Quaker United Nations Office

Implementing the paragraph 6 decision and Doha Declaration: Solving practical problems to make the system work

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This report is not a consensus document but a collection of opinions and experiences expressed at the seminar from a wide range of participants well informed of the issues involved in the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public health. These do not necessarily represent any views of the Quaker United Nations Office.

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Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[1] at the World Trade Organisation (WTO) has become a subject of controversy over the last few years. The agreement, which sets out detailed international law on patent rights, has been criticised for making medicines and other essential products unnecessarily expensive in poor countries, thereby undermining public health priorities and broader national development goals.

The WTO's Ministerial Conference in 2001 produced the *Doha Declaration on the TRIPS Agreement and Public Health*[2]: this was a public expression of WTO Members' conviction that the TRIPS agreement does not and should not prevent them from taking measures to protect public health. The Declaration emphasised the need to interpret and implement TRIPS so as to ensure "access to medicines for all".

One issue remained outstanding from Doha: the difficulties faced by WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. The Declaration noted the difficulties these countries could face in making effective use of compulsory licensing to over-ride patents, and agreed to find a solution to the problem. After difficult negotiations, agreement was reached on the issue on 30 August 2003, in the form of a *Decision*[3] and an accompanying *Chairperson's statement at the General council meeting on 30 August 200, (paragraph 29 of the minutes). (Referred to below as the " Chairperson's statement."*

The challenge now facing WTO Members, from both developed and developing countries, is to put this new agreement into action, through prompt and effective implementation measures. It is this challenge which is the focus of the following seminar report.

[1] WT/MIN(01)/DEC/2. http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm
[2] http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[3] WT/L/540. This waived the requirement in TRIPS article 31(f), that compulsory licensing or government use permission shall be authorised "predominantly for the supply of the domestic market of the Member authorising such use".

I. Post-2005: what future for pharmaceuticals and access to medicines?

1. What will change post-2005?

As reported by a senior spokesperson for the Indian generic industry, the most significant change is that India, which is a major source of low-priced quality medicines and active pharmaceutical ingredients, will introduce product patents for pharmaceuticals from 1 January 2005. It is the one most significant change because today almost one-fourth of the global generics markets are serviced by the Indian pharmaceutical industry.

However, even then:

- all products, including those under patent elsewhere, which are currently manufactured and marketed in India: and
- those which are currently not manufactured in India but their patent applications were filed before 1 January 1995, or with priority date before 1 January 2004

will continue to be available in generic form from India.

Countries with insufficient or no manufacturing capacity can continue to source their requirements of these products from India under a compulsory license. The least developed countries have been given an extension of the transition period up to 2016, for pharmaceutical products, in paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health. These countries can procure these medicines even without a compulsory license, as long as they have incorporated the extension of transition periods in their national laws. They will need to make use of the system foreseen under the paragraph 6 solution if the drug is patented in the exporting country.

Thus, all antiretrovirals (ARVs) for HIV/AIDS, anti-tubercular and anti-malarials currently sourced from India will continue to be available. Only new drugs, whose applications were filed in India on or after 1 January 1995, would be patent-protected in India. They cannot be manufactured, sold or exported without appropriate authorisation.

a). The 'mailbox' system, scope of patentability and ever-greening

TRIPS article 70.8 established a 'mailbox' system, which obliges those countries that are taking advantage of the transition periods to provide a system for filing patent claims during this period and also providing protection "as from the grant of the patent and for the remainder of the patent term"[4].

In principle, under this system only those products for which patents were filed after 1995 can claim for a product patent. In India, if the new patent law provides patentability only for new chemical entities, then generic firms would be able to produce a wider range of affordable products.

There has been considerable criticism of the process, in the US system, which allows patent applications to be regularly renewed on the basis of what are often relatively trivial changes. This process, which is known as "ever-greening", would not be permitted under the Indian legislation. Only new chemical entities would be patentable. Given that the majority of patent claims made are for more minor changes - often in fact discoveries rather than innovations - it is arguably unlikely that patents will be granted on a substantial proportion of those claims which are currently being held in the 'mailbox' system in India.

The companies that have submitted applications through the mailbox system clearly hope that the Indian patent system will be based on the US model. However, the current legislation defines the scope of patentability in a more narrow sense than the US system does.

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[4] TRIPS article 70.8(c)

The draft bill sets out the limits to the scope of patentability in its section 3, entitled "inventions not patentable". This section will define precisely what cannot be patented, and would answer questions about products whose status as 'new chemical entities' might otherwise be unclear. Such questions include, for example, whether substances such as polymorphs would be excluded from patentability. TRIPS article 27.1 requires patents to be available "in all fields of technology". However, countries seeking to restrict the scope of patentability so as to be able to address national development priorities could do so through the use of high standards of patentability.

An exclusive marketing right in the mailbox system can only be granted if there is marketing authorisation in another WTO member[5]. But in the mailbox system, the number of applications cannot be assumed to be equivalent to the number of new chemical entities. There could be hundreds of patent applications - which may involve new modifications but not new chemical entities. A key issue therefore is whether the new Indian patent law would accept these.

Part of the context to the domestic debate in India on this subject relates to the parliamentary discussion on the second patent amendment bill. When this bill was being discussed in parliament, the government had to give an assurance that "ever-greening" would never be allowed. The government had to give explicit assurances on this subject to the Congress Party, which was then in opposition, and now is in power.

Indian generic firms are currently assuming that only applications filed after January 1995 would be taken into consideration under the 'mailbox' system. The only factor that could complicate this is the 'priority date' rule, as set out in the Paris Convention. However, Indian generic companies are assuming that there will be no major changes, and that there is no cause for concern in this respect.

b). What would be the impact on India?

Thus, generic versions of all new drugs based on post-1.1.95 patent applications which are now being introduced in the world will not be available even from India until their patent expiry or under a compulsory license. Their availability will be restricted, and prices would be prohibitive for many cases.

In November 2003, a team of economists published a paper on the effects of patent protection for drugs in developing countries, using India as a case study.[6] This is the first such paper based on empirical data on prices and market shares. The economists - Shubham Chaudhuri of Colombia University, and Pinelopi Goldberg and Panle Jia of Yale University - selected a specific class of antibiotics, fluroquinolones, to figure out the impact on consumers and domestic companies if just patented antibiotics remained in the market. Fluroquinolones account for over 20% of the antibiotics market in India. (Antibiotics make up 17% of total retail drug sales).

The economists' conclusion was that, in the absence of any price regulation or compulsory licenses, the total annual welfare losses to the Indian economy would be greater than the sales of all systemic (oral or injected) antibiotics in 2000. The team pointed out that while the prices of patented drugs would definitely rise post 2005, prices of cheaper off-patent drugs in the same class too would increase when consumers opt for them.

Interestingly, the study concluded that availability of drugs would become an issue in a patent regime. Normally, customers who cannot access a domestic brand of a drug substitute it with another brand. So if a domestic brand of a kind of fluroquinalone, say, norfloxacin, is not available, they buy a domestic brand of, say, ciproflaxacin, instead of the foreign brand of norfloxacin. The researchers believe this is because domestic drugs are more widely available than foreign ones, and there are more Indian companies than foreign firms. Once product patents come into play, there will no longer be any copies in the market. Innovators would have to make up for this by widening the distribution reach of their drugs.

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[5] See TRIPS article 70.9

[6] The paper is available at www.colombia.edu/~sc301/pharmaceutical-patents-2004-01.pdf.

Product patenting leads to a loss of flexibility: the liberal use of compulsory licenses is therefore one policy option which can be recommended so as to ensure that drugs remain available.

c). To make the paragraph 6 system work, what steps should be taken?

In order to ensure access to low priced generic medicines, countries with insufficient manufacturing capacity may like to consider the following steps:

(i) Introduce legislative changes permitting grant of compulsory licenses

All importers should introduce legislative changes that would permit grant of compulsory licenses or provide for government use in case of public health problem.

The time needed for a country to issue a compulsory license and import the medicines they need depends on a number of factors. One of these is the time it takes for the government to produce a compulsory license. Past experience suggests that brand-name companies and certain developed country governments would subject intense pressure on a developing country that wished to issue a compulsory license in this way, irrespective of the public health issues at stake.

It would take 3 months for the importer to issue a compulsory license and identify companies that could provide the drugs they are looking for. In India, it should then take one week for the government to go through the administrative process of granting a corresponding compulsory license. However, if the drug concerned is a new one, not previously commercialised in India, the Indian industry would have to develop it. This would take 36-48 months: this is because the production of a new generic drug requires investment in plant and machinery, as well as bio-equivalence tests and regulatory approval.

(ii) Establish a Help Desk at WHO or WIPO

There is a need to create a Help Desk at the World Health Organisation (WHO) or World Intellectual Property Organisation (WIPO), which governments can use to ascertain the current patent status of a product, so as to decide whether a compulsory license is required.

Many developing country legislators have been told by multinational companies that they would be infringing patent law if they changed their laws to take advantage of the paragraph 6 agreement. Legislators are unsure what they are allowed to do, due to a lack of knowledge about patent law: they therefore find it hard to decide. A WHO and WIPO online helpdesk could provide answers to questions such as "I wish to order this drug - what can I do?".

As a practical matter, the MSF[7] study on ARV prices is the only useable resource in this field. Otherwise it is difficult to discover the patent status of any given drug. The research-based pharmaceutical industry has even suggested removing information of this sort from technical assistance guides: they have in general tried to limit access to this information.

(iii) Prepare a notification expressing intention of importing from a company outside the country.

As soon as the August 30 decision came along, countries should in fact have made a general notification to the TRIPS Council of their intention to use the system. This notification can nonetheless be made at any time.

(iv) Consider pooling procurement requests with other countries.

[7] Médecins Sans Frontières

In order to make the manufacture and supply economically viable, the importing country may like to examine the incidence of disease in the neighbouring countries. This would allow the development costs to be aggregated and shared over several countries.

The pooling of resources is an important issue. There may be some initial technical barriers to achieving this, but if three or four countries came together, then it is unlikely that a research-based company would try to block such a deal.

(v) Request only minimal requirements for diversification to prevent diversion

Countries should request only for packaging diversification to prevent diversion, but not insist on product differentiation (shape, size and colour of the tablet), as it may involve additional costs of bio-equivalence and bio-availability tests and higher production costs.

The fact that the product would have a different brand name (from the originator drug) and different packaging would be sufficient to prevent diversion.

(vi) Encourage regional partnership for local production of products required in large quantity for sustained period.

Initiatives of this sort are one way in which 'backward linkages' can be created, and the transfer of technology between developing countries can be made effective. Other ways in which this can be achieved, an Indian expert pointed out, include scholarship programmes allowing qualified medical students to pursue study tours in India, with financial support from the private sector in that country. The Indian government has also launched a $1 million plan, to develop capabilities for treatment for African countries. The scheme includes training in India for nurses for AIDS patients for example. Setting up local production facilities one other approach.

These are all different kinds of steps which eventually can build backward linkages. It is worth noting that, in contrast with the situation for HIV/AIDS drugs, there are not enough suppliers in the world for TB and malaria drugs.

2. What has already changed?

Since 30 August 2003, significant developments have taken place which arguably have a negative impact on access to medicines:

- Bilateral and regional free trade agreements creating new barriers to access
- The emergence of 'a TRIPS-plus world' at WIPO: the Patent Cooperation Treaty (PCT) reforms, the draft Patent Law Treaty (PLT) and the Substantive Patent Law Treaty (SPLT). [8].
- Aggressive pursuit of "market exclusivity" through data protection
- Erection of technical barriers for fixed dose combinations for HIV/AIDS.

A number of events can be identified that support the implementation of the decision and facilitate access to medicines. A number of developments are noteworthy in this respect:

- The Clinton Foundation's decision to source ARVs from generic companies
- The launch of a determined effort by the WHO to defend scientific and technical principles for the use of combination therapy;
- The new non-discrimination policy of the World Bank for procurement of medicines. This determines that medicines should be purchased from the lowest-cost provider, irrespective of whether this is a research-based or generic company:
- The grant of two compulsory licenses in this period, by Malaysia and Mozambique.

[8] For further information, see "Multilateral agreements and a TRIPS-plus world: the World Intellectual Property Organisation". By Sisule F Musungu and Graham Dutfield. QUNO Geneva, 2003.

a). Experience with developing legislation to implement the paragraph 6 decision: India and Canada

Some argue that legislative changes to date have been inadequate for effective implementation of the paragraph 6 decision.[9] It is unclear whether many countries are in fact amending their legislation to take advantage of the system established in the August 30 decision, or, in the case of Least-Developed Countries (LDCs), of the flexibility provided in paragraph 7 of the Doha Declaration. However, two countries which have taken steps to implement the decision are India and Canada.

In India, the current draft legislation stipulates that the Indian government would be required to assess whether an importer such as Kenya had complied with its TRIPS obligations. Indian generics companies have argued that this a matter for the TRIPS Council and Kenya, and the Indian government should not sit in judgement on this question. They have suggested that any new conditions which add to the requirements already existing in the paragraph 6 solution would probably cause further delay. The draft legislation originally had six conditions of this sort; after successive revisions, the issue of TRIPS compatibility is the only one which now remains. This legislation is however still in draft form, and therefore still subject to change.

Another country which has devised and now passed legislation aimed at implementing the paragraph 6 solution is Canada[10]. Canadian generic manufacturers have now given their formal support for the legislation, although some did recently claim informally during the drafting process that the system would not be commercially viable for them. While drafting the legislation, however, the Canadian government was nonetheless keenly aware that the system must not be cumbersome or onerous, if it was to be workable in practice. The government thus took measures to remove draft provisions that were unnecessarily onerous.

For example, an earlier draft contained provisions providing a 'right of first refusal' to the brand-name companies: this was rejected by generic companies and non-governmental organisations (NGOs) active on public health issues. The provision was not included in the final version of the legislation. The government felt that it was not appropriate to redefine the terms of the August 30 decision.

The Canadian generic companies emphasised that they wanted a system which provided the certainty that they would receive a compulsory license. The law therefore says that, if certain conditions are met, the government "shall" provide a compulsory license: not that it "may." Similarly, the Norwegian law also seeks to provide certainty.

The Canadian law includes a cap on prices. If a given threshold is exceeded, there is the potential for judicial review. The legislation stipulates that the generic product should not be more than a quarter of the price of the brand name product in the local Canadian market. Some Canadian generic companies may be concerned that this aspect of the legislation could remove the incentive for them to provide drugs under the system. Generic companies have pointed out that they make money on volume and not margin, unlike the brand-name companies: they are also concerned that forthcoming EU legislation may include this aspect of the Canadian law.

The intention of the Canadian government was to establish an open system, not a closed one: therefore, if products are missing from the list of drugs, and developing countries or other parties feel that these should be included, the government would endeavor to add them to the list.

b). Need for political momentum

There is some indirect evidence that some countries are still working to frustrate the implementation of the Doha Declaration and the paragraph 6 decision. One might wonder

[9] Debate continues over the extent to which such changes have been 'adequate'; there is no consensus yet on this issue.

[10] The Canadian, Netherlands and Indian legislation is considered in more detail below.

why this should be the case, as governments have now debated and discussed the issues at stake, and agreed to a compromise solution. It is therefore surprising that some countries are still working to frustrate the implementation of the August 30 decision. One reason could be that these countries are still not convinced of the justification for differential pricing. Another possibility is that they feel their concerns are not adequately addressed in the August 30 decision, and therefore seek to prevent the agreement from being implemented.

Most African countries have legislation which would need changing in order to take advantage of the new flexibilities. The legal situation at the WTO is now favourable, as paragraph 7 of the Doha Declaration provides LDCs with the legal basis to action. Governments now need to demonstrate that they have the necessary political will. They also have to overcome political pressure exerted by certain actors who which to prevent such action being taken. How is it possible to build political support for implementation in African countries and in other parts of the developing world? The compulsory licenses which Malaysia and Mozambique have issued are potentially good examples for other countries to follow: these are important first steps.

There is therefore a need to muster all the available resources and work towards making the implementation of the agreement work. The lives of those who need affordable medicines depend on it.

II. The practice of implementation - practical actions being taken or planned to implement Paragraph 6 and the Doha Declaration

1. Exporting developed and developing countries

a). India

The Indian government has prepared three paragraphs of draft legislation, which will be put to the legislative for adoption.

The government is taking full advantage of the transition period available under TRIPS. On the 1.1.05, the country must adopt product patents in order to be TRIPS-compliant. The electorate has recently returned a new government, and so the legislation will now have to be introduced again.

The precise language of the three paragraphs is as follows:

1. …Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided a compulsory licence has been granted by such country.

2. …The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

3. …These provisions shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

The reason the last provision has been included is so as to avoid any possible prejudice to the existing right to export medicines in those cases where the predominant part of the supply is for the domestic Indian market.

This is a very short amendment to the existing legislation. It is an enabling provision, and should be considered in the context of the existing rules and regulations.

Finally, another draft provision provides a definition of "pharmaceutical products" for the purposes of this legislation.

It was unclear why the first paragraph of the draft legislation includes the condition "providing that a compulsory license has been granted in the importing country". It appears that this could exclude the situation where there is no patent in the importing country, for example in an LDC which does not have a patent regime. The reason may be that these paragraphs are only an amendment to existing legislation. The disqualifier stating that the amendment is without prejudice to the possibility of exporting under compulsory license under the other provisions of the Act may cover this.

The Indian legislation is silent on the issue of whether the importer needs to be a WTO Member or not. India also exports to countries which are not Members, such as Vietnam. A compulsory license would not be needed to export to many of these countries, Vietnam included, if there is no patent on the required product.

b). Netherlands

The Netherlands is also implementing the WTO decision so as to provide for medicines to be exported under the paragraph 6 solution. The country itself does not have a large generic industry, but does want to give a positive signal and to be able to call more effectively on the EU and its Member States to adopt similar legislation in order to implement the new mechanism.

Implementation will be done through policy-rules that are attached to the Netherlands patent law and that will give the minister of Economic Affairs of the Netherlands the competence to issue a compulsory licence for export under this system.

The basic thought is that when the conditions of the WTO decision have been met in the importing country, the generic producer of medicines in the Netherlands will have the RIGHT to produce pharmaceuticals for export and to export them.

The Netherlands is seeking 'loyal' implementation, which stays as close as possible to the language of the Doha Declaration and the 30 August Decision. That means that no pharmaceutical products will be excluded and that no extra cumbersome conditions will be set on developing countries making use of this system.

As eligible import countries the ministry of foreign affairs wants to include all LDC's, also non WTO-members, like Norway and Canada have done when they implemented the WTO-decision. (The ministry of economic affairs has agreed to this on June 27th)

In the draft text, the Minister of Economic Affairs before giving out a compulsory license establishes that it was not possible to arrange a voluntary license. The language in this case is close to that of article 31(b) of TRIPs, particularly the exceptions mentioned there. This language is currently being finalised, and should be ready soon.

For determining the compensation for the right holder, the price- and income level of the importing country will be taken into consideration.

The government hopes that legislation will be in place by the summer. The EU also intends to present a draft Regulation by the summer. The Commission has said it would be seeking a 'technical implementation' of the August 30 decision, i.e. a 'loyal' implementation. The Netherlands will not wait for this regulation, but finish its own guidelines to emphasise to the Commission the need for rapid and loyal implementation.

c). Canada

(i) Objectives of the legislation

Canada has recently passed domestic legislation to implement the paragraph 6 solution, and the relevant law is now in place. It has five objectives:

1. to promote quick access to medicines;
2. to provide incentives to ensure the generic industry actually exports medicines;
3. to protect intellectual property and the research-based industry;
4. to reflect loyally the August 30 decision; and
5. to hold the exported medicines to the same health and safety standards as apply domestically.

(ii) Would the system be very litigious?

Canada has a strong research-based industry, as well as a strong generic based industry. It has a significant level of exports from the generic industry. The strength of both industries has meant that historically there has been a high level of litigation between the two industries. In order to do this, the government sought to maximum certainty around the conditions in which a generic producer could expect a compulsory license to be granted. The legal language therefore states that the government "shall" issue a compulsory license, and not that it "may" do so.

Some Canadian generics manufacturers have recently suggested that, in their view, the system established under the new legislation would be a very litigious one. They have suggested that, despite the stated intentions of the drafters, there are opportunities to take the generic companies to Court throughout. The government has nonetheless noted that, in their experience drafting the legislation, there was pressure from all sides. The role of the government in such cases is always to sort through all these positions and come up with an arrangement that works. It was noted in this connection that, before the legislation was passed, the generic industry appeared before Senate to support the new system.

(iii) Finished products, active ingredients and diagnostic kits

The August 30 decision applies to finished products, active ingredients and diagnostic kits, but the Canadian law refers to the finished products only. It was noted that, if in practice this excludes active ingredients and diagnostic kits, it would be hard to enhance local production. The provision in the Canadian law relating to active ingredients is ambiguous, because it reads "if applicable". Although the Canadian government has stated that one principle behind the drafting of the law was to avoid litigation, the meaning of "if applicable" in this context remains unclear.

The Canadian government did not intend to limit or exclude active ingredients or diagnostic kits from the scope of the solution. It was confirmed that this provision is intended to include active ingredients, to the extent that they may be under patent in Canada..

(iv) Scope of medicines

The legislation does include a schedule of approved medicines and also of approved countries. This is intended to increase the efficacy of the legislation as an administrative tool. The Patent Commissioner lacks the technical competence necessary to assess these matters. Instead, if a given medicine is on the list, then a compulsory license will be issued.

The use of schedules of permitted drugs in the legislation reflects the administrative need for certainty: The compulsory licensing issue could always remained blocked in Canada's courts, if the system relied overly on discretion.

The use of lists reflects the Canadian situation. The government could have drafted enabling legislation, stating that the government "*may* issue a compulsory license". This official simply has to check through a check-list, and determine whether the importing country is on the list, whether the drug on the list, and whether the paperwork is in order. If the answer to all these is 'yes', then compulsory license would be issued. Generic companies have said they need certainty.

The government has sought to emphasise that the list can nonetheless be expanded as needed, however. If WTO members feel that other products should be on the list, they can notify the TRIPS Council, and the Canadian government would then rapidly move to expand the list. The government suggests that a new medicine could be added to the list in as little as 48 or 72 hours. This time period is not stated in the law, but is the government's assessment of the minimum time this would take.

An expert advisory committee, which would include representatives from the brand-name and generic industries as well as non-governmental public health organisations, would look at the list and make an assessment whether the new medicine should be added. This step should not be a mandatory hurdle for expansion of the list. This is why the drafters also provided for the possibility of an Order in the Council, which could bypass the committee. All stakeholders are nonetheless given the opportunity to provide their views. Potentially, on each drug, there will be extreme lobbying.

It was noted that the idea of having a list of diseases or of countries was rejected after 8 months negotiations. It was unclear therefore why countries might choose to go back on this. There was concern that revising the terms of the August 30 decision in this way sets a very bad precedent, especially in this respect. It was suggested that people lacking access to

affordable medicines needed a regime that faithfully implements the August 30 decision. This agreement represents a compromise which that was reached after very long deliberation.

It could be suggested that there is a difference between establishing a list in the WTO Decision and establishing a list at the national level. In this view, it would have been restrictive to have set a narrow set of criteria at the international level. But at the national level, such a measure arguably provides certainty, and can be added to as well. A list at the national level could therefore be seen as being less limiting, as the country retains the power to include new medicines on the list as needed. Such a measure would nonetheless be a discretionary level, though. Furthermore, it does limit the procedure, and creates new obstacles where previously none existed.

Some have questioned whether it would be appropriate to include all pharmaceutical products in the world. Even though the negotiations ended with an open list, many developed country governments have emphasised that the mechanism should be used strictly for genuine health problems. This would exclude, for example, compulsory licensing for Viagra, or for cholesterol drugs, or hair-replacement products. Viagra is arguably an extreme example: however, during the negotiations in the TRIPS Council some developed country delegates suggested that drugs for diabetes or cancer should be considered as a "lifestyle disease".

There are 12 ARVs on the WHO model Essential Medicines list, but which are not included in the list established by the new legislation The reason for this is that there are no patents on these drugs in Canada.

Because the notification should precede the contract negotiations with the generic company, the company does not take a practical risk in the event that new medicines are added to the list. We might note that no countries to date have made a notification that they wish to use the system as importers.

(v) Scope of countries

The government also considered the issue of the scope of countries to be included, as they drafted the legislation. The list includes LDCs who are not WTO members in the category of eligible importers. It would be possible to add other developing countries, if the relevant request was made through diplomatic channels.

(vi) Waiving requirements under TRIPS 31(b): should the 'emergency' situation be in the importing or exporting country?

The government has tried to stay close to the voluntary licensing requirements of TRIPS article 31(b). The proposed user of the subject matter of the patent needs to show that efforts have been made to seek a voluntary license, and that such efforts have not been successful within a "reasonable period of time", which in the Canadian legislation is defined as being 30 days. This requirement applies in all cases, even though article 31(b) says this requirement can be waived in a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. The government's reading of this provision is that the emergency would have to be an emergency or similar situation in Canada, and not in another country.

The Canadian government recognises that some countries have declared that they will only use the paragraph 6 solution in emergency situations. However, other countries have not done so, which implies that they may be contemplating using the system in non-urgent, non-emergency situations. The Canadian government did not want to have to provide a definition of "emergency" situation in the legislation.

It is nonetheless the case that the clear object and purpose of paragraph 6 was to address the situation of insufficient or no manufacturing capacity in another country. The situation under consideration is therefore almost by definition that of the importing country.

The Canadian government has taken into consideration the various interpretations surrounding this provision in this context. Against the liberal interpretation is the fact that

article 31(h) recognises territoriality. Remuneration is based on the situation in the importing market. This strengthened their view that article 31(b) only contemplates one market. There is also the question of how to distinguish between an emergency and non-emergency situation. This logic is nonetheless precisely opposite that which was used in the negotiations on article 31(b).

In the Doha Declaration, Ministers made a point of saying that these were emergency situations. The intent of paragraph 6 is clearly to address the situation prevailing in the importing country. The interpretation that the Canadian government has chosen to apply arguably makes no sense in the context of paragraph 6.

(vii) Right of first refusal

In an earlier draft, the government had included a "right of first refusal" for the patent holder. However, this was strongly criticised by NGOs and generic companies, who argued that this provision would be a disincentive for companies to make use of the system. The government therefore removed this draft provision.

(viii) Royalty rates

Another issue that was discussed during the consultation process is that of royalty rates. Earlier drafts stipulated a flat royalty rate of 2%. The brand industry later said that there should not be a fixed rate. However, the generic industry preferred the increased certainty that this provided. In the end, the government chose to apply a formula rate, based on the ranking of the country in the UN human development index.

The government sought to ensure that the production requirements would not be unnecessarily onerous.

(ix) 'Good faith' clause

Because of the automaticity of the compulsory licensing, the drafters also included a "good faith clause". There is no built-in review, which would have provided an opportunity for the brand-name companies to make representations if the selling price is less than 25% of the brand name price in Canada.

(x) Health and safety standards

All products for export will go through the same health and safety standards which apply for Canadian medicines on the domestic market.

(xi) Data protection

There is no provision for data protection. Including a five-year data protection period would be counter-productive, given the objective of this legislation.

(xii) The next steps

The next steps are as follows:

1. Domestically, the regulations will be put to the public for comment for 60 days. The regime will therefore probably be operable in nautumn 2004. Both domestic and international comments on the legislation are welcome.

2. The government aims to work with developed countries, and encourage them to take similar measures. Canada will also work with developing countries and LDCs to promote awareness of how to use the system that has been established. Finally, the government will

also work with the WTO, WHO and WIPO to promote coherence in dealing with access to medicines. What is needed is a global approach. The Canadian Prime Minister announced last week that the government would double contributions to the Global Fund and the '3 by 5 initiative': the new legislation should be seen in the broader context.

(xiii) Subsidies for generic firms?

Canada is a high-cost producer, and Canadian generic medicines may still be relatively expensive. Many of the essential active ingredients are even imported from India, to Toronto, and then sent back as the finished product. However, the government does not believe that providing direct subsidies is the best way of lowering costs. Instead, the hope is to encourage competition by other companies, including those in other countries, by taking this step. If it is possible to obtain cheaper drugs from another country, for example India, the government would encourage importers to do so. Similarly, if a brand-name company offers a lower price, then importers should procure the medicines from them. The drugs just need to get to where they are needed.

The Canadian government nonetheless recognises that resources, and not just patents, are a barrier to access. This is motivation for the government's involvement with the 3 by 5 initiative, and the Global Fund.

The government would like to see products exported from Canada. There are niches: the volumes required will mean that Canadian companies can contribute.

(xiv) Need for other developed countries to follow suit

The more potential suppliers there are, the greater the downward pressure on prices. Developing countries who may wish to import drugs to make a notification to this effect to the TRIPS Council. The legislation will change the relationships between different political forces and actors, in this respect.

The success of the new legislation can therefore be defined partly in terms of encouraging other developed countries to implement similar legislation and ultimately facilitating access to medicines. As this happens, Canada will feel that the initiative has been successful.

Canada is the first country to go forward, but has managed to endure the pressure which has been brought to bear on them over this issue. The government has been willing to stand up. Drafters of the legislation have suggested that arguably, on every issue, they have come down in favour of the public health concerns each time. This has been due in no small part to a very effective advocacy campaign by non-governmental public health organisations.

d). EU

The European Commission is now seeking to devise new patent legislation and compulsory licensing laws. These provide an opportunity to implement the paragraph 6 solution. A draft of the legislation, which is to be based on the August 30 decision, will be put to the Council in September.

The Commission is likely to take one of two different approaches. A "regulation" would be a binding ruling. Another option is for the Commission to issue a "directive", which binds the end goal but leaves Members free to reach it as they see best.

It is important to bear in mind that favourable patent legislation is currently in force in several Member States. For example, the UK can be considered as having a fairly liberal regime concerning government use and compulsory licensing.

In contrast, some experts have suggested that the draft Community patent legislation contains rather a lot on compulsory licenses, and is in many places quite restrictive. It remains unclear whether Member States will have the flexibility to adopt laws that are different from that being drafted by the Commission, and whether the Commission will claim exclusive competence in this area. However, it is quite possible that, even if the legislation prepared by

the Commission was relatively liberal, it might still be more restrictive than the UK legislation.

The EU does not have competence on the procedure for issuing compulsory licenses. On earlier EU discussions about patent applications, the debate centred around the number of languages into which it was necessary to translate patent law. This issue remains a bit of an mystery, and it will be important to see how the Commission foresees this working out. It seems however that the Community is not claiming exclusive competence in the entire area of patents.

In fact, the Commission proposal may well be limited only to a specific type of compulsory license. In this case it would not act to restrict Member States' compulsory licensing rules. If the proposal is more restrictive than current legislation in Member States, such as that of the UK, this issue should first be discussed within the Community. The Commission should not intrude on the law established by national governments: where such existing law already provides flexibility, for example in respect of TRIPS article 31(k), this will probably be retained.

It may be that the EU would also have to address some internal coherence issues. There would be a need to ensure that both the Trade Division and the Division responsible for internal markets have a consistent, coherent position in this area.

2. Least developed countries (LDCs)

a). The legal and political context

(i) Introduction

During the negotiations on paragraph 6, the LDCs found themselves in a paradoxical situation. They had already been granted an exemption from TRIPS requirements for patent protection on pharmaceuticals, which lasts until 2016. Arguably, the main additional benefit which LDCs gained from the August 30 decision therefore relates to the issue of building manufacturing capacity.

Until 2005, LDCs will benefit for patent exemption for products in all sectors, and will benefit for patent exemption on pharmaceutical products until 2016. Some have suggested that it may be appropriate to request further extensions of implementation deadlines, given the continuing low level of economic development in these countries.

LDCs have three tools at their disposition which may enable them to address a lack of manufacturing capacity in the pharmaceutical sector, either by procuring affordable medicines from elsewhere, or by developing indigenous manufacturing capacity:

1. The language on regional arrangements in the August 30 decision
2. The 2016 extension in paragraph 7 of the Doha Declaration
3. The separate agreement reached on the implementation of TRIPS article 66.2, on the transfer of technology[11].

However, governments still need to take concrete steps in order to be able to draw the full benefits from these three tools.

(ii) Implementation of TRIPS flexibilities in the LDCs

The first of these steps is a prerequisite: countries must have implemented the flexibility contained in paragraph 7 of the *Doha Declaration on the TRIPS Agreement and Public Health* in their national laws. A survey of LDCs found that approximately 30 countries have not

[11] TRIPS Council members reached an agreement on 28.2.03, contained in document IP/C/28. This fulfils the instructions given by Ministers at Doha in paragraph 11.2 of the *Decision on Implementation-Related Issues and Concerns*. In this paragraph, Ministers agreed that the TRIPS Council would put in place a mechanism for ensuring the monitoring and full implementation of TRIPS article 66.2.

changed their legislation in the necessary way. This is a potential barrier, as without this step countries risk the possibility of challenges under their domestic law. They therefore have to integrate this flexibility first.

Those LDCs who do not have patent law are in a pre-paragraph 6 situation, and do not need to enact any changes to their legislation.

(iii) Regional procurement

If LDCs wish to provide access to affordable medicines, they need to make use of the language in the paragraph 6 decision on regional arrangements. This can allow these countries to harness economies of scale. Pooling resources makes economic sense: access for medicines will then be improved as drug prices come down. By pooling requests for procurement, countries can therefore create "economies of health": LDCs must use the regional dimension instead of purchasing medicines as a single country.

In some countries, the idea of pooling procurement requests has been attempted. Civil society actors in Kenya, Uganda and Tanzania have looked at this possibility, but no conclusive agreement emerged.

An agreement on pooling resources was in fact reached in the margins of the Barcelona AIDS conference, between ECOWAS (the anglophone and francophone group of West African countries) and representatives of the research-based pharmaceutical industry.

LDCs will first avail themselves of the flexibilities which the paragraph 6 solution provides for regional agreements. This concern is also referred to in the Preamble of the August 30 decision.

If countries were to pool their procurement requests in this way, the understanding of LDCs is that all countries would be able to use just one compulsory license to do so, under the paragraph 6 solution.

(iv) Regional patent

Some governments have considered the possibilities that might be afforded by arrangements for a regional patent. The last line of the relevant part of the August 30 decision refers to the "territorial nature" of the patent, which unfortunately has the potential to limit the scope of this provision more than might have been necessary. LDCs have nonetheless made their understanding clear on this issue, namely that this reference should not be construed here as being in any way a barrier to access.

Technical assistance has enabled some LDCs to develop arrangements for a regional patent. This is another tool in the Decision. There are two examples of regions which are co-ordinating at a regional level in this way: one is Francophone West Africa, which has formed the OAPI agreement, with a common patent, territory and common law. The aim of the regional patent has in this case been achieved. Then there is also the example of Anglophone West Africa, which has established ARIPO: this is a co-ordinating umbrella but not a substantive regional patent.

(v) OAPI

OAPI is the organisation of 16 West African francophone countries. It had expected to adopt legislation on patents in February 2003. Meanwhile Geneva-based delegates and legal experts were advising their capitals that an outstanding decision was still in consideration, i.e. the paragraph 6 solution, and that the OAPI legislation should therefore not be adopted. Nonetheless, OAPI did not take this suggestion into consideration and the legislation was adopted without taking account of the new flexibilities.

A conflict of law therefore exists now between the paragraph 6 solution and the Bangui Accord, which is the agreement establishing OAPI. A certain amount of pressure was brought

to bear on governments with regard to this issue: both internally, from industry, and through external political pressure. The process did lack clarity and transparency, therefore. NGOs have however been instrumental in shaping the policy environment, and in paving the way for positive implementation of the new flexibilities.

It was noted that, technically speaking, OAPI can easily suspend the Bangui Accord, through an administrative decision of the Board. This is all that would be needed to do this. Such a decision can take place whenever the 16-member Board is quorum, which is the case whenever 10 countries are present. There is no cumbersome procedure: however, a lack of political will, and the problem of hidden agendas, have to date prevented progress on this.

The presidency of the Executive Committee rotates for a 6-month period, and is currently held by Chad. All that is needed is for the president to state clearly, in the order of business for the meeting, the nature of the item to be considered and consequent action required. An informal committee of country delegates in Geneva has been put together to try to facilitate this decision. Delegates to WHO, WIPO and the WTO are trying to address the outstanding obstacles, yet the biggest hurdles are within the OAPI Secretariat. The Secretariat is encouraging OAPI governments not to take this decision.

(vi) Building manufacturing capacity

LDCs must also find ways to build capacity in the pharmaceutical sector. Paragraph 6 and 7 of the Doha Decision, in conjunction with the Decision on TRIPS article 66.2,[12] together create a framework that provides visibility and certainty. LDCs will be able to attract the necessary investment, and transfer technology.

Firstly, they will also be able to use the August 30 decision to build capacity, which was after all the ultimate goal of the paragraph 6 negotiations for many countries. Secondly, LDCs need to find ways to co-operate with interested countries in the North, such as Canada and Norway, and also with Southern partners, such as India, through South-South co-operation. Thirdly, LDCs should also explore private-public partnerships. They can then use this leverage to create a conducive environment to encourage foreign direct investment and facilitate the transfer of technology. In this sense, the issue of paragraph 7 implementation is linked to implementation of article 66.2: the exemption from providing patents is linked to the issue of investment.

Active ingredients are an essential part of the scope of the solution. LDCs can thus explore not just final products but also find ways to support their infant industries too.

(vii) Coherence between Ministries

The problem of internal co-ordination, between Ministries, is an important challenge that LDCs must address. Raising awareness is a vital step in this process.

The lack of co-ordination between Geneva missions and capitals is also a problem, as is the lack of a co-ordinated position from WIPO, the WTO and the WHO.

One possible approach to this challenge is illustrated by the Netherlands, where the government has set up a coherence unit to facilitate a co-ordinated response in which development concerns are properly and adequately addressed.

b). The example of Bangladesh

(i) The Bangladesh pharmaceutical industry

There is a need to dispel the popular notion that LDCs lack manufacturing capacity. There are exceptions, and Bangladesh is one of them.

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[12] IP/C/28: see footnote above.

At present, the pharmaceutical industry is of the fastest growing sectors in Bangladesh. The total market size in 2003 was US$450million. It is the second highest contributor to the national exchequer - the first highest is tobacco, ironically enough. The pharmaceutical industry is also the largest white-collar intensive employment sector.

In Bangladesh there are 232 registered pharmaceutical companies, and 164 operational pharmaceutical companies. Of the registered pharmaceutical formulations in the country, there are 5000 different brands, and 8000 different dosage forms and strengths.

The market is mainly dominated by local manufacturers. 80% is represented by local firms, and 20% by multinational firms. Out of the top 10 pharmaceutical companies in the country, 8 are local companies. The pharmaceutical sector is furthermore one of the fastest growing sectors in Bangladesh.

In Bangladesh there are more than 166 companies, all of which are local. In addition there are 9 multinational companies with local plant. The market is dominated by the top 10 or 20 companies. The top 2 are the most significant, representing some 30% of the market.

(ii) Manufacturing base: finished products and active ingredients

The finished formulation manufacturing base of the Bangladesh pharmaceutical industry is very strong. All the pharmaceutical companies of Bangladesh have their own manufacturing facilities.

The country has already become self-sufficient in some of the active product ingredients like penicillin, cephalexin, NSAID, and anti pyretic.

For finished formulations, 95% of the country's requirement is manufactured locally, and only 5% is imported. The imports are mainly vaccines and anti-cancer drugs.

Bangladesh is now capable of producing high quality products. The industry employs state-of-the-art technology, sophisticated quality control equipment and apparatus, highly-skilled human resources, and the finest quality materials.

(iii) Historical development of the industry

Today, Bangladesh has fulfilled another "national aspiration" of "turning an import based pharmaceutical industry into an exporter of quality medicines". It is now an exporter of quality-based medicines, even though up until 1979 the country imported up to 80% of its national requirements.

Despite the fact there was no special support or incentive from the government, a few companies under their own initiative started exporting active product ingredients and finished formulations, to some of the neighbouring less-regulated overseas markets like Myanmar, Sri Lanka and Nepal.

After being successful in these less-regulated markets, today a few major companies have also explored some of the moderately-regulated markets such as Russia and Singapore. Success in registering and marketing in these countries was a major breakthrough for the Bangladesh pharmaceutical industry. This was a clear testimony not only to Bangladeshi companies' excellent product quality, but also to their capabilities to meet stringent regulatory requirements. This was especially true in Singapore, whose requirements are now similar to those of the UK.

(iv) Present exports from Bangladesh

Today, the Bangladesh pharmaceutical industry is successfully exporting its quality products to about 52 countries in Asia, Africa and Latin America.

Active product ingredients have been exported to Germany, Iran, Hong Kong, South Korea, Malaysia, Taiwan, Vietnam, Thailand and Nepal. In 1995, BEXIMCO exported active product ingredients to the value of US$2.5million.

Finished formulations have been exported to Russia, Georgia, Ukraine, Pakistan, Myanmar, Bhutan, Singapore, Sri Lanka, Nepal, Yemen, Iraq, Vietnam, Kenya, Djibouti and Sudan, as well as to more regulated markets such as the UK, Germany, France, Holland, Mexico, Brazil, Colombia and Chile.

Bangladesh is exporting a wide range of pharmaceutical products, covering all major therapeutic classes and dosage forms. Besides their regular brands, the industry is also exporting high-tech specialised products such as inhalers, suppositories, nasal sprays, injectables and infusions.

The quality and efficacy of the products being exported from Bangladesh have been highly appreciated in all the countries to which products are being exported.

The packaging and presentation of pharmaceutical products being exported from Bangladesh are comparable to international standards and have been highly appreciated by the doctors, chemists and patients in all the importing countries.

Generic versions of ARVs are from more affordable than the originator products. They are now down to 50 cents a day from the Clinton Foundation. However, even generic companies do not necessarily have uniformly low prices. In Bangladesh, a local firm, Beximco introduced ARVs in the market and are giving ARVs on a “buy one, get one free” basis.

(v) Recent investment and upgrading

During the last couple of years, huge investment has been taking place in this sector in the form of facility expansion and up-grading and new entrants. There have been 32 new entrants already, and a substantial number more are expected by the end of the year.

Square, which is the number 1 pharmaceutical company in Bangladesh, has invested in their new state-of-the art world-class facility. This has already started operating.

Beximco, which is the number 2 company in Bangladesh, has already started manufacturing in its world class MDI plant and is going for certification in the regulated markets. Glaxo out sources to them.

Novartis has also started manufacturing in its new facility for exporting to Europe.

Beximco has made a US$ 50 million investment on a new plant conforming to US FDA standard and is going for USFDA Certification.

(vi) Need for investment

If LDCs could obtain the necessary investment, it would not be difficult to make medicines. The science involved is not prohibitively complicated or difficult. LDCs such as Bangladesh need to be able to get the active product ingredient, and need investment from either the private or public sector, as high quality investment is essential.

In Bangladesh, the industry would like private sector technical assistance for clinical trials. A provision in TRIPS states that developed countries should provide technical assistance - but when and how this provision is to be implemented remains an unanswered question.

There is a need for technical or technological support to develop a world class independent drug testing laboratory; clinical trial, bio-equivalence study; know-how (MDI), and R&D facilities.

It takes time - 5 to 7 years - to develop the active product ingredients. Investment in research and development is therefore important.

Arguably, compulsory licenses are not needed, as the products are already available from LDCs. Quality medicines at affordable prices are available.

(vii) WHO pre-qualification

The Bangladesh pharmaceutical industry is building new plant to produce medicines which are approved by the US Food and Drug Administration (FDA). However, it also seeks pre-qualification approval from the WHO. Although some companies perceive the FDA standards to be the most stringent, it has also been noted that the WHO pre-qualification process has declined to approve some products which have been approved by the US FDA. The assumption that the FDA is the most stringent regulatory authority is therefore questionable.

Pharmaceutical companies now perceive little difference between the US, EU, UK and WHO requirements. Even the Indian government's requirements are now similar, and may perhaps be even more stringent than the US.

(viii) The TRIPS context and the Doha Declaration

Perhaps surprisingly, neither pharmaceutical companies nor many people in the Bangladesh government Ministries have a detailed understanding of the TRIPS agreement and related developments at the WTO. Public interest organisations have nonetheless been instrumental in building capacity on this issue, and have provided a lot of helpful information on the subject. Pharmaceutical companies in Bangladesh now perceive the Doha Declaration and August 30 decision as an opportunity, and believe that as an LDC the country should seek to capitalise on the new flexibilities it offers.

The pharmaceutical industry of Bangladesh is governed by the local FDA, which is called the Directorate of Drug Administration, Bangladesh. It can be difficult to identify individuals in the Drug Administration or the Ministry of Health who have a good level of awareness about TRIPS issues such as requirements related to compulsory licensing and parallel imports. Arguably, it would be useful to develop training programmes to build the capacity of staff to address these issues effectively. This would help the country to develop a pool of resource persons. India and China have consultants who could provide this training.

Bangladesh does in fact have a patent law, the 1911 Patent and Design Act, which was inherited from the British. The government is currently trying to replace this legislation. New legislation to replace it will need to consider issues of patent protection, compulsory licensing, and Paris Convention references. TRIPS provisions on compulsory licensing are not incorporated yet in this law. The government is trying to incorporate the flexibility provided by the Doha Declaration.

In practice the existing law is not given effect in the pharmaceutical sector. Bangladesh generics companies have not been challenged under this law. The law is not considered to be a genuine obstacle by pharmaceutical firms.

Pharmaceutical firms in Bangladesh recognise that the existing law does need to be updated in line with TRIPS requirements. They have noted that no provision is made under the existing law for parallel imports, and that manufacturing under a licensing agreement is not allowed under the existing Drug Ordinance. However, they are not overly concerned about revision to incorporate compulsory licensing flexibilities, on the basis that compulsory licensing only applies in countries where a patent regime is in effect.

One possible reason why no challenges have been brought under this law is the fact that the Bangladesh market is relatively small. Furthermore, research-based companies now may hesitate to bring such a challenge given the extension of the deadline for patent protection under paragraph 7 of the Doha Declaration.

(ix) Importing active ingredients

Although LDCs are allowed to produce patented products, it is unclear where they shall obtain active product ingredients or raw materials from, after 2005.

Furthermore, the inclusion of 'active ingredients' in the August 30 decision is not intended to permit re-formulation and re-exportation of finished products. It is intended strictly to meet the local needs of countries with insufficient or no manufacturing capacity.

Pharmaceutical companies in Bangladesh have emphasised that they urgently need information on which products will be under patent protection after 2005. The prices for imported active ingredients will rise after 2005, including from India and China.

3. Importing developing countries
Challenges to issuing compulsory licenses whether or not under paragraph 6

a). Why is it difficult to get a compulsory license?

(i) Introduction

Compulsory licenses are not new: governments have been able to use this policy tool for many decades. In 1925, the Paris Convention introduced the idea of compulsory licensing. Most countries had compulsory licenses in their national laws before the TRIPS Agreement was adopted. The US is an exception to the general rule, as it grants compulsory licenses under anti-trust law rather than under patent law. The US has granted thousands of compulsory licenses in this way, perhaps ironically.

Except for the US, few countries have granted very many compulsory licenses. For instance, the UK has granted a few. Malaysia has recently over-ridden a patent so as to provide for 'government use' of the subject matter, and Mozambique has issued a compulsory license.

Why is it hard to use this mechanism effectively? There are a number of obstacles:
- legal obstacles
- economic obstacles
- political obstacles

(ii) Legal obstacles

One problem is the limitations imposed by bilateral agreements, which often restrict the government's freedom to grant compulsory licenses. Examples are the bilateral agreements concluded by Jordan and by Chile. These restrict the conditions under which a compulsory license may be granted.

There may be legal disincentives for compulsory licensing. Article 31(f) states that the supply should be predominantly for the domestic market. This can be a disincentive if the country is small and the population represents only a small market.

Another issue is the purpose of the compulsory license. TRIPS does not impose any restrictions in this respect. However, the laws of some developing countries impose conditions, such as the requirement that the request should involve a certain proportion of domestic production. Local production requirements of this sort in national law could be a barrier for implementation of the paragraph 6 solution.

Procedural requirements may also represent an obstacle to compulsory licensing. Who is entitled to grant the compulsory license? The patent office in many countries sees patent-holders as their clientele, and is opposed to granting compulsory licenses. There may be an ideological objection to undermining patent rights. Other Ministries may have different views.

Most laws stipulate that the authorities "may" grant a compulsory license, and not that they "shall" do so. In the latter case, the license shall be granted if certain conditions are met. Other governments and companies can place pressure on the authorities therefore to prevent the license from being granted. In the Dominican Republic, a company requested a compulsory license 3 years ago, and has still had no reply from the government's Patent Office.

The patent-owner can request a review of the decision: TRIPS requires that this be possible, but does contain flexibility in this area. Unfortunately, in many countries the patent-holder can get an injunction, blocking the compulsory license for years. This can make the system non-functional. The design of the national law is therefore a crucial issue.

In connection to this point, a paragraph on the Philippines case was cited:

120 petitions for compulsory licenses were filed under the old Philippine Patent law, out of which 51 compulsory licenses were granted. However, the beneficiary companies were unable to market the products due to appellate proceedings that delayed the execution of the decision. The delay in the proceedings also led to the dismissal of twenty three (23) applications. Fourteen (14) petitions were also dismissed due to a compromise agreement between the parties. Eight (8) petitions were dismissed because the patent expired while the petitions were still pending. The only compulsory license granted after the new Philippine Intellectual Property Code took effect on 1 January 1998 was a compulsory license petition filed on 8 December 1991 when the old Patent Law was in effect. This petition was finally granted on 19 December 2001, i.e., after a period of ten years. The rest of the petitions filed under the old Philippine Patent law are still pending (communication from Susan Villanueva, College of law, Philippines, September 26, 2003).
Anything that could delay a compulsory license is worth avoiding. It is best to establish systems with as much automaticity as possible. Data protection is an effective barrier, in this respect. A company may be granted a compulsory license, but cannot market the product concerned if national law provides for data exclusivity. The only way to way to be able to market the product would be to re-generate all the test data concerned: this would take a lot of time.

A new legal invention, which makes a link between product patent protection and marketing approval, is still worse. Language to this effect appears in the US-Chile bilateral agreement, and in CAFTA. It amounts almost to an absolute assumption of validity for the patent, and would represent an absolute barrier.

(iii) Economic obstacles

Economic factors may also influence whether a compulsory license is used, or even sought in the first place.

In the pharmaceutical sector, domestic enterprises may have an ambivalent relationship with the multinational research-based industry. They may seek to make generic copies of drugs, yet also hope to be granted voluntary licenses. A situation may therefore arise in which, although the compulsory licensing system is good, parties do not seek such licenses, for fear

of being blacklisted by the research-based industry and excluded from future voluntary licenses.

Compulsory licenses can often only get a small section of the market. They must be non-exclusive: the patent owner must be allowed to stay in the market and compete, and other compulsory licensees may also enter the same market. This therefore represents a risk for the company seeking a compulsory license.

The cost of litigation is an obstacle which is both economic and legal. Litigation can take years. The requirement of compensation, amongst other factors, lead to an expectation of higher costs.

(iv) Political obstacles

It is harder to prove the existence of these, or to find evidence that they exist. However governments are often pressured not to grant compulsory licenses. There is a close relationship between the research-based pharmaceutical industry and certain governments. In Malaysia, government use of the subject-matter of a patent was granted despite immense pressures, which were bought to bear both before and after this was granted.

b). Use of compulsory licenses to remedy anti-competitive practices, and remuneration

(i) Legal basis for using compulsory licenses to remedy anti-competitive practices

TRIPS contains language which is favourable for the granting of compulsory licenses if this is done to address anti-competitive practices. Article 40 of TRIPS is important in this respect. Its paragraph 2 states that:

> *"Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."*

It goes on to give some examples - which are only examples, and not a complete list - of the type of activities which may constitute anti-competitive practices.

Article 31(k) also provides governments with some useful flexibility in this respect. This article states that:

> *"Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."*

Taken together with article 40, it therefore provides a strong legal basis for compulsory licensing. The sub-paragraph also states that "the need to correct anti-competitive practices shall be taken into account in determining the amount of remuneration in such cases". In the US, there are many cases where zero remuneration has been provided in the past, although recent legal changes at the national level mean that it is no longer possible.

TRIPS is very flexible in this respect. Article 8, setting out the 'principles' of TRIPS, also provides an important part of the legal context[13].

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[13] TRIPS Article 8*:* Principles
"1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. "

(ii) Republic of South Africa Competition Case

The Republic of South Africa Competition Case provides one example of a situation where a compulsory license was issued to remedy an anti-competitive practice.

In South Africa, the grounds for such a complaint are: excessive price, essential facility, and refusal to deal. In the case, it was argued that a price for essential intellectual property is "excessive" if it is higher than most people can afford.

The procedure for submitting a complaint is very easy and straightforward. The complaint is filed with an administrative body, the Competition Commission. Any South African citizen can do this, by filling in a one-page form asking for the body to consider their complaint. A prominent South African campaign on HIV/AIDS treatment encouraged people with AIDS to submit a complaint.

The Commission had until 2003 to decide the case, which was filed under section 8(a) of the Competition Act, "excessive price". This section states that it is prohibited for a dominant firm to "charge an excessive price to the detriment of consumers".

An excessive price is defined in the Act as a price for a good or service which bears no reasonable relation to, and is higher than, the economic value of that good or service.

A US-based consumer organisation submitted comments on the initial South African organisation's submission, and agreed with the complaint about excessive pricing. Furthermore, the consumer organisation also argued that the situation contravened the standards relating to 'essential facility' and 'refusal to deal' as well. They submitted a report to the Competition Commission arguing that:

- Where essential goods that are protected by intellectual property are at stake, the economic value of the good is the value that most people in need of the good are willing and able to pay for it. Therefore, a price is higher than the economic value if substantial numbers of people cannot afford access to a needed medicine, either through individual incomes or through existing public or private insurance.

- The price of a medicine that is unaffordable to those who need it bears "no reasonable relationship to" its economic value when it is not the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be appropriate.

- Under the above standards, it is appropriate to presume that prices for essential intellectual property goods are excessive if they are so high that most people cannot afford them, as is the case here. To rebut this presumption, the seller of an essential intellectual property good must demonstrate that the good is being sold at the lowest possible price consistent with giving to the patentee due reward.

The organisation argued that there was a need to satisfy the Doha Declaration, including in literal terms its paragraph 4, which affirms that TRIPS should be interpreted and implemented in a manner that promotes "access to medicines for all".

The Commission liked this submission, which had further benefited from legal analysis by a number of international experts in this field. The end result was a 500 page report, even though the original goal had been to produce a theory on 2 or 3 pages. This document never became public. As this was a first case, however, it was necessary to provide a lot of analysis.

The consumer organisation made a distinction between essential and non-essential goods and services, and also between physical goods and services and intellectual property:

	Essential	**Non-essential**

Intellectual property	e.g. intellectual property related to essential medicines	e.g. certain databases
Physical goods and services	e.g. food, shelter	e.g. luxury perfumes

The rules should be different for intellectual property, as it can be copied or not: it therefore becomes a matter of public policy whether this is allowed. "Economic value" is defined as meaning the economic value to the consumer. The submission to the Competition Commission did not look at this issue from the viewpoint of the company, but rather from that of the consumer.

On 16 October 2003, the Competition Commission issued the following press release:

Competition Commission finds pharmaceutical firms in contravention of the Competition Act

The Competition Commission has found that pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) have contravened the Competition Act of 1998. The firms have been found to have abused their dominant positions in the respective anti-retroviral (ARV) markets. In particular the Commission has found the firms have engaged in the following restrictive practices:

- *Denied a competitor access to an essential facility*
- *Excessive pricing*
- *Engaged in an exclusionary act*

In the South African case, different remedies were considered. The staff/consultant report proposed an open license; establishing royalties based upon the Japan royalty guidelines; and global exports. However, the settlement negotiated by the South African organisation limited the number of licenses to generic firms, set a 5% royalty rate, and provided only for exports to Africa.

In a good compulsory license, the government gives no discretion to the right-holder. In a bad compulsory license, the government gives advice but leaves discretion to the right-holder, allowing issues to be resolved through negotiations.

The consumer organisation that was successful in this case is now preparing a new case in South Africa, and also one in Brazil. This time, the submission will only be 12 pages long, and will cover around 20 drugs for illnesses such as heart disease, cancer, and other diseases. It will not be limited solely to drugs for treating HIV/AIDS. If more cases of this sort are successful, this will affect drug prices.

The new submission will argue that for essential drugs anything close to 5% of a person's income is unaffordable. The objective is to develop basic jurisprudence that makes it possible to declare something illegal under competition law.

The issues around access to medicines have now been addressed extensively in Geneva, Doha and elsewhere. The political victories must now be followed with action on the ground. Public interest organisations are actively contributing to the development of jurisprudence in this area.

Roche has now stated that they won't enforce patents on AIDS drugs in South Africa. Other companies have also made statements on similar lines. The challenge now is to move beyond AIDS, and seek, through more compulsory license cases, to make drugs for other diseases accessible too.

(iii) European Biotech Directive

It is worth noting the language of the European Biotech Directive, paragraphs 52 and 52:

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

> *(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;*
>
> *(53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;*

What is of interest in this language is the fact that it specifies that access "must" be granted, on payment of a fee, through a compulsory license.

(iv) Areas where liability rules are permitted

There are three areas where liability rules are permitted (i.e. either an automatic license is granted, or none is needed at all). These are:

- public non-commercial use;
- emergency situations; and
- licenses as a remedy to anti-competitive practices.

In these instances, there are no prior negotiations, and there is a right to use the subject matter of the patent. The patent holder has some rights to compensation.

(v) Compensation

Four provisions in TRIPS are relevant to the issue of compensation:

31(b) (Public interest)
- efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions

31(h) (Only requirement for public non-commercial use or emergency)
- the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation

31(k) (Remedy to anti-competitive practices)
- the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases

31(l) (Dependent patents)
- owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent

There are two different approaches to setting royalty rates. One is the approach outlined in the UNDP guidelines: this is the right one for poor countries. If the object is to move towards marginal cost, this approach satisfies such an objective, as the royalty rate is based on the cost of the generic equivalent.

An alternative method is appropriate if the object is to equitably share the burden of R&D: royalty rates are in this case based upon the therapeutic value of the good, and the capacity to pay.

(vi) Most developing countries must first establish domestic competition law

Many developing countries have no competition law at all. The South African situation may therefore be different from the situation in many other developing countries. It is unclear therefore to what extent it is realistic to rely on competition law as a way of addressing the problem.

There is a need for developing countries to first establish competition law at the national level. Competition laws need to be enacted carefully. Governments need to consider what kind of norms they are establishing, if they use US standards and laws as a model.

In particular, they need to be sure that new legislation developed in this way does not limit their ability to issue compulsory licenses.

South Africa has a well-run bureaucracy. Its competition law is well-developed, compared to many developing countries. The Competition Commission in South Africa was set up to avoid costly litigation: the objective was to establish a kind of 'people's anti-trust law' body.

Organisations active on this issue have emphasised that, if it becomes recognised that pricing essential drugs at high prices is illegal, then this ruling becomes automatic. They have pointed out that TRIPS contains the necessary flexibility, but developing countries need to adapt laws that reflects this.

It is possible to devise a system for issuing a compulsory license that depends on straightforward procedures: on a simple administrative process rather than a complex judicial mechanism.

It depends how the system for issuing compulsory licenses is devised: whether it is a very judicial system, or a very simple, administrative one.

(vii) TRIPS article 31(k)

So far, little has been done to explore the potential of TRIPS article 31(k)[14] It would be good to operationalise this article. Argentina can issue compulsory licenses on the grounds set out in article 31(k). However, other developing countries may find drawing up legislation on this to be a daunting task: rather like asking someone to drive when they've never even seen a car before, let alone only ever ridden a bike.

However, perhaps the complexity of what needs to be done has been overstated. All that is needed is a simple legal text and an administrative process. Developing countries also need a simple theory about what constitutes anti-competitive practice, but not a long and complex report. With these basic elements, organisations that wish to do so could submit a compulsory licensing case on competition grounds in any country.

To develop a competition system, there is a need to have trained people and other resources in place. It is important to be able to prove that a company has abused its dominant position. It may therefore be harder to get a compulsory license in this way than through other channels in the patent system.

(viii) Historical context on competition, intellectual property and development

The question of competition and intellectual property is not a new one for developing countries. In the 1970s, many developing countries took action on this issue. However, these

[14] TRIPS article 31(k).
Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

countries failed to achieve change. Developing countries pushed to reform the Paris Convention, to make it more liberal. They were unhappy with the speed of progress in WIPO, and therefore brought the issue to the Uruguay Round.

This issue was therefore one factor in the inception of TRIPS. It is also one of the areas in which developing countries made substantive gains in the TRIPS negotiations. The language in TRIPS on this issue comes from previous negotiations which had taken place on a Code of Conduct for technology transfer.

(ix) An international competition commission?

In some regions of the world, competition cases are vulnerable because of problems with corruption. Pressure is brought to bear on decisions such as anti-trust cases, and such decisions are thus often vulnerable to change. As a consequence, it has been suggested that developing countries might benefit from the establishment of an international Competition Commission.

However, in the short term we are very far from a situation where this would be feasible. In the WTO working group on competition, there is not much enthusiasm about this issue at the moment. The US does not even want this issue to be addressed in the WTO, preferring instead to maintain the policies they have in this area at present. Historically, however, considerable attention has been given to the issue of international competition law, including in the draft Havana Charter of the International Trade Organisation.

By giving too much attention to this area of patent rules, though, we may risk becoming a little too academic. It is clear that the major players are not interested in tightening the rules in this area. Arguably, no-one is very interested in the negative impact that many multinational companies are having in poor countries.

(xi) Legal action in the US based on companies' activities abroad

One option that has been given consideration is the possibility of taking companies in the US to court for anti-competitive practices abroad. This may not be the easiest approach to take, given that there has been considerable opposition in the US to anything that might be construed as weakening intellectual property rights.

The US Supreme Court is currently considering a case which has a bearing on the issue of whether actions can be brought in the US based on a company's actions overseas. It remains to be determined whether a foreign plaintiff can bring an action in the US in this way, and whether this can happen even if the harm has only been incurred overseas. In every country, the government is sensitive to the idea that another government can sit in judgement over actions that take place on its territory.

It is also worth noting that TRIPS Article 40, paragraph 3, sets out a procedure in this respect. It provides for WTO members to co-operate with others on issues of this sort.

(xii) Credibility of compulsory licensing threats

A compulsory licensing system is effective if threats lead to a useful deal. The threat of a compulsory license can be used to force the company into negotiations to establish fair conditions. However, for this to occur, the threat invoked must be a credible one. Brazil was able to effectively threaten a compulsory license, due to the fact that manufacturing was possible in Brazil, the relevant cost estimates had been made, and a number of other measures had been taken.

In 1994, the WTO Secretariat produced a paper which said that refusal to deal was a ground for compulsory licensing under TRIPS. It would be good to see a provision to this effect included, therefore, in developing country laws. The emphasis should nonetheless be clear that compulsory licensing rules come under patent law.

Arguably, the credibility of compulsory licensing comes from the fact that India can export medicines to a country that needs them. Anyone can threaten a compulsory license for import of medicines from India.

Research by some legal experts has led them to claim that many compulsory licence negotiations in fact end with a voluntary license.

c). Thinking ahead

It is often assumed that developing countries do not have a 'developed' framework for competition law and "intellectual property". However, it could equally well be argued that developed countries do not have a 'developed' system for competition and "intellectual property" either. Conceptually, we are looking at these countries as an example of a 'developed' system, but maybe this is a mistake. Instead, maybe we need to consider what systems may work best to promote innovation.

In order for countries to get the most development-oriented compulsory licensing systems, it might be better for people to begin thinking in terms of "innovation" and not "intellectual property". The latter implies that the government is "taking someone's property": the former clearly describes the public interest purpose of the policy mechanism involved.

4. Research and information needs and available resources for legal and technical assistance geared to developing countries legislation and health needs

a). World Bank Global HIV/AIDS programme

(i) Overview of World Bank work on HIV/AIDS

The World Bank has stakeholders - the Bank's shareholders - and, as WTO members do, they have heterogeneous interests.

Over the last 2 years, the Bank has come a long way in appreciating some of the issues around intellectual property and access to medicines. A glance at the current edition of Global Economic Prospects would serve to illustrate this point.

During the negotiations on paragraph 6, one of the Bank's former Chief Economists wrote an Op-Ed in a prominent publication. The operational work of the Bank has also been affected by the debate in this area. The Bank is a player in funding work that improves access to medicines. The help of certain legal experts has been valuable in this process.

The World Bank does not directly procure or purchase drugs. However, it does provide loans and grants to countries to purchase them. In general, the Bank prefers countries to purchase drugs through a competitive bidding process.

The text of the TRIPS agreement provides considerable flexibility for pharmaceutical products. The onus is now on developing countries to take advantage of this flexibility.

The Bank wants countries to follow laws and also to take advantage of any flexibility they may provide. Under paragraph 7 of the Doha Declaration, LDCs have the right to delay implementation of patent and data protection and not to enforce existing patents and data protection on pharmaceutical product: The government only has to make a decision not to enforce patent and data protection to be able import or produce medicines when this might otherwise be blocked by such protection.

LDCs would be interested in the possibility of receiving technical assistance from the World Bank, to help them implement the flexibility contained in the paragraph 6 solution. This is a health issue with an important economic dimension, and LDCs have suggested they could benefit from the Bank's assistance.

The Bank does in fact hope to help developing countries put in place legal systems that allow them to take advantage of the flexibility that exists.

(ii) The World Bank Technical Guide

The World Bank has been looking at how to make HIV/AIDS medicine procurement systems work better.

About two years ago, it was recognized that the Bank had yet established a formal policy on purchasing generics. This led to the involvement of legal experts who helped establish the World Bank policy on the procurement of generics, and helped draft the World Bank technical guide rules on IPRs. The full title of the guide is "Battling HIV/AIDS: A decision-maker's guide to the procurement of medicines and related supplies".

The Guide advises LDCs and developing countries to actively seek low-cost medicines, and indicates that in doing so they are likely to encounter issues and obstacles related to intellectual property rules.

The IPRs section of the Technical Guide consists of two parts. Part 1 is the 'Concise Guide". The Technical Guide also contains, in its Annex B, a detailed discussion of TRIPS, intellectual property, flexibility etc. Staff from the WTO secretariat have informally reviewed the Guide, and confirmed that the technical position set out therein is accurate.

The Concise Guide was prepared after World Bank senior officers asked whether the advice in the Annex could be reduced to a few pages which can be more readily understood by those less familiar with the technical issues. The "Concise Guide" therefore states:

1. Countries seeking low-cost medicines should consider the purchase of generics
2. Paragraph 7 allows LDCs not to enforce patents on pharmaceutical products. LDCs are therefore advised that they can make a decision not to enforce patents and may import generics even if there are patents in force within the country. There is a flowchart on the decision-making process for LDCs, on page 20.
3. Developing countries can issue government use licenses to overcome patent obstacles. They may also permit registration based on (a) the right to use a regulatory review exception for patents, and (b) the fact that use of generics to address HIV/AIDS will not constitute "unfair commercial use" under Article 39.3 of the TRIPS Agreement.

The guide has been reviewed informally by the WTO secretariat, and by the IFPMA. The positions set out in the guide can therefore be taken as authoritative.

The guide focuses on the government use licensing because Bank funds are usually provided to governments and will be used by their procurement authorities. Government use licensing is typically facilitated under national law, and the TRIPS Agreement incorporates special flexibilities for government use.

On the test data issue, the guide indicates that legal challenges on this issue are unlikely in the context of the HIV/AIDS situation.

Page 24 has a flow chart on a real-life example, where a least developed African country has asked the World Bank whether Multi-country Acquisition Program (MAP) funds from the World Bank can be used to buy off-patent ARVs from India.

President Wolfensohn has supported the guide, which has also been approved by his office.

Training modules have also been developed to accompany the Guide, covering: quantity and cost-estimating, selection; supply chain management, intellectual property, pricing, World Bank procurement policy; and other issues as well.

The World Bank is preparing in-country training programmes, in conjunction with organisations such as UNAIDS and WHO. The next presentation will be in Bangkok in connection with an AIDS meeting. The Bank is also carrying out a major assessment project, looking at national laws so as to be able to provide better on-the-ground advice.

The guide makes it clear that the paragraph 6 solution only applies if the country is acting under paragraph 6, and also makes the point that TRIPS article 31(k) can be used to address anti-competitive practice.

The World Bank is also interested in regional pooling purchases. The Bank is interested in the process, and in providing the assistance that countries require.

The World Bank will use these documents in its country programmes. A first step has been that the World Bank and the Clinton Foundation have established an agreement to use World Bank funds under the terms of the Clinton Foundation's procurement arrangement. The Clinton Foundation is also arranging a team of *pro bono* lawyers to help developing countries in negotiations.

The desire is to present to governments a set of model rules that facilitate rapid procurement of cheap drugs.

b). WHO

There is a need for policy to structure the conditions under which procurement of affordable medicines takes place.

The WHO list of essential medicines has been a step forward in this respect. The WHO is now developing standard treatment guidelines, for HIV/AIDS drugs for example. There is a need to establish drug guidelines favouring generic procurement. Some pre-conditions are needed for this, however.

The first of these preconditions is pricing information. WHO, UNICEF, MSF and others are collaborating on pricing guides, and are working with Health Action International on pricing surveys.

The WHO has not established a single coherent position on the procurement of medicines and intellectual property. The WHO position on TRIPS and on the paragraph 6 negotiations has been clear. However, different programmes within the organisation may approach this issue differently. There is a clear focus on intellectual property and pharmaceuticals, but the WHO also needs to consider how intellectual property rules affect the procurement of vaccines. The organisation needs to develop a coherent position on intellectual property.

The WHO Drug Action Programme has been involved in the development and formulation of national policies. 26 national offices have been active advising governments on selection and rational use. Increasingly, the WHO has been active providing technical assistance, using money from the Global Fund for example. This technical assistance has been provided on the basis of the position that WHO has set out in its statements at TRIPS Council meetings.

WHO has received a number of requests: these relate to procurement; the patent status of drugs in different developing countries; and whether patents on certain drugs are in force in different countries. The organisation seeks to become able to provide more information on these issues to enquirers.

Under paragraph 7, LDC are not required to provide or enforce patents on pharmaceutical products until 2016. Mozambique's experience of compulsory licensing does raise the question of whether this is the most efficient way to ensure access. Implementation of paragraph 7 may be preferable, so as to avoid the risk that the patent-owner seeks compensation, or initiates litigation.

Some companies have announced that they will not enforce patents on particular drugs in developing countries. One avenue to explore is whether more drug companies would be able to make a public announcement along these lines.

There is a need to look in greater detail at licensing, using South Africa as a possible precedent. It might be possible for the WHO and others to develop model terms for the issue of obligatory licenses.

c). UNAIDS

UNAIDS is a small Secretariat for 9 co-sponsoring organisations, which include the World Bank and the WHO. The policies of these organisations are thus also the policies of UNAIDS. The UNAIDS position is also similar to that of the Global Fund, although they are not a UNAIDS co-sponsor: UNAIDS encourages governments to seek the lowest price for drugs, and to use the flexibility in TRIPS to achieve this.

The UNAIDS secretariat has a field presence of people in 90 different countries, all working on HIV/AIDS. A lot of attention has until recently been focused on the situation in Geneva, and the TRIPS negotiations at the WTO. The challenge now is to get information on patents and AIDS out beyond Geneva, as increasing access will depend on country level activity.

The underlying issue is how patents affect treatment access.

The 3 by 5 initiative demonstrates that the necessary political commitment exists, and that international funds are available. The World Bank has US$1 billion, largely in the form of grants. In total $1 billion has been allocated for Africa, and $150 million for the Caribbean.

Many people active on intellectual property issues do not think of themselves as fundraisers or as people working in external relations. Yet the impact of activism on issues associated

with intellectual property has led to dramatic price decreases, in many countries, for many drugs.

This activism has led to political commitment on the ground, which has led to international financing, over the last few years.

UNAIDS has followed the intellectual property issues since 1998, when key non-governmental organisations held a conference on the subject in Geneva. UNAIDS also contributed to the WTO TRIPS Council debate, bringing together developing countries on the issue.

UNAIDS has promoted partnerships with both research-based companies and generic firms, supporting the development of the group headed by Bill Haddad. The role of UNAIDS as an organisation in the UN system is to support countries' initiatives, and fill gaps. Many UNAIDS co-sponsor organisations are now working in this area.

The WTO noted recently that it had had 6 regional workshops addressing issues in these areas: the WHO and UNDP are now involved as participants in these workshops too. It is useful to bring people together, as this enables better co-ordination, and more effective work in support of countries' own efforts.

UNAIDS also has concerns over CAFTA. It would be useful if the World Bank, WHO, and non-governmental organisation active on this issue could help bring together people working on health and trade in Central American countries.

UNAIDS work on intellectual property also takes place through the activities of National School of Public Health in Rio. We have benefited from the support of the government of France for this work.

UNAIDS is interested in identifying ways in which its work can be more helpful to governments on this issue. For example, the organisation may be able to take steps towards enabling LDCs to make use of the extension of transition periods for pharmaceutical products.

(d) Requirement for notification of product quantity

The August 30 Decision contains language on notification of product quantity. However, the Decision does not prescribe how this quantity should be described. It could be described as a fixed quantity over the duration of the license, or a per-period quantity, or by using other terms of description. The formulation "x over y period for drug z" has been recommended by non-governmental organisations that are active in this field.

There was concern in Canada about the notion that it would be necessary to indicate specific doses in order to fulfil the requirement for quantity in the August 30 decision. Non-governmental organisations were concerned that this would hamstring the system, and possibly lead to the need for constant re-notifying of the WTO. It is questionable, however, whether a TRIPS Council dispute could arise over this issue.

(e) Requirement in 31(b) for consultation with the patent holder

TRIPS article 31(b)[15] states that efforts must be made to obtain authorization from the right holder on reasonable commercial terms and conditions. In implementing the August 30

[15] "Article 31*:* Other Use Without Authorization of the Right Holder
Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
…
b). such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other

decision, however, it is important to ensure the most effective and expeditious compulsory licensing procedure possible. There is a need for advice that is relevant to grassroots decision-makers.

LDCs should be advised to ignore the patent, after first having made and implemented a decision to take advantage of the flexibility they have under paragraph 7 of the Doha Declaration. Suppliers typically make complex agreements, and are worried about being sued. It is therefore advisable that the government of an LDC has a piece of paper ready to give people to provide concrete evidence that a decision has been taken,.

At the outset of negotiations, and even as far back as the developing countries' original draft for the Doha Declaration, legal experts were encouraging inclusion of an automatic recognition of the compulsory license that had been issued in the importing country. Many proposals were put forward on this issue. Arguably, the exporter is still entitled to rely on the situation in the importing country in this respect.

In paragraph 6, compulsory licensing applies in the context of a conflict between the government and the patent-owner. The patent-owner could supply the drug, but is unwilling to do so at the price required. So the patent-owner is likely to challenge whatever is done.

There is a need to comply with the laws as necessary. Some legal experts interpret the obligation in 31(b) as a requirement for negotiations in the exporting and in the importing country, whether or not this promotes access to affordable medicines. They consider however that it is possible to hold these negotiations jointly, with participation of representatives of the exporting and the importing country involved. In the interpretation of other experts, the August 30 decision is a requirement for a single negotiation, as described under TRIPS article 31(b).

Part of the challenge is to devise a means of implementing the requirements of the August 30 decision in a way that can be reconciled with competitive bidding processes. Mechanisms that allow for automaticity in the exporting country are arguably part of the solution here.

It is advisable that only one Minister is actually responsible for issuing the compulsory license. This may be the Minister of Health, as this is more likely to facilitate a health-oriented solution. In South Africa, there was some controversy about who was responsible for issuing the compulsory license. Many 'government use' licenses refer to "the Minister with responsibility for use of the product".

The law should be as automatic as possible. One step that can be taken in this respect is for the relevant provision to state that "the Minister *shall*" issue a compulsory license.

(f) Competitive bidding

It has been suggested that competitive bidding is an important element in establishing equitable procurement processes. Opening up WHO procurement to competitive bidding would therefore be a positive step forward. The World Bank already encourages procurement to be organised through multi-sourced competitive bidding.

There are some considerations which may mean that competitive bidding is not always the best approach, however. These include: cost; fairness requirements; situations in which it is not known who might want to tender; or situations in which negotiations might lead to better deals. Negotiations are not always to be recommended, either: but similarly a competitive bidding might not always lead to the best results.

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circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;"
(A footnote indicates that ""Other use" refers to use other than that allowed under Article 30")

The World Bank Guidelines include a requirement on competitive bidding. There are exceptions to this: for example, in situations in which only one supplier exists. If the country concerned is an LDC, and generic suppliers are in the market, it may be useful to go through a competitive bidding process.

(g) Finding information on the patent status of products: a role for WIPO?

It can be difficult to ascertain what patents exist, in which countries, on what products. Arguably, WIPO has a clear public service role to provide such information, it its capacity as a UN agency with responsibility for intellectual property. If WIPO was mandated to provide this information, it might be possible for it to provide a useful public role. This could be a first step for moving the organisation out of its current mindset.

WIPO has in fact been asked informally why they have not established a system allowing people to find information of this sort on the patent status of products. In a complex answer, they suggested that this task would be particularly difficult, and it would not be possible for anyone to devise a system that could provide this information. They emphasised that, if you take any one given medicine, it may have 100 or 150 patents on it.

It is unclear whether, from a public interest perspective, it would be desirable to mandate WIPO to do this. It may be possible for other organisations to provide this information instead.

The assumption that WIPO would be unable to provide this information has been called into question. Databases do exist which provide information on all the patents that exist, and WIPO subscribes to these databases. The organisation therefore could certainly provide enquirers with this information.

Pharmaceutical companies do not in general claim patents on a product in all countries of the world. Instead, they submit claims in thirty or forty countries. Pharmaceutical companies do not like to disclose the countries in which their products are patented. Often, they seek to claim that patent protection has been granted, without having to pay the fees. However, world bodies should ask companies to disclose where their patents are held.

In the US, the "Orange Book" does provide a list of patents. However, many of these are 'bad' patents: their subject matter is not in reality new, does not involve an inventive step or is not capable of industrial application. Even at the national level, the Orange Book presents a problem of 'information overload'.

WIPO does also register patents itself: in this case, it should be possible to see what the patent is. In the Patent Cooperation Treaty (PCT), there should be an initiative on transparency and quality.

It is true that patent landscapes are often complex: many patents can be held on one particular product. Situations in which multiple patent-holders have been granted patents on one product present another challenge.

WIPO Member governments may be able to take action on this issue. For three or four years, WIPO has been working on traditional knowledge, to debatable effect. However, public access to information on the patent status of products is an issue that should be fundamental to WIPO's responsibilities as a UN body. Member governments could require WIPO to take effective action on this issue.

III. Obstacles to implementation and means to challenge them

1. Those experienced by both exporting and importing / developing and developed countries

a). Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks

The South Centre has recently published a book entitled "Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks", and written by Sisule Musungu, Susan Villanueva and Roxana Blasetti. The book discusses options, and provides one general way to deal with them. It identifies six different obstacles and challenges which countries face:

(i). A lack of technical expertise to incorporate and implement TRIPS flexibilities in national law and policy

One such obstacle which countries face is the lack of technical expertise for incorporating and implementing TRIPS flexibilities in national law and policy. The book looks at how regional mechanisms might be used to address these problems.

Different problems require different solutions, and different structures. Regional economic communities are one way in which countries can share expertise and experience. The use of regional patent organisations - such as OAPI and ARIPO - is discouraged as a means to achieve this objective. These organisations have not so far demonstrated that they are really engaged in the debate on promoting access to medicines.

There is still a need for regional co-operation, and there may be ways to include regional patent organisations in certain ways. Arguably however, it is important that these organisations do not become the main drivers for implementing TRIPS flexibility. Patent offices have inherent limitations, and cannot be drivers in this context. Medical regulation, and health issues, need to be led by health ministries or perhaps regional organisations. Patent offices can be part of this, though.

There have been failures in regional organisations: some worked, and some didn't. There is a need to look at different constellations that might work. This perspective is different from that of some people in the European Commission who have responsibility for TRIPS: in their view, regional patent organisations should lead the process.

Arguably, the idea of involving these organisations should not become an automatic "red flag". More research is however needed. Regional harmonisation of patent standards should be discouraged: this is problematic, for the same reasons as is WIPO harmonisation. Countries are often at different levels of development, and one standard or one situation should not be expected to apply to all of them.

(ii). Insufficient domestic research and manufacturing capacities in the pharmaceutical sector

A second obstacle which countries face is the problem of insufficient manufacturing capacity. There has been a lot of discussion about this issue. Countries need to consider whether they will ever build capacity. It is important that no assumptions be made in either way.

(iii). Insufficient technical and infrastructural capacities for medicines regulation

Countries also face the challenge of insufficient technical and infrastructural capacities for medicines regulation. Mechanisms do exist in the area of medical regulation. Pooling procurement is one approach. The book looks at the work of some management scientists of health who have done some analysis of this issue.

(iv) Other obstacles and challenges

The book also addresses in detail three other broad areas:

- Difficulties in establishing efficient pharmaceutical management and procurement systems
- Bilateral and other TRIPS-plus pressures
- Difficulties in tackling anti-competitive practices and abuse of intellectual property rights

b). Long-term systemic problems, short-term challenge

Many of the issues currently under discussion relate to systemic problems: yet at the same time, there is a need to respond to a short-term challenge. HIV/AIDS, TB and malaria must be dealt with now. This affects how we structure solutions. People get frustrated if too much attention is paid to the long-term, systemic dimensions of the challenge when there are people dying from these illnesses now. There is a need to address the immediate issues, and yet there are also systemic problems too. This affects the North-South discussions.

c). Legal security of a waiver

No convincing argument has yet been made to suggest that a permanent solution is needed for the implementation of the paragraph 6 solution. A waiver provides the necessary legal security: countries should not wait for an amendment before they take action. Far more dramatic changes than this have been made in countries, based on waivers.

The ACP countries have undertaken major economic decisions based only on a waiver from the EU. There is also the example of AGOA: countries made huge changes, based on a discretionary waiver from the US.

Even if an amendment was adopted as a permanent solution, the likely outcome would be the emergence of two parallel groups of countries. There would be those that ratified the amendment and those that did not. Yet the wording of the waiver is such that its conditions in any case have immediate effect. There is no guarantee that, if there is an amendment, countries will ratify it.

d). Implementation requires new government-NGO dynamics

It may be the case that partners who have, until now, been traditional allies on the TRIPS and health issue may have to start sending some 'friendly fire'. The challenge is now going to be at the national level, as implementation gets under way within countries. Governments and NGOs therefore may not be allies any more, at least within developing countries, at the practical level - unless all works well. Some gentle nudges will be needed.

There is a need for different interest groups to have a better understanding of the debate. The Quaker UN Office has recently produced a series of background papers which seek to explain clearly the key issues at stake: this includes one paper on 'patents, trade and health'. Oxfam America have just ordered 2000 copies. Other organisations may find they are able to use them too - to train activists, and get the debate going on the ground.

Many groups are already actively sending 'friendly fire' at governments. For example, trade unions are pushing governments to take action. The dynamics are nonetheless changing in government-civil society partnership, and there is a need to manage this in a productive way. Long-term partnership is needed: the question is how to ensure that it works.

e). Implementation requires broader consultation

Implementation has a multi-disciplinary nature which is different from negotiations. A larger community of people will need to be involved: not just lawyers, but also health experts and others. For example, in Canada, no consultations were held while negotiations were taking place, yet these were needed once implementation began.

f). Brazil: scaling up access to medicines; challenging and overcoming the obstacles

(i). Collating lessons learnt in Brazil; the National Health System and universal access to medicines

The main principles of the Brazilian National Health System are strongly based on the 1978 Alma Ata Declaration, and guided by WHO guidelines. The principles include: universal care; health as a citizenship right and State duty (under the 1998 Constitution); and principles of universality, integratility, equity, decentralisation and social control. An adequate legal framework is provided by the Brazilian Constitution, Law 8,080 and 8,142, and Operational Norms from 1991, 1993, 1996, 2001 and 2003.

The 2003 Ministry of Health Guidelines specified expansion of access to health services and actions, including pharmaceutical care, to ensure quality. They proposed the intensification of endemic diseases control and strengthening of health surveillance actions, and formulation and implementation of a Human Resources policy. Finally, they envisioned a strengthening of democratic management in the system.

The Ministry of Health guidelines recommended scaling up access to medicines. A National Drug Policy (NDP) was set up, and the Essential Medicines List was revised in line with WHO guidelines. Basic pharmaceutical care was decentralised. In 1999, a new regulatory agency - ANVISA - was also set up. The same year, a Generics Law was passed which regulated bio-availability and bio-equivalence with interchangeability of medicines. The objective was to establish a comprehensive system, with both central and decentralised procurement of medicines to ensure universal access. Actions were taken to ensure universal access to ARVs. Measures were also put in place to ensure the proper economic regulation of the pharmaceutical sector: the Medicines Chamber thus involved the Ministries of Health, Justice, Financing and the Civil House.

Brazil also has a network of manufacturing facilities in its different States: there are 16 regional manufacturers. Brazil may be unique in this respect: it is the only country with a network of this kind. The objective is to for public manufacturing to be able to address public problems.

(ii). Data on intellectual property rights in Brazil and the region of the Americas

The National School of Public Health is a PAHO/WHO collaborating centre. It has several different core activities. These include work on access to medicines: assessing methodology, indicators, evaluation and assessment in the Americas; work on the 'rational use of medicines' (RUM), including translation of WHO documents for Portuguese-speaking countries; work on the TRIPS Agreement and access to medicines monitoring network, assessing the Region of the Americas; and work on access to care for the PLWHA[16] network. This latter is a joint project with UNAIDS and the French Ministry of Foreign Affairs.

The network strategies of the National School of Public Health include:
- The CARE e-workspace: this is composed of over 500 members world-wide, and circulates in three languages (English, French and Spanish)
- A website, www.financingcare.org.br. This contains relevant documents and information shared on CARE.
- Satellite meetings

The National School of Public Health studied several countries to determine what legal regime on intellectual property, and how this might affect access to medicines. This assessment noted when countries had joined the WTO, and studied their legislation to whether the country had taken advantage of the transitional period under TRIPS. Often, they had not.

16 People Living with HIV/AIDS

Similarly, had the country used the available flexibility, incorporating provisions for compulsory licensing, parallel imports, and the early working option? Under what conditions could compulsory licenses be granted? The research exercise also looked at who claims patents in Brazil: most patents were claimed by US companies, some were also claimed by EU companies, and a few were claimed by Brazilian firms.

An analysis of Brazil's total balance of trade from 1982 to 2002 shows that at one moment the country started exporting more than it imported (this was around 1985). Yet a significant quantity of medicines were still being imported. From this date, it was concluded that countries are not taking full advantage of the TRIPS safeguards, and that they may still improve their legislation by including or expanding the scope of TRIPS safeguards in order to achieve better public health outcomes.

Recently, Brazil successfully negotiated price reductions for ARVs. These negotiations took place in the context of a constitutional guarantee of universal, free and equitable access to the Health System. Law 9.313 of 31/11/96 established the commitment for free treatment for PLWHA. The Ministry of Health offers 14 ARV for universal treatment, of which 3 medicines - Efavirenz (MSD), Nelfinavir (Roche) and Lopinavir / ritonavir (Abbott) - are responsible for R$358 millions in 2003, that is, 63% of the costs associated with ARV in the country.

A Ministry of Health Working Group was set up for the negotiations. This identified the global manufacturing capacity for the medicines. Professional staff members from Far-Manguinhos visited the industrial sectors in India and China, to discuss the possibilities for importation and technology transfer. A presidential decree changed the law on intellectual property, permitting importation (not necessarily from the patent owner) in cases where this was necessary. The decree also covered the declaration of a "situation of national emergency", in necessary cases. Compulsory licenses can thus be issued, under the terms of the WTO TRIPS Agreement.

(iii): Ongoing initiatives to scale up and expand access to care

Several recent initiatives have sought to scale up and expand access to care. These include the *Politica de Medicamentos para el MERCUSOR, Bolivia y Chile (Acuerdo N.5/00)*, 2000[17]; the Brasilia Declaration of the G-15, June 2002; the India-Brazil-South Africa (IBSA) Dialogue Forum, which organised a series of Trilateral Commission meetings in 2003 and 2004; and the work of the UNDP in Brazil, which has included a project on intellectual property rights and the development of capacity to increase access to medicines.

Other such initiatives include technical assistance for national responses to HIV/AIDS in Latin America and the Caribbean (GCTH, WHO and UNAIDS): the PAHO Working Group, Managua, NICARAGUA, 14 to 16 April 2004; and the PAHO Access to Medicines Working Group, which was convened in Washington, USA, 10-11 June 2004.

IBSA Trilateral Commission Meeting, New Delhi, 4-5 March 2004 agreed the following:

> *"45. In the course of discussions, which followed the presentations, the following points of agreement emerged:*

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17 Acuerdo N.5/00 MERCUSOR (Patentes):
"Se prevé (…), un impacto significantivo en los costos (…), en decorrencia del monopolio patentario…
Se propone:

- El estudio, en cada Estada Parte, sobre el impacto del reconocimiento de patentes en el acceso a los medicamentos;
- El estudio de las legislaciones actuales en la perspectiva de alternativas viables para un mejor abastecimiento de los medicamentos bajo patente, considerados esenciales a la población de la región;
- La acción conjunta de los Estados Partes y Associados en el sentido de la flexibilización de las exigencias patentarias, en casos de alto relevancia para la salud."

- *The national statutory frameworks of the three countries should reflect all the flexibilities allowed for by the WTO TRIPS Agreement, Doha Ministerial Declaration…*
- *The bilateral / multilateral trade agreements which are "TRIPS plus" should be opposed*
- *To take all steps (…) to strengthen indigenous manufacturing capacities…*
- *To leverage the opportunity provided by the setting up of the WHO Commission on IPR, Innovation and Public Health (WHA56.27) to put across the commonly agreed point of view of the three countries…*"

The progress achieved in the IBSA Trilateral Forum has since been built on and expanded, including at the 57th World Health Assembly meetings. A preliminary proposal has been put forward for the establishment of a network of technical cooperation on HIV/AIDS among 6 countries (South Africa, Brazil, PRC, India, Russia and Thailand). A joint Declaration of Commitment is also to be signed in Bangkok, July 2004 (XV International Conference on AIDS), followed by bilateral agreements involving public-private-partnerships. Thirdly, interventions are being prepared for the 114th WHO Executive Board Session (24 to 27 May 2004).

The IBSA forum is an excellent example of developing countries working together to implement TRIPS flexibilities. The IBSA Declaration was signed by Foreign Affairs Ministers, not Trade Ministers. Focal points in different Ministries were found, who worked together during the negotiations. There was concrete co-operation in several areas. This developing country co-operation can be built upon in other fora: MERCUSOR is now negotiating a free trade agreement, but will propose clause-by-clause opposition to CAFTA provisions.

The 57th World Health Assembly agreed a proposal on scaling up treatment and care within a co-ordinated and comprehensive response to HIV/AIDS. This:

> "*URGES Member States, as a matter of priority:*
> *(6) To encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health*

There is a need to see health rights as a human right. The warranty of such a right involves access to health services, health prevention, health care and health therapies - including access to drugs.[18]

g). Coherence

In some countries, the Patent Office has an uneasy relationship with the Ministry of Health. In may be unclear who prevails in the case of a policy disagreement.

One way to approach this challenge may be to seek to establish co-operation across Ministries. There will always be different viewpoints, but it also useful to stress the importance of health. The viewpoint of the Ministry of Health will not always be mandatory, however. Countries may like to consider a system in which all patent applications concerning pharmaceutical are submitted to the national regulatory agency as well. The research-based pharmaceutical industry has even criticised this co-ordinating mechanism in a country which operates this system, on the basis that it constitutes a fourth criteria for patentability. Of course this is not in fact the case, however.

Examples of this kind, illustrating practical action between Ministries, can provide a useful insight. In many countries, patent office staff disregard other policies, thereby creating new obstacles to access to medicines. One Asian country had a parallel importing system in its laws, yet the Patent Office opted for national exhaustion. There was an inherent bias towards more restrictive intellectual property regulation.

[18] (UNHCHR, 2000/7)

Some countries can even appear to be suffering from a policy 'schizophrenia'. Arguably, the US continue to consistently undermine TRIPS flexibility, even though it agreed to the Doha Declaration. Other countries then sign bilateral trade agreements with the US, and are therefore silent in multilateral fora when it comes to defending flexibilities afterwards.

Concrete examples can be found which illustrate this 'schizophrenia'. Last year a resolution on innovation and health was passed at the World Health Assembly. The sponsors had the support of China and the Africa Group, as well as other countries. If this resolution had come to a vote this year, the US would have lost: it would have been embarrassing for them. The EU also supported this resolution, so the US would have been isolated. Arguably, the US will nonetheless do what they want in practice, as this is a Declaration and therefore is not mandatory. In these situations it is nonetheless always possible to point out these contradictions to the media.

h). Brazil an emerging exporter?

Brazil is not planning on becoming a big ARV exporter, although has entered its drugs for WHO pre-qualification. Instead, the government has established technical co-operation projects with ten countries, and is giving away free ARVs to African and Asian countries. The reason for this is that Brazil is not a private manufacturer, but a public manufacturer.

There are a couple of private ARV manufacturers in Brazil, and some organisations have suggested that these could perhaps export under the paragraph 6 solution. The government has nonetheless pointed out that the Brazilian HIV/AIDS programme is a comprehensive programme, which is focused on much more then manufacturing low-cost ARVs. The benefits include, for example, lower costs through reduced rates of hospitalisation. There are numerous benefits to the national health system.

i). Strategies for addressing TRIPS-plus

Strong countries can credibly resist the drive towards increasingly prohibitive 'TRIPS-plus' patent legislation, of the sort contained in regional free trade agreements like CAFTA. However, small countries are far less capable of doing so. We may be forced to recognise that the policy of just saying 'no' to TRIPS-plus has failed in small countries. Instead, it may be necessary to reconsider the terms of the debate. For example, it might be more productive to try to change the focus onto the need for "R&D-plus" instead of "TRIPS-plus" measures. Perhaps negotiations between rich countries on drug prices would be a good place to address this issue. If countries insisted on an "R&D-plus" focus in bilateral negotiations, this may furthermore provide a counterbalance to the TRIPS-plus focus of rich countries.

The WHO has now established a Commission on Intellectual Property Rights, Innovation and Public Health. There is a lot of pressure on this issue. We also should consider this issue from the perspective of the US government: the US Congress asks itself, "why are we paying for the development of drugs?". A rebellion is now taking place in the US Congress, with even conservative Republicans such as Trent Lott supporting a bill on parallel trade. The discussions on prices mean we can rethink the framework. We need to consider the possibility of new negotiations on who pays for what: now is the time to engage on this issue, as opportunities for constructive discussion may exist.

j). Government role critical in developing India's industry

In India, the government helped to set up the industry in the 1960s. India was an importer of drugs during that period. In India in the 1960s, drug prices were higher than in the US. The government wanted to buy technology from Western manufacturers. India bought the technology from the USSR, and from Italy - which did not have product patents then. Companies like Dr Reddy's then set up, as people moved out into the private sector. The Indian public sector was the key force: most countries can learn from this.

Rambaxy came into being in the 1960s as a small unit: ten years ago, they set up a joint venture company with Eli Lilly, and developed ciplaflor. They wanted to stop this being sourced elsewhere. The partnership with Lilly dissolved when the patent expired.

India manufactures a lot of equipment that is used for manufacturing drugs. This probably has an important role in lowering drug production prices. The equipment for manufacturing drugs in India can be bought at around one-third of the price of comparable equipment from Europe or elsewhere.

Bangladesh also has government-owned manufacturing capacity. The government makes drugs which are on the country's essential drugs list, and which are not being made by the private sector. The private sector does not manufacture many of these drugs because the low fixed prices
make them unprofitable. The public manufacturers therefore make these drugs, but at a loss.

2. Those arising from:
- *bilateral, regional and multilateral agreements, including rules on market approval, data protection, and patent terms, and*
- *existing legislation, e.g. in least developed countries*

a). Data protection under TRIPS article 39.3.

(i) Introduction

To get marketing approval, a company must submit test data to the national authorities for registration. In the past, in developing countries, local companies relied on the data from the 'originator country', in developed or developing countries, to get marketing approval. This allowed a supply of generic 'off-patent' products.

During the TRIPS negotiations the US tried to introduce a clause on data protection, which became article 39.3[19]. The US argued that the cost of developing this data is significant, and so relying on this data is an unfair commercial practice. They therefore sought to exclude its use.

(ii) An analysis of the provision

But article 39 contains a provision on unfair competition, in its paragraph 1. This makes clear that the protection of data takes place in accordance with article 10bis of the Paris Convention.

Article 39.3 obliges Members to take measures to protect certain data from unfair commercial use. The requirement only covers:

- "undisclosed" information. Yet once it has been approved, test data is generally published.
- Information needed to obtain marketing approval. So information not needed for this approval is not covered. Often, national authorities rely on approval in other countries elsewhere. The test data in itself is therefore not necessary to obtain marketing approval.
- Information resulting from "considerable effort". This reflects a shift it thinking: the notion that IP law is for protecting investment rather than as an incentive or reward for invention.
- Information relating to "new chemical entities".

If we have to interpret article 39.3 on the basis of the Vienna Convention, we cannot interpret it as requiring data exclusivity - as the US and EU argue. These countries have established in their laws data exclusivity for this information. In the US this is for 5 years, and in the EU for 11 years (as of the recent extension). In these countries this system applies. However, there is no possible reading of article 39.3 which could suggest it requires data exclusivity:

- It only relates to undisclosed information, but this information is usually published
- Unfair competition legislation governs this area, and there is nothing in this area which suggests exclusive rights
- To apply, there must be a commercial use for this information. A government authority using data has a public objective, and not make a commercial use.
- When a national authority relies on data in this way, they have no prior contact with the information. There is therefore no "use" of the information as such: "relying on" the data is not the same as "use" of the data.

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[19] TRIPS Article 39.3
"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

- In negotiations, the US submitted text seeking to exclude "use" of data, and also "relying on" the data, but this was rejected by other parties in the negotiations. Now the US bilaterals clearly seek to exclude both.
- An exclusive right is a strong derogation from the normal situation, and is therefore always stated in clear terms in TRIPS, if and where such a right is given. There is no way to interpret article 39.9 in this way.

A book by the South Centre, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the standards of the TRIPS Agreement (2002) documents some of the history of article 39.3, and touches on issues such as the rejection of the US draft.

(iii) Implications of the interpretation which the US ascribes to TRIPS article 39.3

If this article was interpreted in the manner advocated by the US government, local companies would have to regenerate the test data. They would have to carry out lengthy clinical trials, with animals and also with humans, to prove meets regulatory standards. This would be a waste of resources, in time and money, as well as causing unnecessary suffering and death for thousands of animals as well as for patients in the process. This is both unethical and illogical.

Again, if the interpretation promoted by the US was applied to this article, this could affect the process for issuing compulsory licenses. Unless there was a specific provision on this in national law, the beneficiary of a compulsory license would be prevented from marketing the products until clinical trials had been completed. This could perhaps take 5 years.

Data protection does not start at the same time as the approval of the patent. So the US interpretation would be a major obstacle to providing generic access.

Arguments in favour of the US interpretation have been made on the basis of morality. It has been argued that it is unfair to take advantage of the investment made by the originator. However, in the capitalist system, externalities occur every day: companies take advantage of other companies' discoveries or activities. One company may have a lead time, but others often follow their activities. There is nothing inherently dishonest in this.

Whether conduct is considered 'honest' or 'moral' depends on the country. Drinking alcohol is 'immoral' in some countries, but in Switzerland it is not. In many countries it is not considered "immoral" or dishonest to rely on others' public health data.

(iv) The current situation

Argentina relies on test data from other countries, so two years ago the US started a case against the government. Discussions continued for 2 years. Despite the economic crisis, Argentina maintained the position that article 39.3 does not require data exclusivity. The agreement settling the dispute states that each country may retain its own interpretation. The US reserves the right to request a panel on the issue. No panel has been requested, although this issue arose two years ago. This suggests that the US has abandoned the idea that its interpretation of 39.3 can be enforced through the DSU..

In some countries, generic pharmaceutical manufacturers are asking the regulatory authorities not even to actively 'require' test data. So the question of whether the data is to be 'used' or not does not even arise. The applicant should specify what is confidential data.

b). The Doha Declaration and contradictory trends in bilateral and regional agreements[20]

[20] For further information see QUNO Occasional Paper 14: "*The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*" http://geneva.quno.info/pdf/OP14Abbottfinal.pdf

The recent bilateral and regional agreements raise a number of new challenges. There is a need to consider the technical details of what these agreements actually contain, before beginning any assessment of the policy conclusions that might be appropriate.

The United States has recently concluded free trade agreements with Jordan, Singapore, Chile, Central America, Australia and Morocco. Not all of these agreements are yet in force. Negotiations are now also beginning with the Andean Community, ASEAN and others.

CAFTA contains, in its article 15.1 paragraph 7, a non-derogation clause, which is curious. This states that

> *"Nothing in this Chapter shall be construed to derogate from the obligations and rights of one Party with respect to the other by virtue of the TRIPS Agreement or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organisation and to which they are party."*

However, other provisions in the agreement directly constrain the rights a Member has under the TRIPS agreement. There is therefore a contradiction. The US-Australia and US-Morocco free trade agreements do not include this non-derogation clause.

With respect to the granting of a regulatory review exception, CAFTA does contains a restriction in its Article 15.9(5): marketing approval may only be effective "once the patent expires". Under TRIPS however, patent expiration is not the sole mechanism for authorized use of an invention without the consent of the patent holder. Compulsory licensing provides just one such example.

CAFTA article 15.9 states that:

> *"6. Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays."*

This is not limited to medicine, but does represent a TRIPS-plus standard.

CAFTA article 15.10 would have a major impact on pharmaceuticals.

Article 15.10.1 states that if an originator company is granted marketing approval, based on the information they have submitted, they will receive 5 years of marketing exclusivity for pharmaceutical products, or 10 years for agricultural products, starting from the date of approval in that country[21]. This eliminates the flexibility in the term “unfair commercial use” as set out in the second sentence of TRIPS article 39.3.

There is a new take in article 15.10.1(b): if a product has been "previously approved in another territory", evidence of foreign registration cannot be used. This is the codification of the notion of extra-territorial rights in the data - arguably, this is partially directed towards the WHO's pre-qualification system.

[21] CAFTA 15.10.1(a): "If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party."

There is a provision in the CAFTA stating that a pharmaceutical company may wait five years before seeking the five years data exclusivity in the other country. This provides an effective ten-year period of exclusivity for non-patented products. This is distinct from the protection provided by patent protection: it provides a formal monopoly.

Article 15.10.1(c) extends the scope of the term "new chemical entities" (used in TRIPS article 39.3) to any "new product" defined as "one that does not contain a chemical entity that has been previously approved in the Party". In the Morocco bilateral, the scope is extended still further. Far more extensive protection is thus provided.

CAFTA article 15.10.3(a) contains wording which, from a compulsory license standpoint, is very problematic. This effectively states that a generic producer must be prevented from obtaining marketing approval that would allow that producer to market the approved product, or to use the data, for the term of the patent, unless the patent-holder approves. This puts into the hands of the regulatory authority the decision on whether a patent is a valid one or not. The major companies flood the Orange Book of the US FDA with all kinds of patents, both good and bad. The FDA has said that they don't know whether patents are good or bad, but under this legislation would automatically have to block marketing approval for the product concerned.

The CAFTA draft also addresses the issue non-violation or impairment causes of action: although the TRIPS Council is still actively considering the question of whether these complaints can be brought at the WTO, the CAFTA intellectual property chapter determines that they can be.

The 'side letter' between the US and Morocco effectively re-writes the Doha Declaration. This letter states that both governments understand that chapter 15 does not "affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all. This will concern, in particular, cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency or national emergency."

In the U.S.-Morocco Agreement, there is a new take on data exclusivity: this provision effectively allows the ever-greening of data exclusivity based on new clinical information. These kind of determinations are very different in practice to figure out.

These are very complex provisions: it takes days to work out what they actually mean in the first place. It remains very unclear how regulatory authorities in developing countries could possibly work with them at all. The policy space for regulation of medicines is being shut down in developing countries, by means of these free trade agreements.

These provisions get included because trade-offs are made: the developing country government considers they are worthwhile. For example, the developing country government might be offered increased market access for textile-factory owners in return. However, from a public health perspective it is reasonable to query whether these trade-offs are really worthwhile. Does the government then transfer money from the textile-factory owners to the public health budget? Even if there is not an asymmetry of negotiations in economic terms, there is an asymmetry of outcomes.

It is unclear to what extent governments in developing countries have conducted impact studies to assess the outcome of deals of this sort. There is a need to make a proper assessment of the economic or public health impact of any new agreement. It is doubtful whether any such studies have been conducted.

c). Article 39.3: an exception clause?

In TRIPS article 39.3, the last sentence refers to the need to protect data against disclosure, "except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use". Some people see this as an exception clause.

This clause is an exception with regard to information to be disclosed, yet not with regard to the protection of data against unfair commercial use. It only says, if information is vital for the public, it can be disclosed: but it has nothing to do with the protection of information. It has nothing to do with compulsory licensing.

d). Non-derogation principle

The CAFTA non-derogation principle is also included in the US-Chile bilateral. At first reading, the non-derogation principle does make sense, given that the agreement is TRIPS-plus. It therefore could be seen as logical that a provision of this sort should be included, to mean that, in other areas otherwise unaffected by the agreement, there is no derogation from TRIPS.

However, a non-derogation clause is arguably irrelevant because TRIPS only establishes minimum standards. It is perfectly possible to go beyond TRIPS. CAFTA is "US-law-plus" in some respects.

The parallel trade bill now before US Congress may contravene some of the provisions in CAFTA.

e). "Linkage" between marketing approval and consent of the patentee

CAFTA makes a "linkage", therefore, between marketing approval and the consent of the patentee, which would have a major impact on compulsory licensing. Issuing a compulsory license may not allow the government to completely bypass the patent-holder's consent.

However, this is a piece of clever drafting. The text does not say that this is an additional right, but rather an obligation of the national authority.

f). Possibility of facilitating interpretations that reflect developing country needs

It would be desirable to facilitate more friendly interpretations of these provisions so as to facilitate a positive long-term impact on access to medicines, especially in developing countries.

However, industry and certain governments have historically put forward very aggressive interpretations of disputed provisions. Any ambiguity they contain is a disadvantage for developing countries. It would be unwise to write restrictive rules and then try to re-interpret these over 4 or 5 years of back-and-forth with USTR[22]. Instead, it is better to decide whether or not those rules should be written in the first place.

It is always possible to hire capable lawyers who will try to deal with these difficult questions. It is nonetheless preferable for government not to put themselves into a position in which this should be necessary.

g). Need for information about patent status of drugs

To issue a compulsory license, the government needs to know the patent status of a given drug.
It is difficult for developing countries to find information, and this leads to delay in the production of generics. Developing countries need their own data. It would be useful if the patentee was required to disclose all the patents they hold on a product.

h). Reconsidering basic assumptions about protecting investment and promoting innovation

[22] Office of the United States Trade Representative

There is a need to consider what mechanism might be able to address the flawed bilateral agreements that are being negotiated.

In 1991, under the former President Bush, the US negotiated many bilateral agreements, which were also badly unbalanced. They contained sweeping prohibitions on compulsory licensing, and other unnecessarily restrictive measures. The incoming Democrat, President Clinton, just ignored these agreements. Even USTR officials say these agreements went further than they should have done. If a new US president is elected in November, it might be possible to revisit some of these agreements next year.

The term for data exclusivity in the US is just 3 to 5 years. WIPO treaties on broadcasting contain a protection term of 50 years. In the EU, protection of some forms of intellectual property is effectively perpetual, in that there is a renewable 15-year term. There is a need to ask where data protection trends are leading.

Data is not a form of creativity. Exclusive rights are not the most appropriate mechanism for protection. Compensatory liability regimes are one possible alternative.

In the US debate, there is a need to recommend a policy tool which falls somewhere in between exclusive rights and public domain. Otherwise, exclusive rights will always be chosen as the best means of protection. Patent protection is increasingly about protecting investment: the way forward therefore may be to revisit first principles about the best ways to protect investment and to promote innovation.

IV: Ways forward

1. Mobilising alliances and new actors, e.g. employers and labour groups

a). Coherence and co-operation

Developing countries still have important challenges to face. One of these is the need to develop greater policy coherence. The use of flexibility is currently being limited by bilaterals, by the nature of the technical assistance that certain bodies are providing, and other factors

Most countries are not dealing with the issue of coherence. Inter-agency coherence is needed, at national, regional and international levels. Interesting initiatives involving South-South co-operation are under way, such as the IBSA Dialogue Forum between India, Brazil and South Africa. But we also need North-South co-operation. Civil society involvement is important, for example, especially to address TRIPS-plus phenomena.

There is also a need to bring in parliamentarians. It may be possible to revisit the role that the International Parliamentary Union (IPU) could play. The IPU has already been active with other organisations on the human rights and AIDS issues, although issues such the CAFTA agreement needs urgent attention, which may be better addressed through other networks. There is a need to support civil society on this.

Institutional coherence at the national level is important to implement the August 30 decision. The problem is that it is patent offices who are expected to take the lead. In general, this is not appropriate though. Geneva-based actors have a role to mobilise support, and promote coherence in the area of technical assistance.

b) Building manufacturing capacity

1. Developing countries are not all equal, not are they necessarily in similar situations. There is a need to go beyond paragraph 6: the August 30 decision is perhaps best seen as a useful but partial solution to the problem of the lack of manufacturing capacity in developing countries.

Bangladesh is an example of (the importance of developing) tools for (establishing) manufacturing capacity. Paragraph 7 of the Doha Declaration provides an opportunity to start the transfer of technology to LDCs. There is a need to look at medium and long term solutions.

An international treaty to promote research and development, or innovation, may be one way forward. Professor Barton has made a proposal on this subject.

LDCs should take a lead role on this issue, amongst the developing countries. They have three valuable tools at their disposal: the paragraph 6 solution, paragraph 7, and the Decision on technology transfer related to TRIPS article 66.2.

LDCs are not just a market, they also want to establish capacity. South-South co-operation would be important in establishing this. India has capabilities for manufacturing the machinery needed to make medicines. LDCs could even involve brand-name companies, and build partnerships. There is a need for the governments of these countries to draft a business plan to implement the paragraph 6 solution.

c) Need for national level implementation

The impediments to implementation may now be among developing countries themselves: it is important for governments to take action now, rather than waiting for an amendment to be agreed. Importers can take a first step by making the necessary notification to the TRIPS Council, and then moving forward to make use of the system that has been established.

The technical advice that organisations such as the World Bank are providing is key. Other international organisations may also be able to provide concrete assistance of this sort.

There is a need to engage the generic industry, and provide incentives for implementation. There is a need to lobby them to ensure that they make their contribution. Non-governmental organisations and developing countries can communicate this clearly.

There is a need to raise awareness about paragraph 6 implementation. Governments should not just rely on technical assistance. The available flexibility must be included in national legislation. Once the issue is back in the spotlight, it will be possible to re-establish momentum.

Civil society organisations, such as trade unions, may have different departments with information on various aspects of TRIPS. It is important to look at the challenges to implementation: the political challenges, for example, that stand in the way.

As well as detailed technical information addressing the complex legal issues, it is important that simplified information is also available for grassroots activists. These groups can lobby for domestic legislation that is needed. They are the ones who are best placed to determine whether the government at a particular moment may be favourable on moving ahead with implementation.

Implementation at the national level must be the priority. There is a need to work on paragraph 6 implementation, in conjunction with implementation of paragraph 7 in the case of LDCs. There is a need to look at all the available flexibility, and move towards co-ordinated implementation in this way.

In many developing countries, it seems that there is a lack of interest in implementing the paragraph 6 solution. To take action, we must understand why this is the case. Various theories could be put forward as possible reasons for this:

- Is it no longer needed, due to market changes and generic availability? Or;
- There is a need, but the agreement is too cumbersome and complex? Or
- The agreement is fine, but it is too early to implement yet, as problems will arise post-2005. The solution is there now but countries will use it in 2006, 2007, etc?
- There is a lack of knowledge and awareness about the solution in capitals?

We need to be clear on the reason, and why there seems to be this lack of interest, in order to take action.

One reason might be that India's new law is not in place yet, and the post-2005 situation therefore remains unknown.

Other indications suggest however that there is interest in implementing legislation on this. Some international organisations which provide support to developing countries have had so many questions and expressions of interest that they have had to turn down many requests for help.

The problem may be a lack of knowledge about how to implement, rather than a lack of interest. A North-South alliance is crucial: developing countries can build alliances with interested countries in the North that have already taken steps to implement, or may do so soon.

Civil society organisations can be effective in communicating development issues around access to medicines through the media. This is not always something that can be best achieved from Geneva. Some such organisations with specific legal expertise may also be able to initiate compulsory licensing cases and help develop jurisprudence.

2. Assessing political opportunities to resist TRIPS-plus obstacles to implementation

a) Bilateral and regional free trade agreements

Legal experts with knowledge of the difficult and complex issues around bilateral agreements do need to speak out and take a position. Otherwise, free trade agreements of this sort are only likely to proliferate further.

The attention given to issues around bilateral agreements, including new restrictions on data protection, is perhaps a reflection of many organisations' real priorities. Focusing time and resources on an amendment may therefore not be the right use of energy.

Considerable analysis of the issues at stake has helped clarify some issues. Yet there is still a need to identify practical solutions in this area. For example, what steps can be taken in practical terms to address the TRIPS-plus nature of free trade agreements? At a practical level, what can be done in particular developing countries or LDCs?

Issues that could dilute efforts to move forward on paragraph 6 implementation have been highlighted, however. Bilateral agreements, such as the Moroccan free trade agreement, could undermine paragraph 6 implementation.

Bilateral agreements are already creating 'facts on the ground': but developing countries can also take immediate steps to implement paragraph 6, thereby creating facts on the ground as well.

3. Reflections on an amendment under paragraph 6

The August 30 waiver decision mandates the TRIPS Council to begin negotiations on a permanent amendment to TRIPS. These negotiations have been initiated, as required, but are not moving at the moment with any particular momentum. Given that the waiver provides a legally-secure basis for implementation and action, developing countries may not wish to over-invest scarce negotiating resources on this issue. Alternatively, they may wish to take advantage of the mandate in this area and seek to ensure that their concerns are fully recognised. The difficult nature of the negotiations in this area has led some to suggest that negotiating capital might be more effectively channelled elsewhere, especially given that proposals for further change would most likely meet with significant opposition from developed countries.

a) A fresh approach?

Some non-governmental organisations have nonetheless suggested that the mandate provides an opportunity to make a fresh start. They have argued that:

1. There is a need to simplify the procedures and safeguards.

2. There is a need to eliminate the protectionist principle that rich countries can sell to poor countries, but poor countries cannot sell to rich ones.

3. There is a need to address parallel trade issues and reference pricing in a way that addresses the legitimate concerns of the research-based pharmaceutical industry. The political situation in the US could be different in six months time, if John Kerry is elected as president.

Governmental actors have suggested, however, that re-opening the discussion on the detail of the agreement is unlikely to be very productive. They have pointed out that some developed countries have now implemented the August 30 decision as it stands. This fact can be used to generate a policy debate about implementation. In order to maintain credibility, there is a need to capitalise on the achievements that have already been made.

b) Recent political developments around an amendment

The new TRIPS Council Chair will hold consultations on the topic of an amendment. Certain developing countries have already started consultations about an alternative possible basis to the August 30 decision. If developing countries do not develop alternatives, the August 30

decision will automatically be used. The substance of this alternative process has yet to be determined in detail, however.

Realistically, developing countries need to assess what value added might be gained through any new elements. They could seek to counterbalance the insistence on using both the Chairman's statement and the August 30 decision. A radically new approach would not be necessary, but some elements could be re-assessed. Elements that could be reconsidered include the requirement that countries notify product quantity to the TRIPS Council, and the requirement for notification of insufficient or no manufacturing capacity.

The Canadian implementation process has been very revealing, as the research-based pharmaceutical industry sought to 'correct' certain aspects of the August 30 decision which they considered to be too liberal. It is important to bear in mind that amendment would not just involve developing countries improving the existing draft. Any proposals for changes would probably be met with counter-proposals from certain developed countries. Tactically, it may be useful to have a strong alternative perspective from developing countries, for example calling for the removal of the Chairman's statement.

c) Countries must move ahead with implementation now, and not wait for an amendment

Although the Decision states that negotiations should be undertaken with a view to adoption of an amendment by a certain date, the waiver is not conditioned on an amendment being adopted within any set time period. It is certainly possible that the amendment could become something like the article 27.3(b) review: it will take a long time to reach any decision.

Furthermore, countries have had no experience of implementation, so the amendment should be postponed for the time being.

An amendment is not foreseeable in the near future. However, the waiver provides the legal certainty that countries need in order to take action.

International organisations which work to support developing countries are looking at states' legislation, and helping them to implement the solution on the basis of the existing waiver.