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## FOUR LESSONS FOR DEVELOPING COUNTRIES FROM THE TRADE NEGOTIATIONS OVER ACCESS TO MEDICINES

**ABSTRACT.** After the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into operation in 1995 developing countries have found themselves in a process of continual negotiation over intellectual property rights and access to medicines. These negotiations have taken place in the World Trade Organization and in the context of free trade agreements. The paper suggests that the only real win for developing countries has been the Doha Declaration on the TRIPS Agreement and Public Health in 2001. What have been the lessons for developing countries in a decade of negotiations over access to medicines? Drawing on themes of rule complexity and regulatory ritualism the paper discusses four key lessons for developing countries. It concludes by arguing that developing countries will do better if they adopt a networked governance approach to negotiation rather than continuing to rely on traditional coalition formation.

**KEY WORDS:** access to medicines, free trade agreements, patents, trade negotiations, TRIPS, WTO

### INTRODUCTION

This paper examines a set of distinct but linked negotiations in the World Trade Organization (WTO) over issues that are broadly referred to as access-to-medicines issues. Drawing on the experience of these access-to-medicines negotiations in the WTO, the paper derives the following four lessons:

1. In a situation where a coalition of weak bargainers obtains a negotiating gain there has to be a strategy that is aimed at the realization of that gain.
2. Weak actors have to be alert to the dangers of negotiating fatigue.
3. Where a coalition of weak bargainers obtains a negotiating gain that requires high levels of rule complexity to implement, it reduces its chances of successfully realizing that gain.

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4. Where a coalition of weak bargainers obtains a negotiating gain it must have a strategy for countering forum shifting by a powerful losing state that is aimed at recapturing that gain.

The problems that patents cause for access to medicines have been a structural issue for developing country consumers for many decades.<sup>1</sup> For the purposes of this paper, one can trace the political genealogy of the current crop of negotiations over access to medicines back to the emergence of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), an agreement that came into operation on 1 January 1995. TRIPS was the outcome of a sophisticated networked power wielded by a coalition of powerful developed states and corporate actors seeking greater economic rents for their intellectual property assets. Section 2 briefly sets out the negotiating reality of TRIPS. Over time as the patent provisions of TRIPS came to be better understood the opposition to TRIPS began to grow. In November in 2001 at the Ministerial Conference of the WTO in Doha, Qatar a coalition of developing states and civil society actors secured a major negotiating victory in the form of the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).<sup>2</sup> Amongst other things, the Doha Declaration affirmed the right of states to use, under certain conditions, patents without the permission of the patent owner. In practice, however, this right could not be exercised by a country if there was no capacity in a country to manufacture the needed pharmaceutical product and there were legal problems in being able to import the needed medicine from another country. TRIPS had added to these complications by imposing a requirement that where a patented good had been manufactured under a compulsory licence, the use of that good had to be “predominantly for the supply of the domestic market”.<sup>3</sup> Once a state began to export more than 50% of what had been manufactured it left itself open to the argument that it had breached its obligation under Article 31 of TRIPS. WTO Members in Paragraph 6 of the Doha Declaration instructed “the Council for TRIPS to find an expeditious solution to this problem”. The solution that was adopted by the WTO General Council on August 30 of 2003 took the form of waivers of the

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<sup>1</sup> See Gereffi, Gary *The Pharmaceutical Industry and Dependency in the Third World*, Princeton University Press, Princeton, New Jersey, 1983.

<sup>2</sup> See WT/MIN(01)/DEC/W/2, 14 November 2001.

<sup>3</sup> See Article 31(f). This condition does not apply where the compulsory licence is issued as part of an anti-competitive remedy. See Article 31(k).

obligations in Article 31.<sup>4</sup> The waivers would only operate if a number of conditions were met. The Paragraph 6 solution, as it is often referred to, received a more muted reception from public health advocates.<sup>5</sup> The basic problem was that the Paragraph 6 solution took the form of a system of rules that many saw as promoting uncertainty, the very thing that potential exporters of generic medicines along with importers of those medicines would want to avoid. Some saw the Paragraph 6 solution as a defeat for developing countries.<sup>6</sup>

At the same time as these WTO negotiations had been taking place the US (and to a lesser extent the EU) had been negotiating bilateral agreements relating to intellectual property.<sup>7</sup> The US had been on this parallel negotiating track since the 1980s, but beginning with Jordan in 2000 it began to insert into regional trade agreements (more commonly referred to as free trade agreements (FTAs)) comprehensive chapters on intellectual property standards. Many of these standards go beyond what is required under TRIPS or create new obligations altogether. A recent report by the Committee on Government Reform in the United States House of Representatives examined a number of these FTAs and came to the conclusion that “U.S. trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices”.<sup>8</sup>

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<sup>4</sup> Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003.

<sup>5</sup> See, for example, ‘MSF Comments on the Draft Chairman’s Statement of 21 August ‘03’ available at <http://www.accessmed-msf.org/prod/publications.asp?scntid=26820031712133contenttype=PARA>; ‘Joint NGO Statement on TRIPS public health’ available at [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/wtodeal\\_300803.htm](http://www.oxfam.org.uk/what_we_do/issues/health/wtodeal_300803.htm).

<sup>6</sup> See. Baker, Brook K ‘Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, 14 *Indiana International Comparative Law Review* (2004), 613.

<sup>7</sup> Drahos, Peter “BITS and BIPS: Bilateralism in Intellectual Property”, 4 (2001) *Journal of World Intellectual Property* (2001), 791.

<sup>8</sup> Trade Agreements and Access to Medications Under the Bush Administration, United States House of Representatives, Committee on Government Reform-Minority Staff, Special Investigations Division, June 2005, I, available at [www.reform.house.gov/min](http://www.reform.house.gov/min).

If we simplify these complex negotiations in win-loss terms (using the US and developing countries as representatives of opposing coalitions) we end up with the summary below:

TRIPS 1995 (WIN – US)

Doha Declaration 2001 (WIN – Developing Countries)

Paragraph 6 Solution 2003 (LOSS – Developing Countries)

IP Chapters of US FTAs (WIN – US (Beginning with US-Jordan FTA 2000<sup>9</sup>))

There are two important points to make about this win-loss sequence. The most-favoured nation clause (Article 4) in TRIPS picks up any higher standard of protection that WTO members may agree to in a FTA. In the context of access to medicines this means that when a developing country agrees with the US to an increase in patent standards, the benefit of that increase in protection is available to the nationals of all WTO members. A second point worth noting about this win-loss sequence is that the one win for developing countries, the Doha Declaration, takes the form of a declaration. The status of declarations in international law is not a topic to be pursued here, but we can observe that the degree of legal entrenchment of the principles won in the Doha negotiation does not match the entrenchment by hard law that the US has achieved for its negotiating wins. By way of example, TRIPS began the process of placing conditions and restrictions on the capacity of states to issue compulsory licences, a process that has been continued by subsequent FTAs. The Doha Declaration articulates the principle that nothing in TRIPS prevents WTO members “from taking measures to protect public health”, but it does not stop WTO members from agreeing to restrictions on the measures available to them for the purposes of protecting public health. US FTAs that impose new restrictions on the capacity of states to regulate intellectual property for public health purposes take advantage of the fact that the Doha Declaration does not establish peremptory norms for this purpose.

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<sup>9</sup> The US-Jordan FTA was the first preferential trade agreement that the US signed post-TRIPS that contained a full chapter on intellectual property. As Mohammed El Said observes this FTA “came to represent the cornerstone” of subsequent US agreements. See El Said, Mohammed “The Evolution of the Jordanian TRIPS-Plus Model: Multilateralism vs. Bilateralism and the Implications for the Jordanian IPRs Regime” 37 *International Review of Intellectual Property and Competition Law* 5 (2006), 13.

## TRIPS

The claim that the Doha Declaration was a negotiating success for a coalition of weak actors can only be understood by reference to the negotiations that had produced TRIPS. Susan Sell points out that some twelve US corporations were primarily responsible for the lobbying that brought TRIPS into being.<sup>10</sup> Others have come to a similar conclusion.<sup>11</sup> TRIPS was a stunning negotiating victory that was made possible because a small group of individuals saw in the 1980s the possibilities of networked governance, especially when those networks could capture and deploy a ‘big stick’ in the form of US trade threats. TRIPS was the product of politically powerful and linked networks deploying a regulatory pyramid with the threat of trade sanctions at its apex.<sup>12</sup> Within these intersecting networks there were pools of technical expertise upon which to draw for the purposes of producing a draft agreement, while other networks steered the draft through a multilateral trade negotiation involving more than one hundred states that lasted from 1986 to 1993. Important to this achievement were a small number of business actors who created ever-widening circles of influence that enrolled more actors in networks that had TRIPS as their mission. In the actual negotiations developing countries were not part of the informal groupings where much of the real negotiating was done and where the consensus and agreement that mattered was obtained. A list of these groups in roughly their order of importance would be:<sup>13</sup>

1. US and Europe
2. US, Europe, Japan
3. US, Europe, Japan, Canada (Quad)
4. Quad ‘plus’ (membership depended on issue, but Switzerland and Australia were regulars in this group)

<sup>10</sup> Sell, Susan *Private Power, Public Law: The Globalization of Intellectual Property Rights*, Cambridge University Press, Cambridge, 2003.

<sup>11</sup> See Drahos, Peter with Braithwaite, John *Information Feudalism: Who Owns the Knowledge Economy?* Earthscan, London, 2002.

<sup>12</sup> For an explanation of how the theory of the regulatory pyramid applies to US trade regulation as well as the theory of the nodally co-ordinated pyramid see Drahos, Peter ‘Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach’, 77 *Temple Law Review* (2004), 401.

<sup>13</sup> Drahos, Peter “Negotiating Intellectual Property Rights: Between Coercion and Dialogue” in Drahos and Mayne, eds *Global Intellectual Property Rights: Knowledge Access and Development*, Palgrave Macmillan, Hampshire and New York, 2002, 161.

5. Friends of Intellectual Property (a larger group that included the Quad, Australia, and Switzerland)
6. 10 + 10 (and the variants thereof such as 5 + 5, 3 + 3).  
(The US and the European Community were always part of any such group if the issue was important. Other active members were Japan, Nordics, Canada, Argentina, Australia, Brazil, Hong Kong, India, Malaysia, Switzerland and Thailand.)
7. Developing country groups (for example, the Andean Group - Bolivia, Colombia, Peru and Venezuela; Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, Nigeria, Peru, Tanzania and Uruguay combined to submit a developing countries draft text in 1990).
8. Group 11 (the entire TRIPS negotiating group - about 40 countries were active in this group)

It was the first three circles of consensus that really mattered in the TRIPS negotiations. Through the use of these circles the process became one of hierarchical rather than democratic management. Those in the inner circle of groups knew what TRIPS had to contain. They worked on those in the outer circle until the agreement of all groups to a text had been obtained. TRIPS was much more the product of the first three groups than it was of the last five.

TRIPS covers a range of intellectual property rights and has a number of legal and economic consequences for developing countries. It achieves one thing in its provisions on patents that is essential to understanding the debates around access to medicines. Article 27.1 of TRIPS obliges all Members of the WTO to recognize patents on products in all fields of technology. Before TRIPS some countries did not recognize patents on pharmaceutical products (India, for example). Product patents are the foundation stone of complex patent portfolios that are built by large pharmaceutical companies around the basic compound they wish to protect. Once the product patent is in place they use other types of patents such as formulation patents, process patents and method-of-treatment patents to build a wall of protection around the original compound. Generic companies have to wait for the product patent to expire before they can enter the market. They may well encounter dozens of other patents around the basic molecule, but many of these are of doubtful validity (and therefore may be litigated) or can be circumvented (eg another process of manufacture can be found). It is product patents that are the fundamental building blocks of protection. By globalizing product patent protection for

pharmaceuticals TRIPS released a wave of change in pharmaceutical markets that will be felt for many years to come.

During the 1990s public health experts began to develop an understanding of TRIPS. They began to ask what would happen to the supply of medicines, especially for HIV/AIDS, if pharmaceutical multinationals began to register large numbers of patents in the relatively small number of developing countries that had generic industries with export capacity.<sup>14</sup> Product patents in pharmaceuticals potentially confer enormous market power because of the fact that often there are no ready substitutes for the product. In order to deal with this market power developed countries have over a long period of time used a range of regulatory tools, including compulsory licensing and parallel importation of pharmaceuticals. These are available under TRIPS.<sup>15</sup> Public health advocates aimed to make clear to developing countries that these flexibilities were available to them and that they should not hesitate to use them. Building the institutional capacity to regulate the use of intellectual property does not happen overnight. One important purpose of the Doha Declaration was to clear the air of the uncertainty that had arisen in many developing countries surrounding the use of TRIP flexibilities because of a lack of experience and administrative know how in these countries in the regulation of patents.

#### WINNING DOHA

During the TRIPS negotiations international NGOs and African states were not significant players. The two most striking features in terms of actors involved in the post-TRIPS scene has been the

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<sup>14</sup> Only a small number of developing countries possess reverse engineering capabilities on an industrial scale. A study in 1992 by UNIDO pointed out that only five developing countries had innovative capabilities in the pharmaceutical sector (defined as the capability of producing new drugs by a process of reverse engineering). These countries were Argentina, China, India, Korea and Mexico. See Balance, Robert, Progan, Janos and Forstner, Helmut (1992) *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*, UNIDO. Since the UNIDO study a number of developing countries have, as a result of the HIV/AIDS crisis, placed resources into the pharmaceutical sector and as a result have a much stronger sector. Brazil and Thailand are leaders in the manufacture of cheap anti-retroviral drugs.

<sup>15</sup> See generally, Musungu, Sisule F., Villanueva, Susan and Blasetti, Roxana "Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks", South Centre, Geneva, 2004.

engagement of international NGOs in TRIPS issues and the leadership of the Africa group on health and biodiversity issues. The Organization of African Unity (OAU), Ethiopia, Kenya, the Third World Network and the Institute for Sustainable Development have been prime movers in developing model legislation for African states which sets out regulatory principles for the ownership and use of biological resources and related local community knowledge. The special sessions of the TRIPS Council on the issue of intellectual property rights and access to medicines, the first of which was held in June of 2001, were inspired by a proposal from the African Group that was discussed and agreed to at a TRIPS Council meeting in April of 2001. This initiative ultimately culminated in the Doha Declaration.

There is little doubt that the rise in influence of the Africa Group has been enabled by a partnership with NGOs. In a study conducted for the UK Commission on Intellectual Property Rights, every single developing country negotiator that was interviewed commented on the positive role that NGOs have played in the debate over TRIPS and access to medicines.<sup>16</sup> (The role of the Quaker Geneva Secretariat came in for express mention. Another interviewee said “what negotiators like me failed to accomplish Oxfam and MSF have accomplished”).

Northern NGOs have broadly followed the reactive sequence of regulatory change that Braithwaite and Drahos identify empirically as one of the sequences that results in global regulatory change.<sup>17</sup> This sequence begins with a crisis that sees a regulatory entrepreneur seize the initiative by putting a regulatory model on the table, a model that eventually globalizes. The death toll in Africa from AIDS has created one of the greatest international public health crises in history. Using this crisis NGOs have reframed the contest of principles surrounding intellectual property rights.<sup>18</sup> During the TRIPS negotiations, US multinationals framed the contest as one between the protection of private property rights versus piracy by developing countries. During the late 1990s NGOs presented the contest as one between the rights of states to protect public health

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<sup>16</sup> See Drahos, Peter *Intellectual Property Standard Setting and Developing Countries*, Paper for the UK Commission on Intellectual Property Rights, available as Study Paper 8 at <http://www.iprcommission.org>.

<sup>17</sup> Braithwaite, John and Drahos, Peter *Global Business Regulation*, Cambridge, Cambridge University Press, 2000, 33.

<sup>18</sup> Braithwaite and Drahos, *supra*, n.17, 575–76.

versus the extension of patent monopoly power. The Doha Declaration, the outcome of this contest, elevates the former principle over the latter.

The Doha Declaration is a case of a weak coalition making a gain that an observer would not have predicted given the power resources of the US-led coalition. The explanation for this success lies in the fact that we live in a networked world and in such a world, as John Braithwaite has observed, “the prescription for potency is not to sit around waiting for your own power to grow ... [r]ather the prescription is to actively network with those with power that you do not yourself control.”<sup>19</sup> Through networking the weak actor becomes connected to other pools of capacity/power, pools that can then flow through the network to achieve the goals of members of the network. The Africa Group could never have achieved the Doha Declaration because they were and remain a weak group. But an Africa Group that joined with a large coalition of developing countries that included Brazil and India, that drew on the power of Northern NGOs to work the Northern mass media, that gained the quiet support of some European states, that drew on independent technical expertise to evaluate draft text, that gained resources from Geneva-based NGOs was a group strengthened by many ties.<sup>20</sup> If TRIPS was about a form of networked governance in which the powerful built ever larger circles of consensus in the shadow of credible threats of trade coercion, the Doha Declaration was about the weak networking networks that surrounded and eventually isolated the US and in the final instance its pharmaceutical industry. At Doha the then USTR Robert Zoellick faced a choice between appearing to be against access to medicines or abandoning the US pharmaceutical industry. Neither were especially palatable alternatives. He chose the latter. There was also another factor at play. The networking of networks by the weak had created a form of sanction that cast its shadow over Doha, that of the court of global public opinion. Northern NGOs had succeeded in reducing the complexities of patent law and

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<sup>19</sup> Braithwaite, John ‘Responsive Regulation and Developing Economies’, 34 *World Development* (2006), 884, 892.

<sup>20</sup> For a detailed account of how these factors played out in the negotiation see Odell, John S and Sell, Susan K ‘Reframing the issue: the WTO coalition on intellectual property and public health, 2001’ in John S. Odell (ed), *Negotiating Trade: Developing Countries in the WTO and NAFTA*, Cambridge University Press, Cambridge, 2006, 85.

HIV/AIDS down to a simple choice readily understood by mass publics. Moreover, WTO negotiations were globally visible and transparent in ways that FTA negotiations were simply not. With the world's press watching, the US-led coalition was faced with coming out in support of a declaration that unambiguously helped to prevent millions of needless deaths or declaring itself in favour of putting patents and profit first. The former was a basic moral canon understood by all. No individual, country or organization could be seen to be deciding the latter.

### FRAIL VICTORY – THE PARAGRAPH 6 SOLUTION

We saw in the introduction to this paper that the Doha Declaration had left the TRIPS Council with a task that was defined in Paragraph 6. The Council had to find a solution to the problem of how developing countries that lacked manufacturing capacity in the pharmaceutical sector could make use of the flexibilities of TRIPS, which the Doha Declaration stated were available, when TRIPS itself imposed a limit on export under compulsory licence. This solution had to be found against a background in which trade law, patent law and treaty law all converged to produce a high level of legal complexity. From the point of view of US pharmaceutical multinationals, a Paragraph 6 solution had the potential to make it easier for developing country exporters such as India to export medicines that were needed by other countries. One of the key long term objectives of US pharmaceutical multinationals was to create an international patent regime that would make it difficult for generic exporters to contest the US market or third markets in cases where a product had gone off patent or a compulsory licence had been issued. In particular, US corporations were worried about the use that India, which was the principal developing country exporter, might make of a Paragraph 6 solution. India had always been the main target of the TRIPS negotiations, because it had not bowed to US bilateral pressure during the 1980s. Moreover, US pharmaceutical companies were not content with TRIPS standards for India, as the following letter from Pfizer written in 1994 to the United States Trade Representative makes clear:

Finally, GATT does not do it. Many Indians mistakenly (often very honestly) believe that if they endorse GATT they will have solved their IP and pharmaceutical patent issue. Not so, particularly if they truly want to create an environment that attracts investment and provides better medicine – legalistically

agreeing to something (GATT) that brings this into play in ten years or more achieves neither of these two objectives.<sup>21</sup>

When the solution to the Paragraph 6 problem was adopted by the WTO General Council on August 30, 2003 it took the form of 6 pages of rules that specified conditions under which an importing country would be able to bring in a consignment of drugs from an exporting country. For present purposes, it is important to note that the solution is characterized by a high degree of rule complexity. Rule complexity has some basic indicators; density, technicality, differentiation and uncertainty.<sup>22</sup> The Paragraph 6 solution covers the import/export transaction (density of coverage), it requires specialist expertise to apply (technicality), it involves the application of domestic and treaty law (differentiation) and it requires a number of conditions to be satisfied before it can be applied (uncertainty). Civil society advocates in particular were keen on a solution that kept rule complexity to a minimum. For this reason key players such as CPTech and Médecins Sans Frontières pushed what became known as an Article 30 solution.<sup>23</sup>

Article 30 is an important provision in TRIPS that recognizes that states may limit the right of the patent holder for certain purposes. The Article 30 principle of a limitation of rights could potentially be used to create new exceptions and limitations on patent rights. In its simplest form an Article 30 solution could have seen WTO members simply agreeing that in cases where a country lacked manufacturing capacity and needed medicines, Article 30 would permit the creation of an exception to the restriction imposed by Article 31(f) of TRIPS. Over time a state practice around this exception would have emerged as states implemented this approach into their national laws. Disagreements over the scope of the Article 30 solution could have been dealt with through negotiation, consultation and ultimately the WTO's dispute resolution

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<sup>21</sup> Letter from C.L. Clemente, Senior Vice President – Corporate Affairs, Pfizer Inc to Joseph Papovich, Deputy Assistant U.S. Trade Representative for Intellectual Property, June 7, 1994.

<sup>22</sup> Schuck, Peter 'Legal Complexity: Some Causes, Consequences, and Cures' 42 *Duke Law Journal* (1992), 1.

<sup>23</sup> For an explanation as to why CPTech, MSF, Oxfam and Health Action International preferred an Article 30 solution see 'Letter from CPTech, Oxfam, MSF and HAI to WTO Delegates regarding December 16, 2002 Chairman's Text for "solution" to Paragraph 6 of the Doha Declaration on TRIPS and Public Health, available at <http://www.accessmed-msf.org/prod/publications.asp?scentid=6120031111255contenttype=PARA>

process. An Article 30 solution could have laid the basis for the evolution of a responsive state practice and custom on public health and intellectual property issues. The important point for present purposes is that a principle-based solution was available. What WTO Members actually negotiated was a rule-intensive solution. We shall see in the next section that this type of solution has real costs for weaker actors when it comes to realizing the gains of a negotiation.

#### RULE COMPLEX SOLUTIONS – COSTS AND LESSONS FROM DOHA

We can now turn to the four propositions that we put forward at the beginning of this paper and show how they are supported by the negotiations around the Doha Declaration and the Paragraph 6 solution.

*In a Situation where a Coalition of Weak Bargainers Obtains a Negotiating Gain there has to be a Strategy that is Aimed at the Realization of that Gain*

Negotiating wins or gains may or may not turn into real gains. Within the context of trade negotiation an example of a negotiating gain that is turned into a real gain is where a state wins a tariff concession and the state granting the concession does nothing to frustrate its grant with the result that the first state gains a share of an export market that it did not have before.<sup>24</sup> Much of trade law can be read as providing mechanisms for ensuring that states stick to the concessions that they have negotiated and that they do not use other devices and stratagems for defeating the thrust of those concessions. In the case of international negotiations, a negotiating win is most likely to be realized where the parties to the agreement both have strong interests in meeting their promises or where the breach of a promise by one party is likely to be detected and there is a robust enforcement mechanism that will deliver a sanction for that breach. Where mutual gains providing for self-enforcement do not exist or where there is no strong enforcement mechanism there

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<sup>24</sup> In economic terms the state granting the concession also wins, but this is not how it is seen in the world of trade negotiators. See Finger, J. Michael 'A Diplomat's Economics: Reciprocity in the Uruguay Round Negotiations', 4 *World Trade Review* (2005), 27.

is a real danger that a negotiating win, especially one by a weaker actor, will not be realized. Under these conditions if a negotiating win is not accompanied by some strategy of post-negotiation implementation there is a real risk that the gain will never be realized.

The Doha Declaration is an example of a rare negotiating win for developing countries in the context of intellectual property rights. However, developing countries had no common or even individual strategy for exploiting its potential. The negotiations over the Doha Declaration were not about trade gains in any conventional sense. Instead, as the opening paragraph makes clear, the negotiation was about recognizing that developing countries were facing severe public health problems and TRIPS (and therefore the WTO) had to be part of the solution rather than part of the problem. The Declaration does not create new rights that override TRIPS. Rather it provides a constitutional-like ordering of principle in which the principle of intellectual property protection is expressly subordinated to the right of states to protect public health. Following on from this constitutional ordering in Paragraph 4 of the Doha Declaration, Paragraph 5 lists some of the flexibilities that TRIPS contains and that can be used to serve the principle of protecting public health.

Winning a contest of principles, however, is only the beginning of securing a desired regulatory outcome. Principles are by their nature open-ended and so have to be secured through practices and rules that institutionalize those principles. Victory in a contest of principles that is not secured through institutionalization can be lost, if the losing party shifts the contest to another forum or if the losing party counters by generating a rule complexity that does not support the spirit of the principle.

Following the Doha Declaration, developing states had the opportunity to create forms of state practice around the Doha Declaration and TRIPS that would have clearly established that intellectual property rights were the regulatory servants of public health. The kinds of practices that states might have engaged in would have been to begin routinely issuing compulsory licences for needed medicines, establishing an exhaustion regime for patents that best suited their circumstances and if necessary making use of Article 30. This sounds very much like a bootstraps enterprise, but this is a form of enterprise that international law expressly recognizes.<sup>25</sup>

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<sup>25</sup> For example, Article 31(3)(b) of the *Vienna Convention on the Law of Treaties* 1969 states that “any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation” shall be taken into account.

States can through practice and custom create law and give meaning to treaties. More important than the rules of international law are the politics. If developing countries had collectively, vigorously and with media savvy pursued the kind of options outlined above would the US in particular have opposed them by, for example, threatening litigation in the WTO? Bearing in mind the public relations disaster of the litigation by pharmaceutical multinationals against South Africa<sup>26</sup> and the fact that the US would have been globally seen to be undermining the Doha Declaration as a moral canon, one suspects that the costs to the US of a WTO litigation strategy would have been simply too high. The more widespread and longer the practices of developing countries became the more weight as a matter of international law those practices would have gained.

As it turned out, developing countries did not have any such post-negotiation implementation strategy in place for the realization of the gains of Doha. Table I below illustrates just how little compulsory licensing activity actually took place on the ground in developing countries in the first three years after Doha. It might be said that the explanation for this lack of activity lies in the lack of patents on pharmaceutical products in developing countries and so there was no need on their part to resort to the issue of compulsory licences. Ascertaining the patent status of a given drug is difficult, especially in developing countries where often the patent office does not have electronic search facilities. In many cases one can only find out the patent status of a drug by going to the office in question and doing a physical search.<sup>27</sup> Moreover, questions of patent status are often a matter of interpretation of complex claims. Organizations like Médecins Sans Frontières (MSF) have invested heavily in ascertaining the patent status of anti retroviral drugs. In a recent report MSF reported that nevirapine was still under patent in Kenya, Malawi, Uganda, Zambia, Zimbabwe and most francophone African countries.<sup>28</sup> This is just one important

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<sup>26</sup> Odell and Sell, *supra*, n.20, 98.

<sup>27</sup> Hence studies that claim that patents are not the problem and rely on indirect evidence of patent status are on shaky ground. The study by the International Intellectual Property Institute concedes as much. See 'Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa', A Report Prepared for the World Intellectual Property Organization by the International Intellectual Property Institute, 2000, 37.

<sup>28</sup> See Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries, MSF, July 2006, 7, available at [www.accessmed-msf.org](http://www.accessmed-msf.org).

TABLE I  
Compulsory Licences after the Doha Declaration – 2001–2004<sup>a</sup>

Country	Year	Licence activity
Brazil	2001	From 2001 Brazil has on a number of occasions threatened the use of compulsory licences but no licence has been issued to date.
Indonesia	2004	On October 5, 2004, Indonesia issued a compulsory license for lamivudine and nevirapine
Korea	2002	Application for compulsory non-exclusive licence for importation of Glivec from India. Rejected 2003.
Malaysia	2003	On 29 October 2003, the Malaysian Minister of Domestic Trade and Consumer Affairs issued a two-year compulsory license for importation of didanosine (ddI), zidovudine (AZT) and lamivudine + zidovudine (Combivir) from Cipla, India.
Mozambique	2004	On April 5, 2004, Mozambique's Deputy Minister of Industry and Commerce issued compulsory licenses for patent rights to lamivudine, stavudine and nevirapine
South Africa	2003	On 10 December 2003 South Africa's Competition Commission reached a settlement with GlaxoSmithKline and Boehringer Ingelheim. The complaint charged these corporations with excessive pricing in respect of ritonavir, lamivudine, ritonavir + lamivudine and nevirapine.
Zambia	2004	On 21 September 2004 the Zambian Minister of Domestic Trade and Consumer Affairs issued a compulsory license for lamivudine, stavudine and nevirapine. The license was granted to Pharco Ltd., a local producer, which will produce a triple fixed-dose combination.

Table I continued

Country	Year	Licence activity
Zimbabwe	2004	On May 27, 2004, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs declared a Period of Emergency in order to override antiretroviral drug patents. With assistance from India, Zimbabwe has begun local production of antiretrovirals.

<sup>a</sup> This table is compiled from the page that is kept by the Consumer Project on Technology on compulsory licences and health matters. It is the best public source of information on this issue that is known to the author. Available at <http://www.cptech.org/ip/health/cl/recent-examples.html>

AIDS drug. The point for present purposes is that the explanation for the lack of compulsory licensing activity shown by Table I below almost certainly does not lie in an absence of pharmaceutical patents in developing countries (although levels of pharmaceutical patenting will be lower), but rather in the lack of a politically-backed legal strategy aimed at realizing the negotiating gain of the Doha Declaration. In the absence of such a strategy developing countries allowed themselves to be drawn into another negotiation in the WTO on the Paragraph 6 issue. It is from this negotiation that our next two propositions are derived.

*Weaker Actors Have to be Alert to the Dangers of 'Negotiating Fatigue'*

During their fieldwork at the WTO in the early 1990s Braithwaite and Drahos found that senior personnel saw the organization as suffering from "negotiating fatigue":

A situation of negotiating fatigue 'suits the US and Europe' with their large infrastructure for trade negotiation in Geneva. They want the WTO to take on 'more and more good things' that will liberalize trade, knowing that only they can resource the committees properly. 'Big players can afford to play cat and mouse ... when they are suffering less negotiating fatigue than others' (WTO official).<sup>29</sup>

One only needs to look at the meeting schedule of the WTO on any given day in Geneva, along with other relevant meetings in organizations such as UNCTAD or WIPO to see that developing and many

<sup>29</sup> Braithwaite and Drahos, *supra*, n.17, 196.

middle developed country economies have little capacity to service negotiations on so many fronts on which there are constant demands. Drahos in a separate fieldwork exercise conducted in 2000 found that the cycle of negotiating fatigue had intensified since the early 1990s.<sup>30</sup> He interviewed developing country representatives that had responsibility for up to a dozen different areas across a number of international organizations. Expert tracking of so many areas is not, as the interviewees readily conceded, a realistic possibility. Instead many negotiators stumble from one meeting to another with little evidence-based understanding of what they are dealing with, largely repeating what they have picked up in conversation or read in a summary briefing paper that has found its way onto their desk.

The Paragraph 6 negotiations provide a useful illustration of the dangers of negotiating fatigue. They also illustrate that in a world of perpetual negotiation all negotiating wins should be treated as temporary. Any other attitude to victory leaves one open to the dangers of hubris and nemesis.

An alliance of developing countries and civil society actors using a combination of evidence-based analysis and skilful public campaigning along with the issue of credible threats (No Doha Declaration, No Doha Round) won the Doha Declaration. After the Doha Declaration two fundamental things happened. The US pharmaceutical industry realizing the dangers to it of Doha's guarantees and freedoms for public health came to the Paragraph 6 negotiations with the clear objective of finding a 'solution' that would limit the freedoms of Doha. The Paragraph 6 negotiations became an opportunity for the US industry to recoup its losses. At the same time, the US intensified its strategy of obtaining stronger standards of intellectual property protection through FTAs. Developing countries by contrast were not especially well prepared for another negotiation on intellectual property rights and public health. The launch of the Doha Trade Round meant that their already strained trade bureaucracies would confront extra demands. Facing this situation, developing countries would have done better to post-pone the Paragraph 6 negotiation and concentrate on developing supportive state practices that would have released the full potential of the Doha Declaration. Instead they entered into another WTO negotiating cycle at a time when the US had also opened up a bilateral front on intellectual property.

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<sup>30</sup> See Drahos, *supra*, 16.

Negotiating fatigue is a real phenomenon. The US and EU know that pressure-ridden negotiating cycles over complex issues will strain and eventually overwhelm the capacities of most weaker actors. For weaker actors part of the art of negotiation is knowing when to walk away, when not to be drawn into a cycle of negotiation and when to put on the negotiating agenda items that they can service in terms of analysis and personnel. Agreeing to tight negotiating schedules and deadlines creates pressures that the stronger actor is better able to absorb. Where these pressures produce a negotiating impasse between the stronger and weaker actor, the subsequent political intervention to resolve that impasse may also favour the stronger actor. The political representatives of the stronger party will generally be in a better bargaining position than the representatives of the weaker party.

*Where a Coalition of Weak Bargainers Obtains a Negotiating Gain That Requires High Levels of Rule Complexity to Implement it Reduces its Chances of Successfully Realizing that Gain*

We saw earlier that the Paragraph 6 solution is an example of rule complexity. The decision covers all aspects of the export/import transaction in tiny detail (for example, the licensee before shipment has to post on a website information as to quantities and product labelling). It requires technical advice to implement within a national system of patent law and technical advice about how to use it. The implementation and use of the system requires the application of multiple sources of law, including patent law, treaty law and trade law. There is a multi-dimensionality of multiple factors that has to be taken into account before a country can implement or use the decision. If, for example, a country has a free trade agreement with the US its obligations under that free trade agreement may impede the effective use of the system. It is worth noting that a 64 page guide to the Paragraph 6 decision published by the World Bank cautions the following:

[T]his Guide can only provide a starting point. The actual implementation of the Paragraph 6 Decision will take place within the contours of each country's existing legislative and regulatory framework, practice and jurisprudence. The authorities of each country will have to work with their own legal experts to arrive at a solution that is right for their situation.<sup>31</sup>

<sup>31</sup> Abbott, Frederick M. and Van Puymbroeck, Rudolf V. 'Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision, World Bank Working Paper No. 61, World Bank, Washington DC, 2005, 3.

The real gain to developing countries of the Paragraph 6 decision, as opposed to the negotiating gain, is if large numbers of generic companies use the Paragraph 6 system to export medicines to developing countries. The more generic companies that enter the system the greater will be the real gains. Developing countries will have access to a wider range of medicines (generic companies specialize eg injectable medicines v oral medicines). Increased numbers of generic companies also mean greater competition on price, the first necessary condition of access.

At base if the Paragraph 6 solution is to work it must provide generic exporters with enough certainty about access to export markets so as to induce them to enter those markets. Many of the costs of medicines in developing countries related to the treatment of diseases such as HIV Aids, tuberculosis and malaria are being met by a combination of private public initiatives from developed countries. Organizations like MSF, the Clinton Foundation, The Bill and Melinda Gates Foundation and developed country governments acting independently or together through mechanisms like the Global Fund have created global export markets for medicines in developing countries where none existed before. The crucial issue then becomes whether, as a matter of commercial reality, the Paragraph 6 solution as presently cast helps generic exporters to enter these new markets. This is an empirical question about the future conduct of companies. Roberto Danino, Senior Vice President and General Counsel of the World Bank in his foreword to the World Bank's Guide observes that despite the wide coverage the Paragraph 6 decision has been given, "the decision has still not been used to bring affordable, life-saving medicines to countries" that need them.<sup>32</sup>

One factor that may help to explain the slow uptake of the decision is its very rule complexity. Clear rules that bring transparency and certainty to decisions about investment are essential to encouraging investment activity of any kind. Rules do not always deliver certainty.<sup>33</sup> Patent rules are standardly justified as a means for offering investors the certainty that for a limited period they will have the right to exploit the product of their investment. However, from the point of view of social welfare, which the patent system is meant to serve, it is just as important that the rules about the end of the patent

<sup>32</sup> Abbott and Puymbroeck, *supra*, n.31, v.

<sup>33</sup> For an argument for simpler rules see Epstein, Richard A. *Simple Rules for a Complex World*, Harvard University Press, Cambridge, 1995.

period are equally certain. Investors in generic companies need to know that there really is a pharmaceutical market in which they may freely compete with other companies to produce the product. Clear and simple rules about when a product goes off patent are fundamental to the operation of competitive markets in pharmaceuticals.

One problem with the Paragraph 6 solution may be that it is generating additional uncertainty that will lead generic companies not to use it. All companies have live with the brute fact of risk and uncertainty. Rule-based regulatory complexity is fact of life for pharmaceutical companies. But at some point a company will conclude that additional risks and uncertainty are not worth any potential reward ie the company will adopt a risk-averse strategy. This may well turn out to be the case for many generic companies when they look at the Paragraph 6 decision. The present author as part of a project that is looking at the impact of free trade agreements on public health interviewed five generic companies based in Australia.<sup>34</sup> All those interviewed saw the WTO solution as somewhat remote from their interests and plans. Dealing with risk and uncertainty was a recurring theme in the interviews with the companies reporting that they were seeing higher levels of patenting by brand companies and that navigating through these patents was increasing their costs. The companies were not well informed about the details of the Paragraph 6 solution. In the one or two cases where they had more information about it they saw no real value in it. The companies interviewed in Australia spoke about the need for simple clear export rules that would allow them to access markets in a timely fashion. One company pointed out that in any implementation of the Paragraph 6 solution where a large pharmaceutical company was given the opportunity to hinder or stop export by a generic company that large company would always take that opportunity. This would be a rational business practice. This kind of observation is consistent with the gaming of patent rules that can be seen more broadly within the pharmaceutical industry.<sup>35</sup>

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<sup>34</sup> (with Tom Faunce and David Henry) Discovery Grant from the Australian Research Council, 'The Impact of International Trade Agreements on the Regulation and Provision of Medicines in Australia'.

<sup>35</sup> See 'Generic Drug Entry Prior to Patent Expiration', Federal Trade Commission, July 2002. For an account of the gaming of aspects of Canadian patent regulations from the perspective of the Canadian generic industry see Hore, Edward *Patently Absurd: Evergreening of pharmaceutical patent protection under the Patented Medicines (Notice of Compliance) Regulations of Canada's Patent Act, 2004*, available from the Canadian Generic Pharmaceutical's Association.

Of course, other generic companies in other parts of the world may study the Paragraph 6 decision and come to a different conclusion to these Australian companies. Many, one suspects, will reach a similar conclusion. There is a real possibility that developing country negotiators have agreed to a solution that is simply not rooted in the realities of commercial life. The obvious cost of encasing a negotiating outcome in complex rules is the risk of losing the gains that were meant to flow from the negotiated solution. There may also be other costs that flow from complex rule solutions. The solution may be sold to concerned mass publics as having solved the problem. Mass publics, which in any case have short attention spans, are hardly likely to follow the technical details of implementation in the improbable event that the press chooses to report them. The passage of the Paragraph 6 rules was an important symbolic ritual that allowed the WTO and its supporters to claim that the trade regime had done what it could do about the HIV/AIDS pandemic and now it was time to move on to the real business of trade liberalization.<sup>36</sup> In this variant of regulatory ritualism the actors in the trade regime accepted that the WTO and TRIPS mattered to the goal of achieving more competitive pharmaceutical markets and cheaper drug prices, but then some of those actors deliberately worked towards a regulatory solution that protected their monopoly interests, thereby preventing the goal from being achieved.<sup>37</sup> Their aim was to achieve regulatory comfort for the WTO on access to medicines, but not results. The rule complexity of Paragraph 6 had handed the reframing initiative back to US and the pharmaceutical industry. What Paragraph 6 and its supporting rhetoric concealed was that the

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<sup>36</sup> See the press release by the WTO, 'Decision removes final obstacle to cheap drug imports', Press/350/Rev.1 available at [http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm). See also 'Statement of the U.S. Trade Representative Robert B. Zoellick on TRIPS and access to medicines, 30-08-2003, available at [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2003/August/Statement\\_of\\_US\\_Trade\\_Representative\\_Robert\\_B\\_Zoellick\\_on\\_TRIPS\\_access\\_to\\_medicines.html](http://www.ustr.gov/Document_Library/Press_Releases/2003/August/Statement_of_US_Trade_Representative_Robert_B_Zoellick_on_TRIPS_access_to_medicines.html). The Pharmaceutical Research and Manufacturers of America also viewed the Paragraph 6 solution as positive and welcomed its codification. See its press release of 6-12-05 available at [http://www.phrma.org/news\\_room/press\\_releases/phrma\\_welcomes\\_trips\\_and\\_public\\_health\\_agreement/](http://www.phrma.org/news_room/press_releases/phrma_welcomes_trips_and_public_health_agreement/).

<sup>37</sup> Regulatory ritualism is a widespread phenomenon that means "acceptance of institutionalized means for securing regulatory goals while losing all focus on achieving the goals or outcomes themselves". Braithwaite, John, Makkai, Toni Braithwaite, Valerie Regulating Aged Care: Ritualism and the New Pyramid (forthcoming, 2007).

opportunity to create more competitive pharmaceutical markets for poor people around the world had been sacrificed in favour of perpetuating the pharmaceutical monopoly interests of the US and Europe.

This raises the question of how can weaker actors avoid or minimize the risk of becoming the victims of regulatory ritualism and rule complexity? A basic, but important point is that negotiators must be aware of the risk before they can decide what, if anything, they will or are able to do about the risk. This leads directly into the issue of information, or rather the lack of it. Generally, the problem of imperfect information (or bounded rationality) in the context of negotiation relates to lack of information that negotiators have about each others' bottom lines, preferences, goals etc. In the case of the Paragraph 6 solution we are dealing with information about the workability of a solution that was available, or least enough information was available to make a better probability calculation about the chances of the solution working. This information could have been obtained from generic companies many of which had had years of experience with the export of pharmaceuticals and the gaming of rules by brand pharmaceutical companies. Even the small number of interviews conducted by the author in Australia turned up enough information to show that the risks of gaming complex rules for the export of pharmaceuticals was very real. This example suggests that where weaker actors can correct for imperfect information they should do so. As John Odell correctly observes there are times in negotiations when negotiators have to operate using rules of thumb.<sup>38</sup> But there are other occasions when they should not economize on obtaining information, especially where that information is reasonably available. The investment of resources into finding out about the workability of any proposed Paragraph 6 solution would have repaid itself many times over, given what was at stake in the negotiation – the structure of pharmaceutical export markets for poor people. A corollary of correcting for imperfect information is that weaker actors should not be drawn into deadlines and negotiating timetables (which in any case promote negotiating fatigue) until that information is obtained.

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<sup>38</sup> Odell, John S. 'Introduction' in Odell John S., (ed), *Negotiating Trade: Developing Countries in the WTO and NAFTA*, Cambridge University Press, Cambridge, 2006, 1, 10.

*Where a Coalition of Weak Bargainers Obtains a Negotiating Gain, It must have a Strategy for Countering Forum Shifting by a Powerful Losing Coalition that is Aimed at Negotiating that Gain Away*

Forum shifting is a practice that has been utilized primarily by the US since the Second World War.<sup>39</sup> Essentially it allows the US to increase its opportunities to play for a win by not confining the pursuit of its negotiating agenda to one international forum. Three basic strategies are involved. A negotiating agenda may be moved from one international organization to another, a negotiating agenda may be pursued in parallel in more than one international organization, or an international organization may be abandoned by the strong player. Forum shifting has been fundamental to the globalization of intellectual property rights. The US shifted its agenda on strong enforceable intellectual property rights from the World Intellectual Property Organization to the GATT during the 1980s. That move led to TRIPS. During the 1990s the US made little progress in the TRIPS Council on the issues that mattered to it. The US was sending impressive delegations of intellectual property experts to TRIPS Council meetings only to be confronted by developing country coalitions pushing issues related to health and biodiversity, issues that the US did not see as related to trade in intellectual property rights.<sup>40</sup> The US switched its negotiating agenda on intellectual property to FTAs. Since the FTA with Jordan in 2000 it has maintained an impressive track record of securing TRIPS plus standards through FTAs.<sup>41</sup>

One clear effect of these FTAs is to restrict the rights that a country would otherwise have had under TRIPS to protect public health by inserting in them provisions that delay the approval of generic drugs, require patent extensions, link drug approval to patent status, restrict compulsory licensing, prohibit parallel importation and expand patent protection.<sup>42</sup> There are basically two negative effects that developing countries risk by agreeing to the

<sup>39</sup> Braithwaite and Drahos, *supra*, n.16, 29.

<sup>40</sup> Interview in USTR's Office, Geneva, 2001.

<sup>41</sup> See Thomas, John R. 'Intellectual Property and the Free Trade Agreements: Innovation policy Issues, Congressional Research Service, The Library of Congress, December 21, 2005.

<sup>42</sup> See Trade Agreements and Access to Medications Under the Bush Administration, United States House of Representatives, Committee on Government Reform-Minority Staff, Special Investigations Division, June 2005, I, available at [www.reform.house.gov/min](http://www.reform.house.gov/min).

intellectual property chapters in US FTAs. Both flow from the fact that these chapters are being used to create multiple barriers to entry for generic companies. The first risk is that generic companies will find it harder to compete in their domestic market and the second is that as more and more countries sign these agreements they collectively limit the export/import markets for generic companies overall.<sup>43</sup> Of course, how these risks play out in a given market will depend on local variables such as the specific implementation of the FTA obligations, the capacity of local generic companies to litigate patents, the regulatory competence of the local patent office and so on. The point for present purposes is that the US would never have been able to obtain in the WTO the standards on intellectual property that it has in FTAs.

From the point of view of the US the shift to a FTA has the effect of taking the target state out of an effective WTO coalition and reinstating an inequality of bargaining power that existed before the coalition came into existence. Even if, as is usually the case, the economics of the FTA do not favour the weaker state,<sup>44</sup> the leaders from that weaker state may see political benefit in having a bilateral relationship with the world's strongest state. Political leaders from a weak state may well be ready to give up hard won negotiating gains in other fora as part of the price of securing a 'special' relationship with the US. The gain to a weak state may have little to do with trade and much more to do with its perceptions of security and how to manage the military power of the US.<sup>45</sup> In this context it is worth recalling Robert Keohane's insight of the 'Al Capone alliance' between small and great powers. In this type of alliance "remaining a faithful ally protects one not against the mythical outside threat but rather against the great power ally itself, just as, by paying 'protection money' to Capone's gang in Chicago, businessmen protected themselves not against other gangs but against Capone's own thugs".<sup>46</sup>

<sup>43</sup> For a discussion of how these two risks are playing out in the context of the US-Jordan FTA see El-Said, Hamed and El-Said, Mohammed 'TRIPS, Bilateralism, Multilateralism Implications for Developing Countries: Jordan's Drug Sector', 2 *Manchester Journal of International Economic Law* (2005), 59.

<sup>44</sup> See Freund, Caroline 'Reciprocity in Free Trade Agreements', World Bank, April 2003, available at <http://www.sice.oas.org/geograph/mktacc/freund.pdf>.

<sup>45</sup> This point has special salience for the Arab world. See El-Said, H and El-Said, M, *supra*, n.43, 75.

<sup>46</sup> Keohane, Robert "Lilliputians' Dilemma: Small States in International Politics" 23 *International Organization* (1969), 291, 302.

From the point of view of the strong state forum shifting is all about cycling through fora to find one at a moment in time where its power is optimized and the advantages of negotiation for the weak are minimized. From the point of view of weak states forum shifting poses a great danger because when the weak states make clear negotiating gains, as did developing countries with the Doha Declaration, a stronger actor may simply recontest that outcome in another forum. Forum shifting means that some negotiations are never really over. It also suggests that some negotiations are best studied longitudinally and as linked sequences rather than statically and as individual case studies. This is certainly the case for trade negotiations where in the last decade there has been an explosion in free trade negotiations.<sup>47</sup>

Turning now to the question of what lesson to derive from the negotiations around access to medicines, it is important to bear in mind that this latest example of forum shifting by the US is part of a 25 year pattern on intellectual property issues. Developing country responses to this pattern represent a record of failure. Developing country negotiators can point to individual successes like the Doha Declaration, but those successes are being undermined by the greater power and capability of the US, much as structural realist theory would predict. If an answer to this problem is to be found it lies in developing countries evolving superior kinds of organizational forms for the conduct of negotiations that have a clear longitudinal and spatial dimension. If it is efficient to hold the line on the globalization of patent monopolies in Geneva in the WTO it is also efficient to do so back in the capitols in the context of a FTA.

The possibility of developing states evolving a joint negotiating strategy to defeat the rent-seeking politics of intellectual property rights that is robust over time and place is, of course, no small challenge. Nevertheless it is a challenge that developing countries must begin to address. The starting point is to focus on the differences in performance between coalitions and networks. For present purposes we can distinguish coalitions and networks by stipulating that the former consist of governments that coordinate<sup>48</sup> while the latter consist of nodal actors (whether state or non-state) that coordinate. Stating the distinction in this way we can say that the

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<sup>47</sup> See Crawford, Jo-Ann and Fiorentino, Roberto V. *The Changing Landscape of Regional Trade Agreements*, Discussion Paper No. 8, World Trade Organization, 2005.

<sup>48</sup> Odell, *supra*, n.38.

coalitionist in a negotiation places the emphasis on enrolling governments while the networker looks more widely to enrolling nodal actors that can help the cause. Coalitions have been the conventional form of organization in multilateral trade negotiations, but they also have potential weaknesses. The long time frames of a multilateral trade negotiation may mean that an individual government may end up discounting its future value compared to the present value a tightly scheduled bilateral negotiation can deliver. Discount calculations that are personal to a government may tempt that government into defecting from a coalition. Networks, on the other hand, may perform the discount calculation in a different way if those networks are more broadly representative of the interests that are going to be affected by the outcome of the longer term negotiation. Networks may also have much greater information gathering powers than a coalition of weak governments and they may have more technical expertise to deploy in the analysis of problems and positions. Empirically this distinction between networks and coalitions and the success of the former over the latter also has some support. The actors that secured the Doha Declaration were more a network than a coalition and the Like Minded Group of countries that achieved little at the WTO Ministerial Conference in Doha in 2001 (and probably could be said to have failed) was a coalition and not a network.<sup>49</sup> There is also considerable evidence that the US runs its trade negotiations as a form of networked governance rather than as a simple process of domestic coalition building.<sup>50</sup>

Developing country coalitions in the WTO have tended to be temporary, informal, single issue groups with little emphasis on institutionalization beyond a single negotiation.<sup>51</sup> Perhaps the best example of an institutionalized coalition that does not fit this

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<sup>49</sup> For an excellent case study of the Like Minded Group see Narlikar, Amrita and Odell, John S. 'The strict distributive strategy for a bargaining coalition: the Like Minded Group in the World Trade Organization' in John S. Odell (ed), *Negotiating Trade: Developing Countries in the WTO and NAFTA*, Cambridge University Press, Cambridge, 2006, 115.

<sup>50</sup> See Shaffer, Gregory C. *Defending Interests: Public-Private Partnerships in WTO Litigation*, Brookings Institution Press, Washington, D.C., 2003; Drahos, *supra*, n.12, 401.

<sup>51</sup> Drahos, Peter "When the Weak Bargain with the Strong: Negotiations in the World Trade Organization" 8 *International Negotiation* (2003) 79-109.

generalization has been the Cairns group on agriculture that was formed during the Uruguay Round of the GATT.<sup>52</sup> Site specific and temporary coalitions are not a strong organizational form for dealing with negotiations in which a strong actor has the capacity to cycle that negotiating agenda through a number of fora. A coalition of weak actors that arises in one organization may, for a variety of reasons, simply not arise in another. Developing countries with limited resources may simply concentrate their attention on the WTO and limit, for example, their participation in WIPO, or they may send different representatives to WIPO who may not coalesce in the same way on an issue in WIPO as their counterparts do in the WTO. Moreover, if the strong actor shifts to a bilateral negotiation the possibility of a coalition to oppose the strong actor is simply removed.

All developing countries have, as the Doha Declaration demonstrated, strong interests in access to medicines. Coalitions have proven not to be a successful means of longitudinal coordination on this issue and have failed to counter the strategy of forum shifting. Developing states have to find ways of protecting negotiating gains on access to medicines across fora and across time. One way of achieving this kind of coordination is through an institutionalized network that has enrolled in it as many nodal actors as possible. The core of the network would be those states that were prepared to unite around the basic premise of the Doha Declaration. The network could start as a Cairns-style, Health and Intellectual Property (HIP) group. As with the Cairns Group it would have a secretariat. The HIP group, however, would place the emphasis on enrolling actors whether state or non-state to increase its capacity and power. For example, the strategy of framing, which was central to the success of developing countries in the Doha Declaration, requires the assistance of media savvy NGOs. More importantly, and unlike the Cairns group, the HIP group would operate as a network to coordinate the positions of its members across fora whenever the issue of public health and intellectual property was being negotiated (for example, in WIPO, WTO, WHO and FTAs). The goal would be to avoid defections by single states in any negotiating context that end up compromising the goal of the overall group (for example, the FTA between Australia (a Cairns group leader) and the US has probably undermined the goal of the Cairns

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<sup>52</sup> The Cairns Group was formed in 1986 and continues as a group in the WTO. See <http://www.cairnsgroup.org/milestones.html>.

group in the WTO). Coalitions of weak actors that are site specific cannot prevent this kind of defection. By joining the HIP group states would be signaling that they would only agree to intellectual property standards that did not compromise their right to protect public health. States that stayed out of the HIP group would have to account to various NGOs and ultimately their publics as to why they were staying out of a network designed to protect public health.

The HIP network could remain a single-issue network, just as the Cairns group is a single issue group. This would help avoid the fragmentation of the network. The goal of the network would be to enroll as many nodal actors as possible on the single issue of public health and intellectual property rights, with a view to isolating the proponents of stronger intellectual property protection at the expense of public health. Developing countries would simply agree that the issue of access to medicines was of such fundamental importance that they would develop a common bargaining strategy around it. A joint strategy of this kind would not prevent them from going their different ways on other issues such as services or government procurement. This limited joint form of bargaining would be a means of ensuring that any gains from negotiations over public health and intellectual property were realized rather than being recaptured over time by the US through a strategy of forum shifting. Irrespective of how developing countries respond to forum shifting the clear lesson from the access to medicines negotiations is that they must respond. In a trade world of perpetual negotiation and many fora, the negotiating gains of the weak are fragile and may end up being taken away.

#### CONCLUSION

Weak actors do make negotiating gains. The Doha Declaration is a case in point. However, before one can conclude much about the role of negotiation and the limits of structural power in the world one has to recognize that a strong state like the US will shift fora in order to recapture negotiating gains. The FTAs that the US has negotiated since the Doha Declaration are rapidly eroding the gains of the Declaration for developing countries. The experience of developing countries with the Doha Declaration is part of a deeper game of forum shifting around intellectual property that has been in play for at least 25 years. It is only by studying negotiation

in this area longitudinally, as a series of connected episodes, that we can gain a real understanding of the possibilities and limits of negotiation as a tool through which weak actors can make gains. Intellectual property is an area where structural power meets and usually trumps the negotiating coalitions and tactics of the weak. Depending on how one draws the boundaries of property around knowledge and information US, European and Japanese multinationals will get richer or poorer. They would like to get richer. Developing countries also want to get richer. Intellectual property rights are all about transfers of wealth. Negotiations over them will not end any time soon.

For weaker actors the lessons of the Doha Declaration are clear. They must have strategies for realizing the gains of negotiation, acting where they can on the basis of self-help and unilateral action. They have to avoid concessions that are encased in rule complexity. Most importantly, they have to find ways to develop a joint bargaining strategy on at least some intellectual property issues that will counter forum shifting by the US. The key to finding this strategy lies in exploring the possibilities offered by a world of networked governance.<sup>53</sup> Traditional coalition formation will be of little use to developing states in this regard. Defection from these coalitions has and will remain a persistent problem. Instead they must escalate their networking across time and place in order to protect precious negotiating gains made in one time and place.

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<sup>53</sup> On the possibilities in general for developing countries see Drahos, *supra*, n.12, 401; Braithwaite, John 'Methods of Power for Development: Weapons of the Weak, Weapons of the Strong', *Michigan Journal of International Law* (2004), 26.