

A development agenda for implementing TRIPS:
Addressing biodiversity, food and health needs

Report on a seminar
held by the Quaker United Nations Office

Jongny-sur-Vevey, Switzerland
6-8 September 2001

Report prepared by Jonathan Hepburn.

A development agenda for implementing TRIPS:
Addressing biodiversity, food and health needs

This was the fourth seminar on TRIPS for WTO trade delegations and experts organised by the Quaker United Nations Office, Geneva. The objective was to provide an opportunity for informal discussion and dialogue on development, food, health and biodiversity issues in the context of TRIPS negotiations. All discussion was off-the-record. Former seminars addressed issues in Article 27.3(b) and development cooperation and intellectual property rights.

Contents

Part I. An overview of review and implementation issues: – basic challenges and opportunities

A. Introduction to TRIPS and development issues

Overview

B. Issues for developing countries

Mexico

Ecuador

Kenya

Other national situations

The importance of context

Intellectual property rights as a policy tool

Meeting objectives and principles in articles 7 and 8

Financial costs and development benefits

The need for more technical information

Part II. TRIPS and development needs

A. Biodiversity issues:

Background

Clarification of article 27.3b

Other policy coherence concerns

Transfer of technology

Biopiracy and traditional knowledge

Contracts and traditional knowledge

Declarations of origin

Codes of conduct, regulation and multilateral solutions

B. Food issues - the International Undertaking, *sui generis* systems and plant variety protection

Historical context and objectives

Financial mechanism

Conceptualisation of farmers' rights

Historical examples

Plant variety protection and 'obsolescence'

Implementation challenges for developing countries

Legal status and membership

Biosafety

A multilateral framework

The dynamics of the negotiations

Part III. TRIPS and public health – towards a Ministerial Declaration

A. Historical background

Introduction

B. The global context of access to medicines

Global distribution of pharmaceutical sales and HIV infection

Global distribution of patents

Therapeutic relevance of medicines

C. Principles and objectives:

The balance of public benefits and private rights

Articles 7 and 8

D. Price, patents and access to medicine:

Price and patents

FDI and patents

Invention and patents

Compulsory licensing

Parallel imports

Access to test data:

Counterfeit drugs

Bilateral pressures

The role of WIPO

The AIDS epidemic

E. The Doha Ministerial and beyond

From Seattle to Doha: towards a Ministerial Declaration?

Need for constructive responses

Policy coherence

Extension of transition periods for LDCs

A Ministerial Declaration on Public Health and TRIPS

Part I. An overview of review and implementation issues: – basic challenges and opportunities

A. Introduction to TRIPS¹ and development issues

Overview

Discussion about intellectual property rights often becomes confrontational, with advocates for strong intellectual property regimes and critics being drawn into two opposing camps.

Advocates say that intellectual property rights promote innovation, at the firm level. They are an incentive to research and development (R&D), both current and future, and they attract foreign direct investment flows (FDI). Many advocates also argue that stronger intellectual property protection leads to technology transfer, especially to developing countries, and that a strong intellectual property rights regime leads to economic and social development.

Critics of intellectual property rights, on the other hand, argue that strong protection hinders development, by restricting access to technology, and restricting legitimate imitations. The sole winners, in this view, are big corporations, who take advantage of the system to abuse the monopoly rights they are granted. Strong intellectual property protection regimes, it is argued, increase the cost of technology for importing countries.

There is a need to look more closely at certain questions: What is the innovation process? How does technology get transferred? How does FDI operate? And under what circumstances can technology transfer occur?

There is also a need to look at the reality of intellectual property protection in developing countries, especially given their different stages of technological development. In many poor countries, strong intellectual property rights have not been put in place.

Historically, it is possible to identify three major controversies on intellectual property:

1. The 19th century European controversy. This was a major debate between free-traders and those who favoured a patent regime. The result was the Paris Convention, signed by 14 countries. Compulsory licensing was the major compromise that made it possible to agree the Convention.
2. In the 1960s and 1970s, there was another period of controversy. Developing countries posed challenges to the existing system. They were very active in seeking a code of conduct on technology transfer.
3. The third major controversy is the current one, on TRIPS.

There is a need for a solid basis of information to respond to the concerns of developing countries about strong intellectual property regimes. Do these regimes promote, or hinder, technology transfer? Do they induce innovation in developing countries? Or promote FDI? What is their role in relation to R&D? What are the implications for health, biodiversity and food security? There is a need to look more closely at the role of TRIPS in poor countries, and whether they can take advantage of the agreement.

¹ For the full text of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), see www.wto.org

B. Issues for developing countries

Participants discussed specific country situations with which they were familiar:

Mexico

In the 1970s and 1980s, Mexico had a weak intellectual property regime, and a restrictive approach to intellectual property rights. There were requirements for government approval, registration and licensing of technology, ceilings on royalty payments and limits to patenting on pharmaceuticals and biotech. The rationale was to promote national capacity and reduce dependence on foreign enterprises, leading to an atmosphere that was unfriendly towards FDI.

During the mid-1980s, the government decided that this approach was counter-productive. A broad set of economic reforms was introduced, which included the intellectual property regime. The emergence of NAFTA and other free trade agreements were part of this context of reform.

Beginning in 1991, a series of laws were passed to reform the intellectual property regime. Protection was provided for both products and processes, including for pharmaceuticals. Protection terms were increased from 14 to 20 years for patents, and from 5 to 10 years for trademarks. New bodies were set up to deal with intellectual property protection and enforce the law. In 1996 a law was passed to protect plant breeders and in 1998 Mexico signed UPOV 1978. New administrative and judicial procedures were established. Intensive campaigns were conducted to combat piracy and counterfeiting, with raids on counterfeiters.

Considerable financial and human resources were needed over this whole period, to establish and implement the new intellectual property framework. It is nonetheless difficult to balance the costs and benefits against each other. On the one hand, major trading partners welcomed the changes, with greater certainty leading to more FDI, technology transfer and so on, and encouraging national R&D. On the other hand, empirical studies still remain far from conclusive, and it is hard to tell to what extent the positive trends have been due to other factors such as economic growth and development, or improved infrastructure. The government believes that the reform of the intellectual property regime was one indispensable element in a policy mix that included liberalisation, de-regulation and the enactment of legislation such as competition law. It is nonetheless hard to establish whether the proper balance has been reached between the costs of implementing reform and the benefits for society.

Ecuador

Ecuador joined the WTO in 1996, with little awareness of intellectual property. There was almost no institutional capacity to make operational those laws which did exist, nor were there incentives or policy objectives for intellectual property. Andean countries had however started developing common legislation at an early stage. Ecuador had also negotiated a bilateral

agreement with the US which was 'TRIPS plus', but which was ultimately not ratified by Congress.

As part of the implementation process, a legal and institutional framework had to be quickly established, following consultation with the main interested parties. These included industry, patent holders and artists, as well as groups who have traditionally been less involved in this area, such as environmentalists, non-governmental organisations and indigenous peoples' representatives.

Several factors drove Ecuador towards compliance with TRIPS: support from WIPO and industry, pressure to comply with international agreements, pressure from other states to protect intellectual property, and pressure from investors and others with economic interests.

Other aspects – not just the intellectual property regime – have been important in determining whether or not investors have been attracted to Ecuador. Intellectual property rights have in any case been important for protecting domestic inventors, musicians and indigenous people. Now, however, new concerns have arisen, in areas such as genetic resources, biodiversity and traditional knowledge.

Some investment is now occurring in Ecuador. The new intellectual property rules can be seen as an incentive to increase investment, not least in R&D. In the field of technology transfer, there has been some minimal development, but which is still meaningful. In balancing the costs and benefits, the government would consider the new intellectual property regime as generally positive.

Kenya

From 1914 to February 1990, Kenya's patent system was wholly dependent on that of the UK. Only a grantee of a UK patent could register a patent in Kenya, and this would only remain in force as long as it did so in the UK. However, the invention of the AIDS drug "Kemron" led to the hurried enactment of a new intellectual property law. An independent institutionalised system was set up to deal with patents in Kenya as a result.

A decision was taken to amend the Act, to correct the numerous typographical errors and to bring it into conformity with the Paris Convention and with TRIPS. In 1998, it was decided to repeal the Act, and replace it with a new Bill. Legal practitioners and NGOs commented on the proposed bill. They argued that the term of protection should not be increased to 10 years, that provision should be made for traditional knowledge and herbalists' rights, that the bill should be made consistent with government policy on food production, and that the proposed patent system would favour multinational companies.

The Bill lapsed, and was proposed again the following year. NGOs made further comments, to the effect that the Bill should address access to medicines, allow for parallel importing, contain the Bolar Provision, disallow patents for new use, and not go beyond what was already required by TRIPS.

AIDS was declared a national disaster in 2000, and the Ministry of Health became interested in the Bill. The Ministry argued strongly that no effort should be spared in making AIDS medicines accessible to those who need them. The NGO campaigns intensified, as did

lobbying from pharmaceutical companies. Huge public support for the bill resulted in demonstrations on the streets in Nairobi, and petitions favouring the importing of cheap AIDS drugs. The Act was passed after a parliamentary debate, and will be brought into force as soon as the implementing regulations are in place.

Other national situations

Participants also drew on their knowledge of national situations in Peru, the Netherlands, the US and Japan.

In Peru, there is still little evidence that the TRIPS-consistent regime has led to any benefits accruing, despite having been in place for some years now. Benefits have not appeared in the area of FDI; some innovation may have occurred but may not have been linked to the system of intellectual property rights; and some technology transfer has occurred but as a result of privatisation. Compared with Ecuador, and despite common legislation on copyright and plant breeders' rights, a different situation still prevails. This may be a result of the very restrictive intellectual property regime which existed in Peru before the 1990s, and which was also probably not the right way forward.

At the end of the nineteenth century, the Netherlands suspended patent protection. After building up industrial capacity, patent protection was then re-introduced after this period of development. Germany also had no patents on pharmaceutical products until 1960.

Historically, the US did not have any copyright regime, which allowed them to reproduce European books without difficulty. There was a need for literature from Europe, so this policy made sense for them at this stage of their development. Later on, pressure from US publishers eventually led to new laws which recognised copyrights on foreign works. Competition from cheap imports from Europe had led to general dissatisfaction amongst domestic publishers in the US, who lobbied for changes in domestic legislation.

Japan can be seen historically as having had tight restrictions on the licensing of technology. In one instance, a patent was only issued twenty-nine years after the application had been submitted, the time in between having allowed for the development of a massive semiconductor industry.

The importance of context

Participants strongly felt that the historical and developmental context of a country was of a paramount importance in determining whether a particular intellectual property approach would be successful or appropriate. The wide range of examples showed that even countries in the developed world have historically used a range of options to meet specific objectives at given times.

By contrast, it was pointed out that TRIPS adopts a 'one-size-fits-all' approach to intellectual property. Furthermore, it sets the minimum at a very high level. The 20-year patent term stipulated under TRIPS is even higher than that of some OECD countries – countries like Canada and Australia had to specifically amend their legislation in order to conform.

Even countries such as Mexico, Ecuador and Peru, which are similar in many ways, have had very different experiences of implementing TRIPS-style legislation. The different national contexts of these countries meant that the introduction of strong intellectual property regimes had different impacts in each country. Different national policy frameworks, different historical, legal and institutional settings and different trading relations all led to TRIPS implementation being experienced differently in these three countries.

Intellectual property rights as a policy tool

It was pointed out that intellectual property rights should be seen as a tool to achieve certain social goals – they do not exist as an end in themselves, as something intrinsically good, but are valuable insofar as they achieve certain societal ends. They can be considered as private rights which are given in the expectation of public benefits.

From the observation that developed countries have strong intellectual property regimes, we cannot draw the conclusion that strong intellectual property regimes necessarily lead to economic development.

Intellectual property rights should therefore be seen as one tool amongst others to achieve development objectives. In some cases, a particular approach to intellectual property rights can lead to benefits if combined with other economic policy tools, under the right circumstances. The particular approach adopted, however, should depend on broader development objectives.

In this spirit, one participant also questioned the tendency to always view ‘pirating’ or copying in negative terms. Some countries have large copying industries which may bring important economic benefits: it may be both arrogant and unwise to choose to ignore these lobbies.

Meeting objectives and principles in articles 7 and 8

A developed country participant pointed out the importance of bearing in mind the objectives and principles of TRIPS as set out in articles 7 and 8, and of implementing the agreement in ways that support development, health, etc. Governments in the North can be helped to move forward towards a more balanced discussion. In developed countries, intellectual property should not just be seen as something that only concerns the patent office, but should be seen from other perspectives, such as development, the environment, etc.

There was a sense that a lot of emphasis has been put on requiring developing countries to implement their obligations under TRIPS. However, developing countries should also ask developed countries how they are implementing TRIPS in the light of articles 7 and 8.

Least developed countries feel particularly disappointed that technology transfer objectives have not been met. They would like to be given their transition periods to be extended until such time as they cease to be least developed countries.

Financial costs and development benefits

There was a widespread sense that it had been difficult to quantify, measure or assess either the financial costs or development benefits of adopting a particular approach to intellectual property. This was true even of those countries which seemed to have had a successful experience of strong intellectual property protection. It was clear that there was a widespread concern to increase technology transfer, FDI, innovation and R&D. However, up to this point it has been relatively difficult to establish the exact impact of particular intellectual property regimes on these processes.

One participant described a study on Turkey, which aimed to research when technology transfer and FDI flows occur and in what context. The study concluded there was no positive correlation between strong intellectual property rights, FDI and R&D investment. Other studies have shown that often technology transfer and FDI go into a wholly owned subsidiary, and therefore provide little local benefit and can be removed instantly when the company wants to do so. Furthermore, if technology is sold to a wholly owned subsidiary, the transaction goes onto the profit/loss account, and no tax is even paid to the government. Technology transfer is not an automatic process, but can depend on other factors.

The need for more technical information

Participants questioned whether countries are actually collecting the data they need to properly assess static and dynamic gains and losses with regard to intellectual property.

Participants welcomed the ICTSD/UNCTAD joint project, which seeks to develop capacity amongst developing countries through collecting relevant information on intellectual property, and develop greater understanding of the processes involved.

It was clear that more facts and information were needed. Participants also expressed concern that, in the absence of detailed information on the processes at work, we should not be drawn into accepting the orthodoxy that strong intellectual property protection necessarily fosters development.

Part II. TRIPS and development needs

A. Biodiversity issues:

Background

There has been considerable debate about the relationship between TRIPS and the Convention on Biological Diversity (CBD). In 1996, India circulated a paper on this subject, arguing that TRIPS and the CBD are inherently incompatible. At this point, many countries began giving deeper consideration to the relationship between the two instruments.

Since 1999, discussions have moved to the TRIPS Council, with discussion of article 27.3b². In the view of many countries, there is a relationship between TRIPS and the CBD, although during the review different views were expressed on the nature of this relationship. Some countries consider TRIPS and CBD to be incompatible. Some believe TRIPS and CBD are “neutral, to the extent that they are related” (the position of the USA). Some countries argue that TRIPS and CBD should be mutually supportive, and we should therefore take action to ensure they are.

Some see a conflict between the requirement in TRIPS that countries allow patents on plants, animals and micro-organisms, and the requirement in the CBD for ‘sovereign rights’ for these.

Article 15 of the CBD is particularly relevant. This article gives states the authority to determine access to genetic resources, with the prior informed consent of parties. Last year, this requirement was extended to require that the traditional knowledge of indigenous and local communities should also be subject to prior informed consent. The CBD further requires the fair and equitable sharing of the benefits of traditional knowledge. Benefit sharing can be seen to have implications for:

- sharing the results of R&D
- sharing the benefits arising from use and commercialisation
- ensuring the “adequate and effective” protection of intellectual property rights
- sharing the results and benefits of biotech

Clarification of article 27.3b

Some countries have proposed a review or clarification of article 27.3b. This might seek to:

- Identify the genetic material that is involved in the article
- Include a requirement for the prior informed consent of the owner of the resources
- Include a requirement for fair and equitable sharing of benefits
- Take into consideration traditional knowledge.

² “3. Members may also exclude from patentability:

.....

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement”

Because some Members believe that it is not possible to agree to an amendment to article 27.3b, it was suggested that some language could be elaborated in the run-up to Doha to clarify countries' concerns. This could possibly be based on article 16.5 of the CBD, affirming that international and national legislation should not run counter to the CBD. Members may also be willing to discuss identification of genetic resources in article 27.1.

Some countries have argued that there is a risk of a major systematic problem arising if countries take measures to protect biodiversity which are then challenged under the WTO dispute settlement process. In this case, it has been suggested that the panel would be placed in the difficult position of having to make a ruling on a treaty which is outside their competence. It has been suggested that a clarification clause would also be in the interests of industry, who claim that the principles at stake are already widely accepted in practice. It was further argued that clarification would be helpful at a political and practical level.

A range of views was expressed in response to this proposal. These ranged from support to outright rejection, with some participants claiming this scenario was provocative and that Doha is not the appropriate forum for discussion of this issue. Others suggested that there was a need to establish firstly whether or not the CBD and TRIPS really are mutually supportive. Some proposed that there is a need for better information on the issues under discussion. A national regulatory response may be appropriate, or an amendment to the TRIPS agreement if countries are in consensus on this. It was acknowledged that there seems to be agreement over the basic principles, such as the protection of traditional knowledge and biodiversity, but uncertainty over the best practical solutions to achieve them. Questions such as the definition of traditional knowledge or prior informed consent remain unanswered. Some asked whether it was really wise to seek major revision of TRIPS at this stage, whilst also asking what specific benefits might arise from the proposed general language at Doha.

Other countries have argued that if the concerns around article 27.3b are not resolved in Doha, they should be part of the negotiating mandate for afterwards.

Other policy coherence concerns

Some participants drew attention to the fact that overlapping discussions have taken place in different fora. Co-ordination of these would lead to clarification and make it easier for companies to comply with their obligations. A mechanism to allow for this, such as a WIPO intergovernmental committee, would therefore be valuable.

Other participants agreed with these concerns, but noted that the application of the CBD for observer status in the TRIPS Council continues to be blocked by the US. According to the USTR, industry would not allow them to agree with this concession. Awarding the requested status would nonetheless make a valuable contribution towards policy coherence.

Transfer of technology

The transfer of technology is mentioned in article 1 of the CBD, as well as in the TRIPS agreement. Some participants emphasised that this mutually-supportive element from both agreements should be properly implemented.

Concern was expressed that debate on this issue frequently becomes polarised, and fails to promote real solutions. One side in this debate argues that there is no conflict, that everything is neutral, that intellectual property rights promote the objectives of the CBD and lead to technology transfer and innovation. The other side says that intellectual property rights support monopolies, favour big players over small ones, block access to technology and raise prices.

In practical terms, it is important to bear in mind that one technology is not necessarily covered by just one patent. For example, around 75 patents protect “Golden Rice” technology, which was genetically engineered for vitamin A. It can be very complex to transfer technology that is surrounded by this many patents.

Some scepticism was expressed about the article on technology transfer, as developed countries continually claim that they cannot transfer the technology because they do not own it. They argue that the technology is the property of the businesses holding the patents. It was noted that, frequently, developed countries do not take this article seriously and notify anything that they can think of as falling under this obligation. This argument led to the formulation of the language in article 66.2 of TRIPS, which stipulates that developing countries must provide “incentives” for technology transfer. However, others emphasised that the article nonetheless derives directly from the objectives of the agreement, and is mandatory.

Biopiracy and traditional knowledge

Participants asked how patents could be made to work in favour of the CBD, and operationalise its objectives. It is often argued that patents promote biopiracy and exploit traditional knowledge: however, this polarisation was felt to be unhelpful.

Some participants suggested that NGOs are often guilty of a kind of paternalism when working on issues of traditional knowledge. Some agreements have been heavily criticised, for example one that was formalised between the University of Georgia, a certain small company in Wales, and a Mayan community in Chiapas. This agreement was vilified by some NGOs in a way that almost implied the community was incapable of deciding for themselves whether they should have an agreement or not. It was pointed out that this particular agreement was far from being the worst or more exploitative case. Others participants noted that this project led to strong local resistance despite being promoted as a good example of a company seeking prior informed consent. The project, they claimed, exacerbated existing tensions in the region.

It was suggested that regulation is designed under the assumption that industry is heavily dependent on genetic resources, when in fact this may not be the case. Furthermore, it was suggested that much bio-prospecting is done with no commercial concern or objective. Other participants pointed out that industry does demonstrate a willingness to come to countries with abundant genetic resources. Again, there is a lack of detailed information on this. It would be useful to study commercial use and look at the potential value of biodiversity to companies. It was suggested that we need to look more realistically at industry behaviour, researching past practices so as to be able to make future policy.

It was suggested that we should consider traditional knowledge in terms of what communities themselves really want. Others – such as paternalistic NGOs - often hijack their voice. There is a need to explore further the meaning of concepts such as prior informed consent or best practice. These terms are often used very casually, but there has been little attention to what they mean in practice. People in indigenous communities want different things, in fact – some people may just want a commercial deal, and be interested in receiving the money. Others may see their job as about healing people: they want to heal as many people as possible, and it is not important to them what country those people are from.

Contracts and traditional knowledge

Participants discussed whether bilateral contracts between indigenous and local communities could help to address some of the dangers of exploitation and bio-piracy. However, participants questioned whether a contract is in fact as unproblematic as is sometimes supposed. In the event of the parties to a contract being grossly unequal, a contract does not solve the problems but just makes them different. This is the case whether a musician, an author or an indigenous community is contracting with a multinational company.

It was pointed out that, at a practical level, lawyers of pharmaceutical multinationals have far more knowledge about patents than indigenous communities. Indigenous people often have great difficulty getting to court, or getting a visa to go to another country.

One solution therefore would be to develop appropriate guidelines or requirements, either at the national or multilateral level.

Declarations of origin

There was some consideration of a declaration of origin for patents. It was suggested that, although there was no objection to this in principle, practical problems dissuaded companies from doing this. For example, in the Andean region, there is commonality, so it may be inaccurate to state that a plant comes from Peru if in fact it comes from Bolivia. It was suggested that any need to know the origin of genetic resources would be covered by patent law on disclosure, and that there is therefore no need for requirements on benefit-sharing or identification of origin at the multilateral level.

Participants suggested that one solution might be harmonisation of disclosure requirements. However, there would need to be an additional requirement in patent laws for this, as currently there is no obligation on companies to disclose this information. There are different views on whether such a requirement would be TRIPS-consistent, as there are different interpretations of the requirements under articles 27 and 29³.

Codes of conduct, regulation and multilateral solutions

Some participants pointed out that, in industry, there is no objection to principles such as prior informed consent. Companies discuss concerns such as traditional knowledge and access

³ Articles on “patentable subject matter” and “conditions on patent applicants”.

regimes. They would appreciate greater clarity on these issues, especially as there is an information cost for companies, depending what is being 'bought into'. Currently, different intergovernmental organisations and non-governmental organisations have proposed different solutions. Companies have therefore been proposing, and thinking about, a code of conduct which sets out their rules.

Others observed that the FAO has been interested in developing a code of conduct on biotech for about ten years. It would be valuable if the FAO and the biotech industry could begin or develop a dialogue on these issues.

It was pointed out that the EC tends to argue against "burdensome" regulations, on the basis that this will hinder access to genetic resources. But this argument is taken so far that any attempt to regulate is seen as an obstacle. It was argued that we cannot just assume benefit sharing and the seeking of prior informed consent will occur. Opponents of multilateral solutions argue that governments should deal with access to genetic resources either contractually or through a bilateral or regional response. However, in order to enforce this in third countries, governments should develop multilateral solutions.

B. Food issues - the International Undertaking, *sui generis* systems and plant variety protection

Historical context and objectives

The International Undertaking on Plant Genetic Resources for Food and Agriculture (IU) was agreed on 1.7.01. The IU goes back to 1983 as a non-binding instrument, and was initially proposed by India. It was recognised that there is a need for the conservation of agro-biodiversity in agricultural research, and especially in plant breeding. Furthermore, the contributions of small farmers had not been recognised, especially those in developing countries. All countries and regions have their own plant genetic resources, but some places are heavily dependent on plant genetic resources from elsewhere.

The CBD did not address farmers' rights or the special needs of agriculture. The FAO decided that there was a need for an alternative to the CBD, which would cover plant genetic resources for food and agriculture and be in harmony with the CBD. There is also a relationship with TRIPS: it is even possible to see article 15 of the CBD as being a reaction to the influence of intellectual property rights. This article allows for benefits to be captured from the product, while sovereign rights over the raw material remain.

The bilateral arrangements of TRIPs and the CBD do not work for agriculture and agro-biodiversity, as the profit margins involved are too small. Furthermore, it is important that no one should have a monopoly, as everyone needs to have access to food and have proper food security. The IU therefore creates a multilateral system whereby everyone pools their resources and benefits are shared. Not all world crops are important to food security, and so just some crops are included on the FAO list. However, controversy has arisen over the scope of this list.

It is hard to establish who initiated the IU negotiations, however developing countries may have been important in its inception, as might NGOs. After the Green Revolution, there was a widespread recognition that countries were faced with serious problems with the predominance of single crops and consequent diminished biodiversity.

Financial mechanism

The IU provides a financial mechanism, as in the CBD. Priority is given to small farmers in certain areas and categories. For about two years during the negotiations, the mechanism for commercial benefit-sharing was tied to intellectual property rights. However, three or four countries argued that there was a conflict with TRIPS. The reference to intellectual property rights was therefore dropped, and benefit sharing is now triggered by commercialisation. The definition of plant genetic resources remains problematic, in particular with regard to questions about genetic parts and components.

Conceptualisation of farmers' rights

Farmers' rights in the IU are different from intellectual property rights: they are considered as a 'freedom to operate' - to save seed, and to use and exchange seed. Governments should

ensure that this can occur. Farmers' rights are not seen as incompatible with plant variety protection, but rather are seen as being complementary. In the Indian *sui generis* legislation these two are also seen as complementary, in that intellectual property rights, particularly patents, could undermine their own value if they are extended too far. There is a need to protect farmers' rights so as to maintain long-term biodiversity.

Historical examples

The rationale for the IU can be demonstrated by examples from history: the Irish Potato Famine resulted from a new variety of potato blight which destroyed the main potato that was being used, as well as killing 30% of the population. Another example is the recent attack on the main grain variety being used in the United States. In this case, the crop was devastated by a new species of pest.

Plant variety protection and 'obsolescence'

Plant variety protection does not have to be equated with patents. Plant variety protection arguably has a negative effect, by breeding for uniformity and only making marginal improvements to the existing plant. Furthermore, plant variety protection encourages a kind of obsolescence, whereby any variety has a short life-span because it is soon replaced by another variety. By contrast, small farmers constantly cross-breed plant varieties; when they buy new seed it is often also intended for cross-breeding with existing stock. The market is biased towards seed which meets established requirements for distinctiveness, uniformity and stability, however.

Implementation challenges for developing countries

The farmers' rights clause in the IU has remained unchanged since 1998. However, implementation is left to the national level, and developed countries may not implement the agreement in the same way as developing countries. There is a need for developing countries to firstly implement farmers' rights at the national level, so that other countries can go on to use this experience.

There is currently room for different interpretations of the text. By moving ahead with implementation at the national level, developing countries can feed back their experience of implementation into future discussions. The situation is similar to that faced by developing countries when considering implementation of TRIPS article 27.3b. There is a need for developing countries to develop their own systems first.

Legal status and membership

The IU will be a legally binding instrument, according to article 14 of the FAO Constitution. In principle the text should go now to the FAO Conference and be adopted. Because it will be a binding instrument, there have been proposals to change the name to "Convention.

There is a membership of 160 countries of the FAO Commission on Genetic Resources for Food and Agriculture that negotiated the revision of the IU. 113 countries are adherents to the non-binding IU of 1983. The non-adherents include those most concerned about the intellectual property rights element.

Biosafety

It can be argued that there are two main views on the role that intellectual property rights play in underpinning change:

1. The first view is that we'll invent ourselves out of any environmental problems we find ourselves in, with biotech etc.
2. The other view is that small farmers and their livelihoods are important; there is a need for this social and economic basis.

Biosafety is not addressed in the IU. However, a code of conduct on biotech is still in draft in the Commission on Genetic Resources.

Under the Indian legislation, breeders are liable for any varieties they produce which are not up to expectations, and must pay damages. It was recognised that it is good to preserve the option of choice, so that the small farmer can choose to continue as a small farmer if so wished. It is good to have lots of small farmers in the world, because of the implications for biodiversity. The Indian legislation is specifically tied to the WTO: however, questions have been raised over the wisdom of this, as it might be interpreted as implying that farmers' rights are in some way subject to the WTO.

A multilateral framework

In the last negotiations, much emphasis was placed on the idea of the contractual relationship. Now, although some people believe that disputes will be resolved as contract law, others do not see this as a promising solution.

It is very hard to identify the origin of many plant genetic resources, as in many cases they have been moving around different regions for some 8,000 to 10,000 years. To try to track the origin would therefore be very difficult and expensive: one objective of the IU is to avoid this. At the moment, the issue has been avoided. The system is in reality a multilateral system, although the word contract has been included to satisfy some countries' demands. There are likely to be further discussions on this in the Governing Body of the IU. However, there would be little point in proceeding with the IU if tracking of genetic resources becomes necessary: in practice, this would mean it just becomes another framework for bilateral negotiation.

The dynamics of the negotiations

During the negotiations, there has been an alliance between the G77 and the EU. Japan is supporting the G77 and EU position, broadly, although they did waver recently. Three or four countries have been delaying the process considerably by being very cautious about any detail which might possibly have an impact in the WTO. A group of countries which is

approximately the same as the Cairns Group would like the IU to be subject to the WTO; however, no one else favours this approach.

The US may sign but not ratify the IU, which would raise the question of what happens with non-parties. Developing countries are determined that non-parties should not have any rights. The US and others have been frequently stalling the process with minutiae. Genetic parts and components is the outstanding issue, which could perhaps be a decisive issue. However, as the EU and G77 agree on this it is unlikely to destroy the agreement.

Controversy over the scope of the list of crops could still be a problem, however. The EU would like all crops to be included. There are several rationales behind this position. The principle one is that of the interdependence of all countries and regions for the agrobiodiversity they need to maintain the viability of their agricultural systems. Even if a country has a lot of agriculturally useful biodiversity, a disaster could nonetheless occur which would wipe this all out. In these circumstances, the varieties would have to be brought back from an *ex situ* collection.

Part III. TRIPS and public health – towards a Ministerial Declaration

A. Historical background

Introduction

Participants contended that the history of the TRIPS agreement resulted from a shift in the pattern of world trade. Innovation was seen as becoming increasingly important in world trade, and there was a need to protect it. The Reagan administration of the US, and later the EU and Japan, saw this as a core part of the world trading system. They would not finalise the Uruguay Round without strong rules on intellectual property. Pressure was applied to developing countries to make them accept. There was a notable lack of participation from health representatives, the WHO in particular being absent from the negotiations. TRIPS resulted, therefore, from considerable pressure that was applied to developing countries, and from a compromise deal that included concessions for developing countries in the areas of agriculture, textiles and the dispute settlement process.

From January 1st 2005, developing countries should provide patent protection on pharmaceuticals. From 2006, LDCs should also do so. Up until then, the ‘mailbox system’ is in operation – pharmaceutical companies can submit applications to developing country patent offices, which are then held in a queue until the new patent system is operationalised. Gradually, the supply of generic drugs will be reduced, and the pool of patented drugs will increase. The possibility of obtaining low-cost drugs will therefore be reduced.

The US, Switzerland, and up to a point the EU, have pressured countries to implement TRIPS quickly. The US is not only pressing for ‘timely’ implementation of TRIPS, but also questions the advisability of extending time periods.

B. The global context of access to medicines

Global distribution of pharmaceutical sales and HIV infection.

Pharmaceutical sales in developing countries account for only 8% of the total worldwide market share. Sub-Saharan Africa meanwhile accounts for 83% of the world's HIV infection. The total number of people infected is 33.4 million. Europe, North Africa and Japan account for 84% of the pharmaceutical market, whilst Africa represents 1.3% of the world market share.

Global distribution of patents

Companies or individuals in industrialised countries hold 97% of the patents granted worldwide, and 80% of the patents granted in the South belong to companies or individuals in the North.

Therapeutic relevance of medicines:

Participants argued that innovation does not in itself necessarily bring therapeutic relevance:

Out of 2257 new products which were brought to the market in France between 1981–2000, only 7 products (or 0.13%) represented a real therapeutic breakthrough. 63% of new products were 'me-too' products, i.e. they were products which did not in fact bring anything new to the therapeutic arsenal. (For the remaining 30% of products, the therapeutic relevance remains unclear).

There is also a lack of R&D which is relevant for people in developing countries. Between 1975 and 1997, 1223 new chemical entities were discovered, of which:

- 378 were therapeutic innovations
- 13 were for tropical diseases
- 5 were the result of veterinary research
- 2 were developed by the US army
- 3 were the result of R&D by 'research-based industry'

It was pointed out, although multinational companies argue they provide R&D, they do not in fact do so for many diseases which afflict developing countries. Participants reflecting on industry's views acknowledged that the intellectual property system alone will not induce investment where there is no market. They noted that, in order to encourage investment in diseases such as TB and malaria, various initiatives are looking at public-private partnerships, involving for example the creative use of intellectual property rights. Intellectual property rights should therefore not just be discounted.

Other participants suggested that although there is much promotional activity around public-private partnerships, these are not always useful solutions. There are many diseases in the South for which there is no market, and for these there is a need to have a public sector response.

C. Principles and objectives

The balance of public benefits and private rights

There is a complex relationship between R&D, innovation and the role of governments. In the US, less than 5% of the drugs introduced by the top 25 pharmaceutical companies were therapeutic advances. 70% of drugs were developed with government involvement. Some participants argued that an analysis of pharmaceutical company spending shows there is a massive emphasis on marketing, compared to the amount actually spent on R&D.

Other participants also drew attention to the fact that although the TRIPS agreement awards numerous private rights, it does not lay down any corresponding obligations. For example, there is nothing in the TRIPS agreement to determine where the patent rent goes: it might go on exorbitant annual compensation packages to be awarded to CEOs, or might be spent on the development of hair products. It was argued that there is a need to reconsider the balance of rights and obligations embodied in the TRIPS agreement.

It was emphasised that intellectual property rights have different effects, depending on the context in which they are applied. Factors such as the size of the market, the extent and nature of government intervention and many other factors also play a role. There is no single answer as to what kind of patent regime should be used. The TRIPS agreement nonetheless proposes, and the US argues, that all countries should have the same industrial policy approach in this respect. The TRIPS agreement offers a 'one-size-fits-all' approach.

Other participants acknowledged that drugs on HIV/AIDS do have their origin in public funding. They pointed out that the public sector puts technology into the private sector because there is a sense that it would not be appropriate for them to develop and sell drugs. Participants sought to emphasise that this is not a give-away, and that the National Institutes of Health (NIH) in the US licences products to the private sector. It was suggested that it would be more appropriate to see the situation as being one in which the NIH has simply made some bad business deals in the past.

Participants noted that there has always been debate over the proper balance of public and private interests, throughout history.

It was observed that there is a need to look more flexibly at our concept of development. It is important to see public health as both an input and output of development. The costs of public health costs have an impact on development, as well as providing an indicator for measuring development in a given country.

Participants emphasised that medicines are not like CD Roms, Barbie dolls or computer games, but instead are a matter of life and death for millions of people. They also argued that there is a dire imbalance between the sanctity of patents and people's health. Access to essential medicines should not be a luxury reserved for the wealthy, but should be reinforced as a critical component of the human right to health.

Articles 7 and 8

Developing countries argue that article 7, on the objectives, rights and obligations of the TRIPS agreement, has not yet been fully operationalised. Some participants therefore made the recommendation that, at Doha, there is a declaration to the effect that nothing in the TRIPS agreement should prevent Members from taking measures to protect public health.

Other participants observed that Article 8 could be compared with the exception clause in GATT article 20b and the agreement in services. However, an important difference is that Article 8.1 seems to be like a closed circle: it is a tautological statement. It was suggested that is somewhat nonsensical to have an exception clause that contains a further clause requiring compliance with the agreement as a whole.

D. Price, patents and access to medicines

Price and patents

It was noted that problems of access to medicines are caused by several factors, and not just by price. Factors include:

- Inappropriate selection and use
- Lack of R&D
- Supply problems
- Regulatory problems
- Production problems
- Prohibitive drug prices

Two basic points were noted with regard to patents and drug prices: firstly, that generic drugs are usually cheaper, and secondly that competition is effective in reducing prices.

Some participants emphasised the need to find practical solutions to problems as they arise. They gave the example of sub-Saharan Africa, where not all TB drugs are under patent. In this case, there is no problem with patents: the drug just needs to be purchased. So at a practical level, access difficulties in this case would be simply a procurement problem.

The US delegation argues that patents are not the key issue in determining the price of medicines, tending to emphasise instead that the infrastructure is important, and price is just part of a larger picture. Participants attacked this argument as being particularly weak, and pointed out that there is no other product whose sales are going to be more affected by price than life-saving drugs. Everyone who can afford to buy such a product will do so: therefore each incremental price reduction will mean more people will buy it.

It was pointed out that the TRIPS agreement does nothing to reduce prices, except through measures such as parallel importing and compulsory licensing. It also does not inhibit countries from imposing price controls.

FDI and patents

It is often argued that intellectual property encourages FDI: however, there does not seem to be any evidence to support this claim. A study by the UN TNC group showed that in fact there was a direct correlation between those countries that are the worst violators of intellectual property rights, and the highest levels of FDI. Although in itself this correlation does not prove any direct causality, it does nonetheless show the importance of context. We can say that a complex set of factors determines FDI flows, and not just intellectual property rights.

Invention and patents

Participants noted that there is no study which indicates a link between invention and patents. A study by Duke University did interview a number of inventors, and tried to find out what

prompted them to invent. The study came to the conclusion that they invented things because they were essentially curious people. This is not to say that financial gain played no role, as in many cases it was one of the factors at work: however, the study found that it was not possible to find any direct link between invention and patents.

Invention has now become more commercialised, especially in the pharmaceutical sector. It is plausible that patents play a role in the institutionalised form of invention that takes place in large corporations.

The recent legal case involving the UK company Biogen brought into question whether this pattern of behaviour can indeed be described as ‘invention’. The UK’s Court of Appeal ruled that it was not, as the usual aspects of invention such as risks, or a gamble, were not involved. Rather this was a calculated commercial process which was planned and took place over a long period of time. The House of Lords later rejected this interpretation.

Assuming, however, that it is true that patents encourage invention in OECD countries, this nonetheless tells us very little about the process in developing countries.

Compulsory licensing

Compulsory licensing is the main instrument in the TRIPS agreement which developing countries can use if they wish. The relevant provision is article 31⁴.

There has been considerable economic pressure applied to those countries that have threatened to use compulsory licensing. South Africa has even said that compulsory licensing may be perceived in a negative way by foreign investors. Some participants expressed their surprise at this, recalling that the CEOs of both Mercedes-Benz and Anglo-American Mining have publicly expressed grave concern about the AIDS pandemic, and about the impact it is having on their bottom lines.

The fact that no one has issued a compulsory licence is also a result of technical factors. Legislation on pharmaceuticals can become ensnared in the court process. Participants pointed out that countries need to develop a streamlined process. The US has a particularly easy system, in which no administrative process is involved.

Participants recommended that at Doha, governments should confirm the authority they have to issue compulsory licenses, and seek confirmation that they will not be penalised for doing so.

There was discussion of whether a compulsory licence can be issued for a country’s own domestic requirements, but which is satisfied by a manufacturer in a second country. This may lead to problems for the second country if a narrow interpretation of article 31f is applied. This article stipulates that production should be “predominantly for the supply of the domestic market”. It was proposed that Article 30 should be interpreted in such a way that the exporter is one of the “limited exceptions” in this case. The example was given of a case whereby the Netherlands wished to export medicines for humanitarian purposes to sub-Saharan Africa. In this case, there would be a need for a clarification of whether this would be

⁴ “Other use without authorization of the right holder”

considered as a 'limited exception' under article 30 ("exceptions to rights conferred"). Participants recommended that this be clarified in a Ministerial Declaration at Doha. Governments could consider what language might be formulated to express this.

Participants noted that, nowadays, no one will disagree that compulsory licensing is in the TRIPS agreement. In the past, industry and the US government exerted pressure on some intergovernmental organisations to oppose this interpretation. However, the provision on compulsory licensing is clearly in the agreement, and it is not possible to deny this.

Some participants expressed a personal sense that it was wrong to compel someone to do something in this way. When a country issues a compulsory license they are telling someone to produce something, and to give up their trade secrets. They felt that, human nature being as it is, people are unlikely to respond in a charitable way, and would not be inclined to co-operate further in the future. They also pointed out that companies will see business options differently if there is no exclusivity on a product, just a royalties stream.

Other participants recalled that, if a country in the South issues a compulsory license, this is unlikely to have a devastating effect on investment decisions, because the market for pharmaceuticals is mainly in the North.

Parallel imports

Article 28, on rights conferred, establishes the right of patent holders to make parallel imports. Countries follow one of two different policy regimes with regard to the exhaustion of rights, either a policy of "national exhaustion of rights" or "international exhaustion of rights". The US follows a policy of international exhaustion of rights, as does Japan. Switzerland's Supreme Court explicitly ruled that articles 6 and 28 of TRIPS, read together, allow for Members to choose and adopt their own policies in this respect. It is permissible for a country to adopt their own national policy.

Tiered pricing schemes have often been mentioned in connection with parallel imports: however, these can be implemented whether parallel imports are being made or not.

Access to test data

The US and Europe would like article 31.1 to be interpreted as requiring data exclusivity. However, the article does not have to be interpreted in this way. Participants encouraged developing countries to be aware that this issue is at the top of the pharmaceutical companies' agenda, and that this narrow interpretation has already been incorporated explicitly in the NAFTA agreement. Developing country participants agreed that the question of access to test data is a crucial one.

Counterfeit drugs

The pharmaceutical industry often states that generic drugs may be of low quality: however, it was argued that every government should have policies on the health and safety of drugs. Some participants expressed concern at this view, observing that it is difficult for

governments to control piracy. They argued that the luxury packaging of brand name goods provides a useful indication that these are of high quality.

It was recognised that, although it is true that there is a huge international trade in counterfeit goods, this is no reason to particularly equate parallel imports with counterfeits. A government can stamp as authentic those goods which are authentic. Any drug import programme, be it parallel importing or not, must involve safety controls. A parallel import programme is simply one way in which to import a drug. It was argued that industry is therefore using this argument as a political instrument to block cheap imports.

Others noted that an international scheme exists to combat counterfeit goods. Some countries have adopted a policy of limiting parallel imports to the goods of, for example, five companies: this enables them to easily check the source.

Bilateral pressures

Participants pointed out that the US has continually threatened to impose sanctions on countries that try to use measures such as parallel imports or compulsory licensing. The EU also exerted similar pressures, but has more recently drawn back from this. South Africa, Thailand and other countries have experienced this pressure, which is not ephemeral but is long-term and significant.

Developing country participants also spoke of their own experiences of bilateral pressures. They described how USTR had threatened them with being ejected from partnership schemes, or refused aid. They also described how they had been threatened with “TRIPS plus” legislation through bilateral pressure, and the threat of economic sanctions. For many developing countries, exclusion from a preferential access scheme may equate directly with the loss of hundreds of jobs, for example. Preferential access agreements have conditionalities; and because they are outside its framework, WTO rules do not apply.

Other participants sympathised with these experiences, and pointed out that bilateral pressure from the US is the main impediment to governments wanting to act. It is not illegal under the WTO to threaten to withdraw GSP preferences, so there is often little that governments can do. Bilateral pressures of this sort may always be there: NGOs can at least expose this kind of arm-twisting, making it hard for democratic governments to continue. However, it would be possible to make a statement in the WTO affirming that Members shall not threaten unilateral measures of this kind.

The role of WIPO

WIPO was identified as being especially instrumental in the development and implementation of national policies on intellectual property. Some participants acknowledged that WIPO was heavily reliant on funding from the US and from industry, but denied that this meant the organisation was therefore necessarily beholden to these interests. There was recognition of the potential value of greater dialogue and exchange of views, both with other intergovernmental organisations such as WHO, and also with non-governmental organisations active on issues such as access to essential medicines.

Participants spoke of their experience of the pressures at WIPO. They noted that the Secretariat often comes under pressure from certain Members. There is a tendency to give advice that tends to focus on intellectual property rights as an end in themselves, and not just as a tool to meet public interest objectives in developing countries. In the process of developing legislation in developing countries, WIPO has been recommending pure “national exhaustion” laws. There is an internal bias towards high intellectual property protection, which reflects developed country perspectives.

Patent laws are flexible: it was suggested that governments must take far more careful steps before granting patents. Currently, developing countries often rely heavily on the decisions of patent offices in developed countries. It was suggested that developing countries should exercise caution before uncritically accepting advice on patent systems from organisations such as WIPO. UNCTAD and the WHO are now seeking a more development-orientated approach.

The AIDS epidemic

At the time that the TRIPS agreement was negotiated and drafted, no one anticipated the fact that 35 million people would soon contract AIDS and be dying. Governments were encouraged to do all they can to address this epidemic. It was suggested that the long-term research interests of the pharmaceutical industry should take a back seat to this disaster. Developing countries emphasised that the AIDS crisis is a particularly dramatic illustration of the wider public health crisis they are currently facing.

E. The Doha Ministerial and beyond

From Seattle to Doha: towards a Ministerial Declaration?

Some participants expressed their desire to see a new Round launched in Doha, although the breadth of any such Round would be debatable. They emphasised their conviction that another Seattle would be a catastrophe, especially for developing countries.

After the failure in Seattle, a process began on January 1st 2001 which aimed at rebuilding confidence. A fundamental breach of confidence had taken place, especially with those developing countries that had been excluded from the Green Room process (dominated by the EU, US, Canada and Japan). In the past the results of this process had been presented with a dictate and not as a bargain. At Seattle, developing countries rejected their exclusion from the process. A package was therefore needed to restore confidence.

“Implementation” was used as a catchword for several issues, but in general as a means to discuss the problems faced by developing countries in implementing the Uruguay Round agreements, including TRIPS. Early on, developing countries began to table problems of interpretation, and proposed various solutions. They also raised under this rubric what they had seen as the benefits of the Uruguay Round (market access, textiles etc), which had not been delivered. Developing countries sought a rebalancing of the unequal agreements without necessarily entering into a new Round.

Developing countries put some 200 proposals on the table before Seattle. A process began from there. Developing countries wanted a debate to address the problems of protectionism. Meanwhile, developed countries emphasised that the developing countries had signed the Uruguay Round agreement, so now must implement it. They also argued that the issues raised by developing countries were essentially technical in nature, and therefore should be sent to the various technical committees of the WTO. It can be argued that this was in fact just filibustering: an attempt to delay resolution of these concerns.

The subsequent process has been going on now since 3 May 2000, with few real results. Attempts have been made to distil certain “deliverables” or “do-ables”, but this has led to very little. The G7 group of mid-level developing countries sought to develop a breakthrough, but did not manage to do so. Agriculture and services negotiations are still ongoing. The Ministerial Conference in Doha now provides the opportunity for a new impetus.

The Cairns Group is demanding broader agriculture negotiations, as a condition for having a broad Round. They are demanding an ‘article 20 plus’ negotiation. However, the EU is saying that it is not necessary to ‘pre-negotiate’ this issue, and Members should continue on the basis of article 20. There are also some Members who would like trade and investment, trade and the environment, and trade and labour, to be included as part of the negotiations.

At the end of July, governments had a “reality check”, as it was realised that in no area had consensus yet been reached. In each area, it was possible to identify three groups of countries: those that do not want to include it, those that really do want to include it, and thirdly a group of pragmatics who are open to include the area in response for other concessions.

Attention is now turning to the question of how the differences can be bridged. After the summer holidays, the Chair began intensive consultations with Members. He will present a list of elements for negotiation. At the moment, little convergence is taking place, however. It can be argued that major partners such as the EU and the US must give something, without asking for something else in return. The US can be seen as filibustering, and the EU as hiding behind them. The only exception is the area of public health. A session on implementation will be held soon: however, if no concessions are made, the run-up to Doha may not be a promising one.

Need for constructive responses

Some participants expressed scepticism about some of the proposals made. They argued that, as there is already hesitancy from South Africa to use compulsory licensing at all, it is unlikely that they will seek to take advantage of an interpretation permitting compulsory licenses that authorise imports from a third country. It was suggested that the new interpretation would just be academic, if countries do not take advantage of the legal procedures open to them in practice.

However, other participants emphasised that there is a need not to become defeatist, and to remember that the rules on intellectual property do also matter in practice. They noted that public opinion had successfully discouraged the US from pursuing further the dispute settlement process with Brazil. Others expressed the opinion that governments have had the freedom to do more than they have done hitherto, and that it is not just TRIPS that stands in the way of addressing the AIDS crisis. Compulsory licensing rules do matter, as illustrated by the situation in Brazil, and the applications being filed in Malaysia and South Africa. Furthermore, the rules on intellectual property will become increasingly important after 2005, when there is a diminished pool of generic medicines.

Policy coherence

It was agreed that there is a need for greater policy coherence on these issues. One solution might be for the TRIPS Council and the WHO to work together to research the impact of intellectual property rights on health. Another important step might be for governments to develop inter-agency working groups to look at issues such as the impact and future policy directions of rules on intellectual property.

Extension of transition periods for LDCs

In 2005/2006, a situation will arise whereby the supply of off-patent drugs will gradually disappear. LDCs are therefore seeking a minimum 5-year extension of the transition periods. However, they would like to be able to extend these periods indefinitely, or to that point at which they are no longer LDCs.

A Ministerial Declaration on Public Health and TRIPS

Participants suggested that there is a need to address in a technical way what approach should be adopted in Doha: amendment, interpretation, or some other approach.

Many welcomed proposals for a separate Ministerial Declaration on public health and TRIPS. This could accompany a general Declaration, which could also cover implementation issues, could be agreed up-front and include a commitment to deal with these issues in the first year or so of negotiations. There is a precedent for a separate Ministerial Declaration, namely the 1998 declaration on e-commerce, which was adopted at the insistence of the US.

In some areas, the declaration would be legally binding, in others it would just be political, but would in any case serve as a signal to panels.

All participants agreed that, at the very least, it would be appropriate for any Declaration to speak of the horrors of the AIDS pandemic. There is a need to be clear what the situation is and what the practical implications are.

Some expressed their belief that a Ministerial Declaration would be absolutely essential. They suggested that it would be very useful to try to develop a binding declaration on TRIPS and Health now, to clarify key positions.

LDCs emphasised that it is important to use the current momentum for a good declaration on health, and to ensure this covers health questions in general. NGOs can help to ensure high exposure of this issue. A Declaration would give governments the tools they need for flexibility. It would allow them to draw upon the high visibility being given to the AIDS issue to make more general points about health.

Others welcomed the renewed impetus that a Ministerial Declaration could give, and the political guidance that is needed for change. They noted that on this issue there is no time for interpretation to be provided through the formal channels, such as through the TRIPS Council. Some expressed the opinion that a Ministerial Declaration may be the last opportunity for the US and the pharmaceutical industry to save the TRIPS agreement, arguing that even those countries with positions that are close to the industry lobby cannot afford to continue ignoring public opinion on this issue.