP-Health list-serve, 20 Aug. 2003. Ellen 't Hoen, in posting the correspondence, indicated her understanding that a draft response circulated to WTO Members by the Secretariat met with objection from certain Members.

⁹ Though, logically, a rule that would effectively penalise threats and end the practice would be adequate.

¹⁰ This fact is well supported by the historical record. As example, the initiation and conclusion of negotiations on the TRIPS Agreement took place against the backdrop of a series of actions by the United States under Section 301 and Special 301 of the Trade Act of 1974 (as amended) to compel its trading partners to adopt and enforce higher standards of intellectual property protection. When the U.S. Congress approved the Uruguay Round Agreements, it amended Section 301 and Special 301 to permit actions against countries "notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related aspects of Intellectual Property Rights" (19 USC § 2411(d)(3)(B)(II) & 19 USC § 2242(d)(4)).

this task of leadership several times already, and it is currently exercising this important role. Very shortly after adoption of the Decision on Implementation of Paragraph 6 Brazil took measures to import under compulsory licence and is bargaining with patent holders for price reductions on medicines. Although its action is not specifically under Paragraph 6 because it appears to be planning to import medicines that while on-patent in Brazil are off-patent in the supplying country, it is nonetheless apparent that Brazil's action will have the effect of demonstrating that compulsory licensing, including under Paragraph 6, can be used effectively.

What will be important to Brazil is that it receives political support from fellow WTO Members, both developing and developed, so that any counter-measures by Members representing patent holders might be undertaken only at serious political, and even economic, risk to those Members.

Collective response during previous leadership by Brazil included pursuit of supporting resolutions at the UN Human Rights bodies. In this instance, since the incoming Director General of the WHO has announced that his preference to address HIV-AIDS is to pursue the Brazilian model, institutional support for Brazil from the WHO would be very important and welcome. The effective response by the WHO to the SARS outbreak has created a large measure of international public trust and support for WHO, and its voice will be taken very seriously in the international media and public. NGOs will also play an important role with their demonstrated ability to mobilise world public opinion.

A *second* potential mechanism for countering intimidation tactics is the prospect for the organisation of collective support by multilateral institutions, developing and developed Members, and public interest groups concerned with access for smaller less powerful states in taking advantage of TRIPS flexibilities. Here one might envisage UNCTAD, the World Bank, WHO, UN High Commissioner on Human Rights and other institutions providing expertise and financial support for a series of undertakings intended to demonstrate to smaller economies the viability of using the measures that are lawfully permitted under the TRIPS Agreement. I would hope that DG Supachai and other people in the WTO leadership would on these occasions drop the reluctance to stand behind the measures that were specifically adopted to protect developing Members, and stand behind the words that they have used in the media to provide legitimacy to the WTO as an institution.¹¹ The failure of the WTO to support its smaller and less powerful Members would send a strong adverse message about the political basis of the organisation.

When smaller economies begin to act, and if they are subject to counter-measures from the more powerful patent holder Members, it is even more important that collective support be forthcoming. Perhaps the most desirable form of collective action will be for several smaller economy states in different parts of the world to act together, with collective support coming from a set of regional actors.

The problem of threats from more economically powerful Members is fundamentally a political problem requiring leadership and collective action. It is important to recall here that the WTO works on consensus principles, and the TRIPS Council cannot take steps without support of developing Members. This does not mean, however, that lawyers and legal rules cannot and should not play an increasing role in countering abuse of patents by WTO Members and their constituents so as to establish a true rule of law-based WTO system.

A legal response

How can lawyers approach this? How can we prevent repeats of South Africa? How can we force Members of the WTO to play by the rules they have agreed upon?

Some authorities have suggested that making public the behaviour of governments might be enough to create a disincentive to abuse. I am not inclined to agree because I think the powerful actors are generally content to ignore bad publicity.

¹¹ There is no simple way to define the circumstances in which the WTO leadership should publicly speak out on behalf of less powerful Members that are subject to unwarranted threats, as distinguished from intervening in more ordinary good faith disputes concerning the interpretation of rules. An analogy might be trying to define the circumstances in which the Secretary General of the United Nations should appeal to UN Members to abide by the rule of law enshrined in the UN Charter.

The broad answer would appear to be the establishment of real and effective disincentives for non-compliance with those rules. By this I mean sanctions or penalties for bad faith behaviour or abuse of the rules. Although I am only at the early stages of developing these ideas, I would raise here the question of how the WTO legal system can create a concrete and effective threat of penalty (or retaliation) against a Member that, on behalf of an industrial client, threatens another Member.

A private patent holder does not have a recognised power or authority to threaten a government with the withdrawal of trade privileges or withholding of funds from multilateral institutions. The prevailing pattern is for the patent holder (or patent holder industry group) to request its home government to make such threats. The abuse of patents is indirect. Targeted governments are in an extremely difficult position. They cannot take steps to protect themselves against the patent holder without also jeopardizing their full range of economic interests in confronting the patent holder's home government.

Patent holders are subject to sanction under generally accepted principles of competition law for abuse of dominant position. The TRIPS Agreement recognises the right of Members to take measures "to prevent the abuse of intellectual property rights by right holders". Conceptually, threats against governments lawfully preparing to take action under the TRIPS Agreement might be treated as a form of abuse of dominant position, and remedial measures taken under national law against the patent holders that instigate the threats. Thus, for example, a threat instigated under Section 301 in the United States might act to initiate a government action in the targeted country for abuse of dominant position by the patent holder (or its industry association).

The presence of a credible competition law-based response creating real economic risk for patent holders might to some extent begin to reduce the frequency and intensity of threats. Yet this potential solution presents a problem similar to that which it seeks to cure. If a Member will not act to lawfully grant a compulsory license because it is threatened with governmental retaliation, will it be any more willing to initiate a proceeding for abuse of dominant position?

Some form of collective response might insulate the threatened Member acting in its own defence. Such collective response might be possible under the umbrella of a regional organisation. It might also take the form of a joint inter-governmental investigation into abuse of dominant position. Neither the TRIPS Agreement nor WTO law prevents such collective action.

Another possibility is the idea of mutual responsibility. The TRIPS Agreement is the only WTO agreement that purports to establish private rights. Yet in establishing private rights, it leaves the question of liability under WTO rules to Members. There is a fundamental asymmetry. Might a remedy for abuse of the TRIPS Agreement apply not only to a Member, but also to the private party that is the real party in interest in the abuse? There is nothing so unique about private industrial actors playing significant roles in the WTO legal system. Some of the most notable dispute settlement cases are referred to by private actors or their interests: "Kodak-Fuji" as the name for a dispute between the United States and Japan; "Havana Club" for a trademark dispute between the European Union and United States.

Given the unique characteristic of the TRIPS Agreement in which private rights in patents and other IPRs are given express legal protection by the WTO system, might it not then create a preferred symmetry if a private IPRs holder could be joined with a Member abusing the rules as a complained-against party, and with the potential for suffering direct economic loss for its conduct? So, for example, the Appellate Body and DSB might recommend a monetary remedy against the patent holder, or that a compulsory license be issued on a patent, or (in egregious cases) the forfeiture or revocation of a patent, as a remedy for privately instigated abuse. A persistent violator would face the most serious repercussions. Though the recommendation would not, as with other WTO remedies, be directly effective, implementation of a remedy such as compulsory licensing of the patent could be framed to authorise a wide territorial scope of use.

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¹² And also expressly allows measures to address "the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology" (Article 8.2, TRIPS Agreement). *See* Frederick M. Abbott, *Report: Are the Competition Rules in the WTO Agreement on Trade-Related Intellectual Property Rights Adequate?*, in CHALLENGES TO THE LEGITIMACY AND EFFICIENCY OF THE WORLD TRADING SYSTEM: DEMOCRATIC GOVERNANCE AND COMPETITION CULTURE IN THE WTO (E-U Petersmann ed. 2003 forthcoming).

While it may be premature to offer concrete suggestions, WTO Members should begin thinking about real and concrete mechanisms to create disincentives to extra-legal threats. At present, the risks are entirely asymmetric. A pharmaceutical patent holder may encourage its government to threaten a foreign country with economic harm, and face little or no risk from engaging in this behaviour. The patent holder is riding the shirt tails of its government. But if patent holders are accorded rights under WTO law, they should also accept obligations, and failure to comply with those obligations must entail real and effective risk.

The next phase of the Paragraph 6 negotiation, in which an amendment is addressed, might include the subject of potential abuses by the patent holder, and creating real and effective mechanisms to penalise those who attempt to threaten or intimidate WTO Members. The process of thinking about means to achieve this objective are at early stages, and other approaches for addressing the problem of abuse of rights should be explored.

A challenge to the WTO

The WTO claims to be an institution based on the rule of law. It has in the past failed to support the rule of law on behalf of its economically weaker Members. The WTO as an institution must be held to account. It is imperative that the institution assure that the Paragraph 6 agreement can be used in good faith by those who desire to use it, and not allow it to become a baseline for intimidation. If the WTO is going to succeed in its mission as a rule of law-based framework for the conduct of international trade, it must put in safeguards to protect the rights and interests of its less economically and politically powerful Members. If it does not, the institution will face an accelerating crisis of legitimacy.