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Council for Trade-Related Aspects of Intellectual Property Rights

SPECIAL DISCUSSION ON INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

Held in the Centre William Rappard
during the meeting of the Council from 18 to 22 June 2001[1]

Chairperson: Ambassador Boniface Chidyausiku (Zimbabwe)

Table of Contents: Page Nos.

[1] The minutes of the meeting of the Council held from 18 to 22 June 2001 will be circulated as document IP/C/M/32.

Table of Contents: Page Nos.

Introduction by the Chairperson

1. The Chairperson said that, at the previous meeting, the Council had agreed, following a request from Zimbabwe, on behalf of the African Group, to devote a full day to a special discussion of intellectual property issues relevant to access to medicines during the course of the present TRIPS Council meeting. Recalling that, when this matter had been discussed at the Council's last meeting, two specific sub-items had been identified as topics on which Members would exchange their views. One was the interpretation and application of the relevant provisions of the TRIPS Agreement with a view to clarifying the flexibility to which Members were entitled under that Agreement; and the other was the relationship between the TRIPS Agreement and affordable access to medicines. As also discussed at the informal meeting on 21 May, delegations should feel free to address also any aspect that they considered relevant to this item.

2. As requested at the informal meeting of 21 May, the Secretariat had prepared, prior to the present meeting, an information paper listing the meetings relevant to intellectual property and access to medicines, whether organized by intergovernmental or non-governmental organizations, in which the Secretariat had been involved over the past couple of years; what issues had been discussed at those meetings relating to TRIPS; and where additional information about those meetings could be found, for example on web-sites or published documentation. This paper was available in document JOB(01)/82.

3. The European Communities and their member States had submitted a paper on the relationship between the provisions of the TRIPS Agreement and access to medicines. This paper had been circulated a week prior to the present meeting as document IP/C/W/280. On 19 June, Brazil had also submitted a paper on the matter, which was also sponsored by the African Group, Barbados, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, the Philippines, Peru, Sri Lanka, Thailand and Venezuela. This paper would shortly be circulated as document IP/C/W/296.

4. The following statements were then made:

ZIMBABWE (ON BEHALF OF THE AFRICAN GROUP)

Two weeks ago, world attention focused on the Heroes Acre in South Africa where young Nkosi Johnson was laid to rest. In a special way, young Nkosi had become the personification of the plight of millions of people who have died and millions more waiting to die because of HIV/AIDS. Indeed, young Nkosi reminded us of the plight of millions of young children orphaned by AIDS and of many who will not celebrate their fifth birthday; of families robbed of the source of their livelihood and societies robbed of their future due to the scourge of HIV/AIDS and other life threatening diseases.

The death toll from preventable and treatable infectious diseases is unacceptably high. 11 million people, most of them in developing countries, die each year from such diseases. In the case of HIV/AIDS, a human tragedy of horrific dimensions is now at hand. In some countries in Africa, more than a quarter of the adult population has HIV. Life expectancy is projected to fall dramatically. In industrialised countries AIDS deaths have been significantly reduced partly because of the availability of life-saving medicines to many patients. Indeed, patients in developing countries also deserve access to medicines at affordable prices, to treat AIDS and other diseases.

The TRIPS special discussion provides a crucial opportunity to address mounting public perception that implementation of the TRIPS Agreement has hampered people's access to affordable medicines. Members must affirm that the TRIPS Agreement does not stand in the way of urgently-needed solutions to the deepening health crisis. By agreeing to this discussion in the TRIPS

Council we believe Members have taken cognisance of increasing public criticism and civil society campaigns against the perceived negative effects of the TRIPS Agreement, and are ready to respond positively.

Members should reach a common understanding that asserts and confirms the balance in the TRIPS Agreement that recognizes the importance of patent protection and provides that governments may adopt all appropriate measures to protect the health and lives of their people. This is the assurance and guarantee that governments need, to enable them to adopt such measures, without fear of litigation (either at national level or at the WTO) or that bilateral pressures will be applied on them. The African Group is convinced that all Members, as a matter of right and at their discretion, can take advantage of the existing provisions and safeguards in the Agreement.

The purpose of the special discussion is to begin to identify the relevant provisions of the Agreement, and exchange views in order to forge a common understanding of the TRIPS Agreement. As this important and vital task cannot be completed in one special session, Members need to agree on a work programme to complete this work in the shortest time possible, befitting a serious response to the current crisis.

We believe that the Ministerial Conference in Qatar in November 2001, will be an opportunity to demonstrate Members' commitment and contribution to preventing further deaths and saving lives through facilitating easier access to medicines at affordable prices. Therefore, we propose that Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health. The fourth WTO Ministerial Conference will provide an ideal opportunity for Members to affirm this common understanding.

Rather than being seen as an end in itself, intellectual property rights protection is intended as a means to benefit society as a whole. The mere existence and the protection of intellectual property rights, such as patents, does not necessarily result in the fulfilment of the objectives of the TRIPS Agreement. The experience of the past six years since the Agreement was established provides clear evidence of this.

In the context of public health, patent rights should be exercised coherently to the mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to balance rights and obligations.

Article 7 is a key provision with respect to interpreting the Agreement, as it establishes that the protection and enforcement of intellectual property rights does not exist in a vacuum. The objective of the promotion of technological innovation and the transfer and dissemination of technology locates the protection and enforcement of IPRs in the wider interests of society. With regard to public health, protection of intellectual property rights, in particular patent protection, should encourage the development of new medicines and the international transfer of technology to promote the development of manufacturing capacities of pharmaceuticals without restraining policies on access to medicines.

Article 8 explicitly recognizes that Members may adopt measures to protect public health, among other overarching public policy objectives, such as nutrition and socio-economic and technological development.

We believe that each provision of the TRIPS Agreement should be interpreted in the light of the objectives and principles set forth in Articles 7 and 8.

Consequently, the Agreement does not prevent Members from taking measures against abuses of intellectual property rights or anti-competitive practices.

Compulsory licences are an essential tool for governments to carry out effective public health policies. Such licences are a crucial element in the prevention of abuses of patent rights, the promotion of domestic manufacturing capacities in pharmaceuticals production, as well as in situations of national emergency and extreme urgency. The Paris Convention, which is part and parcel of the TRIPS Agreement, explicitly provides for the grant of compulsory licences as a means of countering abuses of intellectual property rights. The mere existence of a legal provision on compulsory licences may be enough to curb anti-competitive practices. Indeed, in the use of compulsory licences we look towards the rich experience of our developed country partners, which have employed compulsory licences to great effect.

In the light of Article 31, it is our understanding that Members can grant compulsory licenses on a range of grounds, including those based on public interest, including health, or to protect the environment. We, therefore, affirm our understanding that nothing in the TRIPS Agreement limits the grounds for governments to issue compulsory licences.

The Group affirms that legitimate grounds for the issuance of compulsory licences include: (1) where there is non-working or insufficient working of a patent; (2) for the importation of a product under patent protection; and (3) for the export of a product under patent protection. It is also affirmed that Members should undertake to recognize and give due effect to a compulsory licence issued by another Member, to a manufacturer in their territory for the production of goods intended for the market of the Member issuing the licence.

Parallel importation is also an important tool to ensure adequate access to medicines. It should be recalled that the Preamble and Part I of the Agreement set out that an important goal of the Agreement is to reduce distortions and impediments to international trade. In this context, parallel importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to vitally-needed medicines. In this regard, parallel importation must be regarded as a legitimate measure, which Members can adopt to protect public health and nutrition. Article 6 allows each Member the freedom to incorporate the principle of international exhaustion of rights - the legal basis for parallel importation. Members should therefore refrain from imposing any limitations on the right of other Members to apply the principle of international exhaustion, and thus allow them to exercise their right to parallel importation without hindrance.

While the Group favours the establishment of differential pricing arrangements provided this is done in a fair manner within a comprehensive and multilateral framework, these arrangements can only be part of a broader set of initiatives to improve access to medicines. Nevertheless, we reaffirm that such arrangements must not prejudice the rights of Members under the TRIPS Agreement.

It is crucial that Members be given the opportunity and sufficient time to acquire the necessary expertise, to incorporate the best possible elements and principles which they deem to be in their national interests when formulating national laws and policies, in order to take advantage of the inherent flexibility in the TRIPS Agreement. For many developing country Members, the implementation process requires development of capacity and expertise in what is a new field for them. This will take time. For this reason, developing country Members should be allowed a reasonable period of time to put into place legal frameworks which properly reflect their understanding of the TRIPS provisions, consistent with their national priorities and needs. Therefore, the Group urges Members to seriously consider the following:

- firstly, extending the transition period for the implementation of their TRIPS obligations by developing country Members in relation to patent protection (both product and process) regarding pharmaceutical drugs;

- secondly, undertaking, through a Ministerial Declaration, to adopt a moratorium in the dispute settlement mechanism to allow Members to take measures to protect public health;

- thirdly, observing with immediate effect a moratorium on dispute settlement action against developing country Members that hinder their ability to promote access to medicines and protect public health (including compulsory licences and parallel imports) measures.

In addition to the above measures, improvements to the TRIPS Agreement are required to take into account recent developments and problems that have arisen in the more than six years of implementation of the TRIPS Agreement. The seriousness of these problems were not anticipated at the time the Agreement was negotiated and concluded. With the benefit of hindsight, Members are now in a position to improve on the Agreement and thus be able to contribute more effectively to dealing with the crisis of AIDS and other infectious diseases.

The issues raised in this paper are not exhaustive. According to the developments in this exercise of interpreting the TRIPS Agreement, we may wish to bring (collectively or individually) further clarifications and complements to this document. All elements and views presented in the document are without prejudice to individual positions that Members may take in further discussions in the TRIPS Council or in other WTO bodies, including the dispute settlement procedures.

Finally, the African Group, together with a number of delegations, have tabled the paper which appears in unrestricted document IP/C/W/296, which we fully endorse and commend to Members for their consideration.

EUROPEAN COMMUNITIES

Let me first say how much the European Communities and their Member States (EC/MS) welcome the very fact that we have this special discussion of the TRIPS Council for the very first time - and I hope it is not for the last time - on the link between intellectual property and health policy.

Secondly, I would wish to thank my colleague of the delegation of Zimbabwe for a very illuminating and appealing statement. I think it sets the tone for a constructive and open discussion today and, I hope, on other occasions between now and the Doha Ministerial Conference. I also would wish to welcome the papers which have been co-sponsored by the African Group, Brazil and quite a number of other countries.

I think that all these papers, including the paper we have tabled, have one thing in common: all of them stress that the TRIPS Agreement and especially its application, and if need be the clarifications to it, should be part of the solution and not part of the problem. And I think that it is in this spirit that we have to work together. It is a complex matter but we are dealing with vital issues in this area, so we should try to tackle this complexity and to find the solutions that we collectively need.

Let me also stress that the EC/MS are fully committed to finding solutions to the problem of access to affordable medicines in developing countries. You are certainly aware that we have been, for quite some time now, in the forefront of all kinds of initiatives, be it in the context of the G-7, be it

in the context of our Round Table and the Action Plan that we tabled in September 2000, be it in the context of very intense discussions which we have had with the World Health Organization (WHO), or together with the WHO, with the pharmaceutical industry, and be it in the context of the Resolution of 14 May 2001 by the Council of Ministers, which endorsed the Commission's comprehensive Programme for Action which was tabled at the beginning of this year and which targeted the combat of the major communicable diseases.

The Resolution of 14 May 2001 focuses on three main goals: maximizing the impact of existing interventions (and that deals notably with what we are doing in the context of developing cooperation and focusing on health education and other matters); increasing the affordability of key pharmaceuticals; and increasing investment in research and development of specific global public goods.

One of the key points of our approach is to encourage the pharmaceutical industry to commit itself to a global tiered pricing (TP) system, which is, in our view, the most effective way to ensure sustainable supply of affordable medicines to the poorest. Although we recognize that the establishment of such a global system is not directly linked to intellectual property protection, we believe that the latter has an important role to play to make the system work. The objective of a TP system is certainly not to deny Members the right to grant compulsory licences or to authorize parallel imports. Our objective is to render recourse to such measures unnecessary.

Let me turn more specifically to the link between TRIPS and health. The EC/MS have, on several occasions, declared their willingness to promote discussions, within the WTO, WIPO and WHO, to address the link between the TRIPS Agreement and public health protection issues. At the same time we have always insisted, and continue to insist, that intellectual property aspects are only one among many aspects to be considered and cannot be dissociated from the global problem of access to health.

The EC/MS welcome that, today, the TRIPS Council will for the first time address the link between intellectual property and health. We remain strongly committed to the TRIPS Agreement, because we consider that intellectual property rights provide an essential stimulus for creativity and innovation. These rights need to be adequately protected in order to encourage investment in research and development into new medicines, and we need the R&D-based pharmaceutical industry to have those new medicines. But they should be more particularly targeted at the major communicable diseases, as recently also stressed by the WHO.

The TRIPS Agreement has, however, sometimes been criticized as limiting policy options in relation to public health concerns. In our view, the Agreement's objectives and principles, as set out in Articles 7 and 8, special transitional arrangements and other broadly drafted provisions give countries a sufficiently wide margin of discretion in implementing it. This margin enables them to set up an intellectual property regime that meets their policy needs and is capable of responding to public health concerns, while preserving an adequate level of intellectual property protection. Downgrading the level of current IP protection should certainly not be the aim of the exercise. In that context, we welcome the constructive contributions by other delegations. We have to look at the different solutions with an open mind, but also have to put a notion of caution: each and every proposal requires careful examination as to its potential positive effects and downsides.

To stimulate substantial and result-oriented work in the TRIPS Council, the EC/MS Communication on TRIPS and access to medicines examines a number of provisions that are relevant in this debate.

One of the TRIPS provisions most cited in this context is Article 31 on compulsory licensing. The lack of any explicit reference to public health in it is said to make some Members wary of using the Article for fear of provoking expensive litigation.

Our view is that, in fact, compulsory licences can be issued for any reason, including of course public health, as long as the procedural safeguards contained in Article 31, as well as other relevant TRIPS-provisions, are respected.

Let me remind you in this context that Article 7 of the TRIPS Agreement - and this has also been stressed in other documents - refers to "social and economic welfare" as an objective of the Agreement, while Article 8 allows Members to take measures necessary to protect public health, provided such measures are consistent with the provisions of the Agreement. Articles 7 and 8 were clearly not drafted as general exception clauses, but they are important for interpreting other provisions of the Agreement, including where measures, such as compulsory licences, are taken by Members to meet public health objectives.

It is important also to note that the requirement under Article 31 to first try to obtain a voluntary licence can be waived in cases of public non-commercial use, a national emergency, or other circumstances of extreme urgency. As for the level of HIV/AIDS infection reported in regrettably quite a number of countries, there would, in our view, appear to be very good reasons for describing it as a "national emergency" or as a "circumstance of extreme urgency". I am sure that all of us can agree on that interpretation.

Article 31 has been further criticized for requiring that goods manufactured under a compulsory licence be "predominantly for the supply of the domestic market of the Member authorizing such use". This provision is sometimes said to prevent a small country that has no production facilities of its own from obtaining cheap medicines from abroad under a compulsory licence. This is an important argument, as the Agreement does not appear to offer any legal certainty on the issue. I think that all of us should be ready to examine this issue with an open mind in order to find solutions that could meet the consensus among all WTO Members. The EC/MS do have that open mind.

Another important provision is Article 39.3 on data protection. Concern has been expressed in some quarters that certain interpretations of this Article could render compulsory licensing ineffective. Let me reassure you that the EC/MS consider that Article 39.3 should certainly not be interpreted in such a way as to weaken or nullify Members' rights under other Articles of the Agreement, such as the "fast-track" procedure in case of emergency foreseen under Article 31(b).

Let me turn now to parallel imports, an issue which has also been addressed by the delegation of Zimbabwe. Much importance will also be attached to Article 6, which enables Members to allow for parallel imports of patent protected goods which have been put on a third market by the right holder or with its consent. While we do not want to put Article 6 into question, we would like to emphasize that the introduction of a global TP scheme will call eventually for measures to avoid for re-importation of TP medicines. This problem should not be ignored. Certain aspects may need to be addressed by the TRIPS Council as a complementary measure to a global TP system. You will all agree that it is in the interest of all that TP medicines remain in the countries to which they were destined, and do not pop up in rich country markets, where customers can afford to pay much more for their medicines.

To conclude, we acknowledge that intellectual property rights play an important role with regard to access to medicines. However, we want to emphasize that the TRIPS Agreement cannot be held responsible for the health crisis in developing countries, while it must not stand in the way for action to combat this crisis. As I said at the beginning of my intervention, the TRIPS Agreement

should be part of the solution and not part of the problem. The EC/MS will therefore continue to actively take part in the expanding global effort to develop a strong global response to the health problems of the developing world.

In this context, the EC/MS are also ready to discuss to what extent technical assistance can take into account health concerns. To make this work, an interactive dialogue is clearly required with the participation of all developing and least-developed countries concerned. We also plead for closer coordination in that respect with other organizations like WIPO and the WHO.

While we remain convinced that the TRIPS Agreement represents a delicate balance between the interests of right holders and consumers, the EC/MS stand ready to contribute in an open way and constructively to any discussion in the TRIPS Council or in other WTO bodies, which should lead, where necessary, to the clarification of certain of the Agreement's provisions. We will see to it that we work together in the coming months also to have a clear indication to this effect in the Doha Ministerial Declaration.

BRAZIL

It is an auspicious sign that the exercise of discussions on "TRIPS and Access to Medicines" takes place under the chairmanship of a representative from an African country, a continent that has been particularly affected by health problems. We trust that discussions under your guidance will be productive and results-oriented.

I also wish to congratulate the African Group for taking the lead in this process. While the question of access to medication concerns the whole WTO membership - and developing countries are particularly interested in achieving results from this process - the African continent deserves special attention in light of the grave situation of AIDS, tuberculosis and malaria pandemics in that continent. We all have a great debt to you and the African Group in this respect.

Brazil is proud to be one of the co-sponsors of a document circulated in this Council on the issue of "TRIPS and Public Health" (document "unrestricted" IP/C/W/296). I will not go into detail on the paper but will make some reference to it. The document reflects the reading of at least 50 developing country Members – and hopefully more as we go along in this debate - on the relevant provisions of the TRIPS Agreement related to public health. In the drafting process of this document, all delegations contributed actively to bring meaningful elements to the discussion. Such a "team work" was largely facilitated by the fact that the participants shared the same goals of ensuring that TRIPS should not - and, indeed, in our view, does not - prevent protection of public health. In the substantive debate, we hope that other delegations may support the elements contained in this paper. Confirmation that the TRIPS Agreement should not run counter to the protection of public health will be crucial to provide clear guidance for Members, avoiding the explicit or implicit threats of using the dispute settlement mechanism to enforce restrictive, unbalanced and, indeed, incorrect interpretations of the TRIPS Agreement.

The Members that subscribe to this paper consider that the special discussion on TRIPS and Public Health at the TRIPS Council is not a one-off event. It should be part of a process to ensure that narrow readings of the TRIPS Agreement do not in any way undermine the legitimate right of WTO Members to formulate and implement their own public health policies. In this regard, and without prejudice to other possible actions, we believe that the Ministerial Conference in Qatar in November this year will be an excellent opportunity to confirm this understanding in an unambiguous and unconditional way. This should go a long way to build the required confidence between developed and developing countries for any future negotiations we may embark on, not only on this subject. It would also send a powerful message to all those growing sectors of civil society, both in the North

and in the South, that see the WTO as a soulless organization at the service of the rich and the powerful.

As it became known to the world public opinion since the beginning of this year, Brazil has a successful Programme for Universal Distribution of HIV/AIDS Medicines. As you know, these medicaments are available free of charge to anyone who requires them. The Programme clearly demonstrates that, important as they are, prevention policies alone are not sufficient to control the AIDS pandemics: indeed prevention and cure are intrinsically linked. I was glad to read in the Herald Tribune today an article by an American medical scientist, which says that experts have agreed that prevention and treatment are inseparable, or in the authoritative words of the UNAIDS expert committee, "their effectiveness is immensely increased when they are used together". So let's not be fooled by the latest attempt to say that the whole question of AIDS relates to prevention and not to treatment. The two go together. Treatment based on access of patients to AIDS drugs plays an essential role in achieving concrete results. In Brazil, the benefits of access to drugs have been concrete: in the last four years, the number of deaths related to AIDS has decreased by half (although in some hospitals in Sao Paulo, where the incidence of HIV-infected patients is the highest in the country, the number of deaths was decreased by 71 per cent). This was obtained by the use of drugs, not by prevention alone. While such an aggressive policy to fight AIDS justifies itself on the ethical ground, as it saves human lives and alleviates suffering of patients, it also brings concrete benefits for the better allocation of scarce resources in developing countries: the dramatic decrease in opportunistic infections resulting from drugs-based treatment has reduced up to 80 per cent the number of admissions in hospitals. This has brought an economy of US$422 million dollars in hospital admissions. Not an insignificant figure for a country like Brazil.

Two elements are absolutely necessary for the success of the Brazilian Programme for Universal Distribution of HIV/AIDS Medicines (and indeed to make it affordable to the Government): the local production of medicines and negotiations with the pharmaceutical industry. The two elements are closely linked to each other and directly related to our discussions here. In the case of drugs used in Brazil in the treatment of AIDS, local manufacturing has been utilized so far for products that were already in the public domain, without any infringement of patents. But the possibility of issuing compulsory licenses is also an essential element of the negotiation between the Government and the pharmaceutical industries. Besides that, local production of pharmaceutical products may be crucial to ensure that medications are readily available at affordable prices. Local manufacturing of pharmaceutical products also encourages sustainable access to medications by insulating the price of patented medicines against currency devaluations, as well as supporting the development of local expertise, which is vital in addressing local needs.

The Brazilian AIDS Programme is strictly consistent with the TRIPS Agreement. The Brazilian Law on Industrial Property provides strong patent protection for pharmaceutical products, and efficient mechanisms to fulfill the objectives of the TRIPS Agreement in a coherent way with our public health policy. While Brazil has not as yet resorted to compulsory licences under the current law, a recent experience of our Ministry of Health in negotiations with one pharmaceutical company has demonstrated that the very existence of a compulsory licensing mechanism - together with the political will of the Government to use it is essential to persuade patent holders not to abuse their rights to the detriment of public health objectives. In this case, a pharmaceutical company, which was refusing to bring its unreasonably high prices on two patented antiretrovirals down, has agreed to cut its prices by 64 per cent and 59 per cent respectively, when the Government gave unambiguous signs of its intention to issue a compulsory licence. So this remains an essential element in our policy and we intend to keep it.

As regards the issue of parallel imports, Brazil believes that Members should confirm their right of applying regimes of exhaustion of rights in their jurisdiction. For developing countries, in particular least-developed countries and smaller economies, parallel importation can be a significant

way of increasing access to medications, where the prices charged by patent holders for their products are unaffordable.

In this respect, we favour discussions on differential prices as a means to improve access to affordable medicines, although the issue may be best discussed in other fora with a mandate to address public health policies, such as UNAIDS, UNICEF and the WHO, for instance. At the same time, discussions on differential pricing should in no way result in restriction to or modification of the rights ensured to Members by the TRIPS Agreement to make use of provisions such as those on parallel imports and compulsory licences, as may be necessary.

The beginning of special discussions on the issue of "TRIPS and Access to Medicines" in the TRIPS Council is a momentous occasion for Members to ensure that nothing in the TRIPS Agreement will prevent, should prevent or can prevent governments from taking measures to protect public health. We hope that the debate here will confirm this understanding.

Economic theory has for a long time established a link between price and value. The nature of such a link, however, has never been fully resolved. In the end, our discussion today is also about the relation between price and value, i.e. the price of medicines seen as profit-bringing commodities and the value of human life. We understand that, as any other industry, the pharmaceutical producers have to remunerate their activity. We are not against them, but we hope that, with our help, they will find ways of doing it without beating what should be the very purpose of their activity: to save lives and to alleviate suffering.

ARGENTINA

We consider these discussions to be particularly important in that they help to ensure that we, the WTO, face up to some of the negative effects of globalization. I think we owe special thanks to the African Group for taking the initiative to propose this special debate, as well as the group of countries like the European Union on the one hand, and Brazil, India and the African Group on the other, whose significant contributions have helped to launch serious discussions.

One way to ensure that negotiations produce an imbalanced result is to confront, at the negotiating table, those who have very specific knowledge, objectives and interests with those who do not. Another way is to fail to implement properly what has been agreed. This is where the problem lies between the TRIPS Agreement and public health objectives.

As the European Union states in its proposal, "it will be the first time that the TRIPS Council discusses intellectual property issues in the context of public health".

Imbalanced negotiations or implementation will obviously lead to the interests and rights of one of the parties being ignored. Some will exaggerate their demands. In extreme conditions, this, in its turn, will lead others to react in a way that could jeopardize the global system of rules as a whole.

It should be made clear before it is too late that excessive demands *are not* sustainable and that the destruction of the global system of rules is in *no one's* interest.

This is exactly why we must tackle the problems by reaching a *consensus interpretation***,** a *common understanding* of the current text of the TRIPS Agreement as regards the issue of public health.

Without going into technical details for the moment, my Government would like to make clear its basic position in these discussions, which we see as the *initial stage* in a process that will assume importance at the Qatar meeting, by highlighting the following fundamental principles:

(1) Articles 7 and 8 of the Agreement recognize that a private right cannot be made to prevail over a social benefit such as health. Specific provisions were therefore included to prevent:

- abuse of intellectual property rights by their holders;

- recourse to practices which unjustifiably limit trade or are detrimental to the international transfer of technology.

At the same time, the Agreement also provides for:

- promotion of technological innovation;

- transfer and dissemination of technology;

- measures to protect public health and nutrition.

(2) By adhering to the Marrakesh Agreement, WTO Members not only took on obligations, but also acquired rights, the implementation and respect of which are hierarchically just as important as the obligations.

The TRIPS Agreement laid down minimum standards for protection through a basic system of rights and obligations. The wording of the Agreement, which is the fruit of complex negotiations, provided considerable "flexibility" or "margin of manoeuvre" in many of the provisions to enable Members to incorporate them in their domestic legislations.

This margin of flexibility in fact constitutes one of the rights acquired by the signatories to the Agreement. Thus, the Agreement enables Members to develop a legal system that strikes a balance between the protection of intellectual property and their public policies.

In our view, these margins do not need to be "interpreted", since some interpretations would merely be imposed at the expense of others, which is exactly what the authors of the Agreement were trying to avoid during the Uruguay Round.

These margins take the form of different options which the States may use in implementing their obligations in a way that is in keeping both with the TRIPS Agreement and their domestic needs or policies.

(3) There is a general understanding, to which Argentina subscribes, that the system of patents plays an important role in research and development of new medicines.

There are two parallel objectives of the TRIPS Agreement whose fulfilment calls for a uniform understanding of its provisions:

(i) due consideration for the rights of those who invest considerable sums in the development of new medicines; and

(ii) public health needs.

We understand the second of these two objectives basically to mean fair prices, availability of quality medicines when and in the form in which they are needed, and dissemination of know-how.

4. To try to limit the field to a series of specific issues that need to be resolved, such as "differential prices", would be to ignore the true dimension of the problem.

The negotiation of differential prices falls outside the scope of intellectual property rights, and hence is not within the competence of this Council. It is merely a tool to which countries and/or enterprises may resort if they so wish, and if they think that this will enable them to resolve an aspect of the problem.

As stated by the Ambassador of Brazil and the Ambassador of the European Communities, it should in no way interfere with the legitimate right of States under the TRIPS Agreement.

5. Finally, we think it is important to take advantage of the experience of the World Health Organization (WHO) in this area and encourage the Council for TRIPS to work on the basis of aspects of *intellectual property - public health - access to medicines* already identified by that organization.

Fortunately, the Council is not beginning its work today in a void. At the international level, much has been done over the past years to identify, study and seriously assess, from the public health point of view, the provisions of the TRIPS Agreement which directly or indirectly affect accessibility to medicines.

Alongside the respectable studies by experts in the field and recognized NGOs, and the documents submitted by various countries to this meeting, the WHO has conducted numerous studies in this area.

Any experience that the WHO could transmit to the Council on this subject would be of value for its future work, which we have defined as the search for a consensus interpretation, a common understanding of the TRIPS Agreement seen as a balance between rights and obligations.

VENEZUELA

Venezuela is fully committed to promoting health as a fundamental social right guaranteed by the State on the grounds that it pertains to the right to life. Our Constitution gives priority to the promotion of health and prevention of disease, and pledges appropriate treatment. We reaffirm our Government's interest in monitoring public health and assuring fair and equal access to medicines. Health is a guarantee for development.

We are aware that health problems affect mainly the low-income sectors of the population and that poor health hampers domestic, and ultimately international, economic growth. The health problems which beset developing countries, coupled with economic crises such as that currently affecting the African continent, make protecting intellectual property rights less viable since upholding these rights may adversely affect economic well-being.

The problem of access to medicines in general has taken on structural dimensions in developing countries. These countries are at a disadvantage, since health problems are closely related to survival itself. It is therefore crucial for our countries to overcome the difficulties relating to services, health care and access to medicines. And indeed, any proper approach to the health problem must go well beyond the mere need to protect intellectual property.

AIDS is a scourge which needs to be dealt with as a matter of urgency, as do the other infectious, contagious and endemic diseases which afflict the developing countries in particular, such as dengue fever, tuberculosis, malaria, meningitis and diarrhoeal diseases. We back international community action designed to guarantee access to medicines and hope that the outcome gives impetus

to the strategy of granting access at affordable prices to the medicines which help to combat such diseases.

Venezuela attaches considerable importance to intellectual property protection in relation to both the development of research and growth. Such rights are neither incompatible with, nor restrictive of health policies if interpreted in the light of the objectives and principles of the TRIPS Agreement. The Venezuelan State is deeply committed to protecting the public interest when implementing the TRIPS Agreement.

The Council for TRIPS has only recently begun to discuss the implications of the Agreement for the implementation of public health policies. Nevertheless, Venezuela's understanding of this issue has been that the very foundation of the multilateral system is the fairness in allowing countries which meet their commitments a degree of flexibility in implementing development policies, in this particular case public health policies. This is the very spirit and rationale of the paper which has been submitted on behalf of developing countries and endorsed by Venezuela. This paper was well summed up by the delegation of Zimbabwe.

We shall touch but briefly on a few aspects which have already been extensively dealt with in the proposal. Firstly, any interpretation of the Agreement must be based on Articles 7 and 8. We are certain that reducing government options with regard to promoting and protecting health or applying other related public policies is not in the spirit of the Agreement.

When some countries' interpretation of a failure to observe patent rights leads them to claim violation of the TRIPS Agreement, they are not taking into consideration the fact that developing countries are entitled to take the necessary measures to promote and protect health pursuant to Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights and the Declaration of Human Rights.

We wish to highlight the importance of compulsory licensing and parallel imports as mechanisms for protecting public health and making medicines available at affordable prices to people with low incomes. Mention should also be made of the use of non-discriminatory price controls, since this does not constitute a breach of the TRIPS Agreement. Such instruments should be studied in the light of the general principles of law, the Preamble to the Marrakesh Agreement and the objectives and principles of the TRIPS Agreement.

We are concerned over restrictive interpretations of the Agreement's provisions which seek to reduce Members' flexibility with regard to the use of compulsory licensing. The patent rights of pharmaceuticals should be managed in such a way as to both protect the interests of the patent owner and safeguard the basic principles of public health.

Likewise, the international principle of exhaustion of rights must be worked into domestic legislation. In particular, it has come to our attention that some proposals do not refer to parallel imports as a way of improving access to medicines. We wish to stress the need to confirm Members' right to apply the principle of exhaustion in their jurisdiction.

It should be noted that some interpretations of Article 39.3 could conflict with the public interest. Venezuela is of the opinion that a request for authorization for a product which has been initially approved by an authority cannot, under any circumstances, be construed as illegal use of data. Should this provision be inappropriately interpreted, it would - by preventing pharmaceuticals from being marketed - be unjustifiably restricting access to medicines.

It is also important to recognize the decisive role played by intellectual property in the development of research and the transfer of technology, and to understand the conditional nature of this relationship and, in particular, the overwhelming importance of development objectives.

Finally, the Council for TRIPS must request that these considerations and precisions be included in the Qatar Ministerial Declaration as a core element of the development dimension. As we have said on previous occasions, we are referring to provisions, interpretations and forms of implementation which enable the State to promote technical progress and stimulate dynamic economic growth with a view to achieving more far-reaching objectives.

NORWAY

During the past century, medical science and technology have made enormous progress. For millions of people in developing countries, however, medicines are largely unavailable, unaffordable, unsafe, of poor quality or improperly used. Over the past two years or so, unprecedented efforts to dismantle these obstacles have been undertaken by governments, various organizations, and industry.

It is important to keep in mind that access to essential medicines depends on several factors. I will mention some of these factors briefly:

(1) rational selection and use of medicines;
(2) sustainable adequate financing;
(3) reliable health and supply systems; and
(4) affordable prices.

Each of these issues is important if developing countries are to have proper access to medicines. For the purpose of our discussion today, let me make a few comments on the issue of *affordable prices*.

While prices are not the only issue, price does make a difference. This is partly because most poor people in developing countries must pay for health care, including drugs, out of their own pockets. During the last year, industry has started, although in a modest way, to sell antiretroviral and other medicines to several developing countries at preferential prices. The issue of how industry could practice differential pricing in a systematic way, was indeed the theme of a joint WTO/WHO workshop at Høsbjør, Norway earlier this year.

Differential pricing may be one way of increasing availability and affordability of medicines in developing countries. In addition, there are other ways whereby many of the same objectives could be pursued. I would just like to underline that neither differential pricing nor such other methods should be used as an argument for not interpreting the TRIPS Agreement as flexible as possible in the area of public health.

Today the TRIPS Council - at the request of the African Group - has embarked upon a first discussion on intellectual property and access to medicines. It is a very complex issue and therefore in our view not a one-off event, but merely the beginning of a larger process.

One aim of this first discussion is to try to seek more legal clarity in the interpretation and application of the relevant provisions of the TRIPS Agreement. In doing so, the TRIPS Council must examine closely relevant provisions taking into account the fundamental principles and objectives of the Agreement. We hope this would contribute to clarifying some of the provisions, including the flexibility to which Members are entitled under the Agreement.

It is important to note that intellectual property standards, including those specified in the TRIPS Agreement, take the protection of public health into account. Moreover, the Agreement contains several provisions which illustrate its flexibility. These provisions, if interpreted in a constructive manner, should enable developing countries, struggling to meet health and development needs of their populations, to make proper use of the public health safeguards built into the Agreement. I agree very much with the Ambassador of Brazil when he underlined that nothing in the TRIPS Agreement should hinder developing countries to take action.

At the same time, we should keep in mind that the main purpose of the patent system is to provide incentives by stimulating research in and development of new technology, *inter alia*, in the medical field. Industry would generally not be prepared to take the risks involved in investing heavily into the development of new medicines, unless it could expect to recoup these investments. I have noted that in the discussions so far this point has been recognized by speakers.

A number of provisions of the Agreement are particularly relevant when examining the issue of public health.

The objectives and principles in Articles 7 and 8 point to the need to strike a balance between intellectual property rights and other interests including those of the users. Moreover, the protection of intellectual property rights should contribute, amongst other, to the promotion of technological innovation in a manner conducive to social and economic welfare and to a balance of rights and obligations. The need for flexibility is also taken into account and Members may adopt measures necessary to protect public health and nutrition and promote the public interest in sectors of vital importance to their socio-economic and technological development.

Article 31 of the Agreement is particularly important in the context of our discussion and must be read in light of the objectives and principles of Articles 7 and 8. The provision allows for the use of a patent without the patent holders' consent, under certain conditions. Article 31 is complex and we will only offer some preliminary observations on a few points.

First, however, it should be underlined that, in principle, patented medicines should be produced or marketed through voluntary licensing agreements, in more or less the same ways as other patented products. It is therefore important that the research based industry seeks to conclude with applicants licensing agreements for the production or distribution on a *voluntary* basis.

We are therefore of the opinion that Article 31 of the TRIPS Agreement should in general only be a last resort. Article 31 is, however, an extremely important provision, and the mere fact that compulsory licensing remains an option could in fact increase the likelihood of concluding voluntary agreements.

An important function of Article 31 is to set the standard terms under which a patented product must be offered to third parties. Under subparagraph (b) the applicant must, within a reasonable period of time, have made prior unsuccessful efforts to obtain authorisation from the patent holder on "reasonable commercial terms and conditions". The concept of "reasonable commercial terms and conditions" should be understood to require both the interests of the patent holder as well as those of the applicant and the consumer to be taken into consideration.

In the case of, *inter alia*, a "national emergency", the subparagraph provides a waiver from the requirement to make prior efforts to obtain authorisation through voluntary arrangements. What constitutes a "national emergency" must be considered on a case-by-case basis. In our opinion, however, a "national emergency" does not have to be limited to sudden or unforeseen events, but could also encompass a *continuous crisis* like the AIDS epidemic in certain Sub-Saharan countries.

Article 31(f) states that "any such use shall be authorised predominantly for the supply of the domestic market of the Member". This subparagraph raises many important questions, most of which cannot be dealt with in-depth at this stage. To which extent the manufacturing of products covered by a compulsory licence may take place outside the country issuing the licence is one of the important questions, particularly for smaller developing countries. This is because production abroad may be the only way these countries may use the compulsory licensing provision.

Under subparagraph (h), the patent holder must be paid "adequate remuneration" "taking into account the economic value of the authorization". It is difficult to give any exact guidance on the interpretation of this provision. Depending on the circumstances of the case, the remuneration which must be paid under (h) may however be less than the minimum amount which the patent holder could have requested under the concept of "reasonable commercial terms and conditions" in subparagraph (b). Moreover, if the compulsory licensed products are lifesaving medicines which are urgently needed, this might also have an influence upon the level of remuneration.

Subparagraph (i) provides for the review - in one instance - at the national level of the decision to authorize a compulsory licence, in order to take into consideration the interests of all parties. It should be noted that, in order not to delay the application of a decision to grant authorization, national law might, under certain conditions, implement subparagraph (i) by, *inter alia*, providing for the *provisional* application of such an authorisation, even though it has been appealed.

In conclusion, it is our view that the rights of developing countries to use the public health safeguards provided for in the TRIPS Agreement must be fully respected. It will be up to each Member in the first place to determine the grounds for granting a compulsory licence under Article 31, taking into account other relevant provisions as well as the principles and objectives of the Agreement. We would in this context urge developed country Members to show due restraint with regard to invoking the dispute settlement procedures under the DSU in matters regarding TRIPS and public health.

Finally, we are open as to how this issue should be pursued, as long as the objective of securing a flexible interpretation of the Agreement as regards access to medicines is achieved. I have noted the statement made by the delegation of Zimbabwe on behalf of the Africa Group for action to be taken at the fourth Ministerial Conference in Doha. We would certainly not rule out the possibility of an authoritative interpretation at the Ministerial Conference if our discussions identify a need for such action.

MALAYSIA (ON BEHALF OF ASEAN)

At the outset, ASEAN would like to thank the African Group for initiating the holding of this special session on intellectual property and access to medicines. The discussion on this subject in the TRIPS Council is both timely and very important for Members to advance our collective understanding of the provisions under the TRIPS Agreement that allow measures to be taken to fulfill public health objectives and the exercise of these rights.

We would like to take this opportunity to thank the European Communities and the group of developing countries that have provided papers to further our discussions in this area. In particular, ASEAN welcomes the paper as presented by Zimbabwe on behalf of almost 50 developing countries, and support the need, as outlined in the paper, to address Members' concerns over the relationship between TRIPS and health and in order to provide certainties as regards Members' rights to fulfill health objectives under the TRIPS Agreement.

In negotiating the TRIPS Agreement, it was recognized that intellectual property rights are private rights. Yet at the same time, the Agreement acknowledged that the protection and

enforcement of intellectual property rights should be done in a manner conducive to social and economic welfare and that Members may adopt measures to protect public health.

Indeed, Articles 7 and 8 are key provisions in implementing the TRIPS Agreement, ensuring a balance between rights and obligations and the prevention of abuse of intellectual property rights.

In particular, we note that the TRIPS Agreement provides for:

(i) the non-authorized use of a patent or otherwise known as the issue of a compulsory licence. The TRIPS Agreement allows Members to issue a compulsory licence, but the grounds for the issue of such a licence are not stated in the TRIPS Agreement. Hence, Members are free to determine the grounds for granting compulsory licences.

(ii) Further, it is noted that the TRIPS Agreement also does not specify whether the compulsory licence can only be issued to a manufacturer in its own territory. We have the provision of Article 31(f) that such use should be predominantly for the supply of the domestic market of the member authorizing such use. Could this mean that Members have the right to confer compulsory licences to a third country manufacturer provided the procedures under Article 31 are met?

(iii) The provisions of Article 31 themselves are meant to be used flexibly to meet public interest objectives. The choice of the words "predominantly" in Article 31(f), and the word "adequate" in Article 31(h) are not specific and hence should lend themselves to a broad interpretation towards meeting public health objectives. The use of the word "predominantly" should also be taken to mean that some portion of the production could be used for exports.

(iv) Members also have the freedom to provide for the principle of the international exhaustion of rights in their legislation. We note that, since the TRIPS Agreement does not address the issue of exhaustion of rights, as stated in Article 6, this provides the right of import from third countries.

We believe that it is important that Members recognize these rights and respect their application. In this context, the language for a common understanding of these rights should be worked out for Ministers' endorsement in Doha.

Members have an excellent opportunity in Doha to inform that the TRIPS Agreement is not against affordable access to medicines. On the contrary, the TRIPS Agreement has a number of provisions that contribute to the achievement of public interest objectives. They should be accorded full recognition in their implementation and application.

CHILE

Today's discussions on intellectual property and access to medicines are absolutely crucial and highly topical and come in answer to a concerted appeal by the international community. The actual issue of access to medicines clearly goes well beyond the mandate, functions and competence of the TRIPS Council, so that we must be particularly careful to ensure that our discussions remain within the strict confines of our competence. We feel that this issue should be addressed not only in the light of the growing international concern over the relationship between intellectual property and access to medicines - proof of which lies in the great media expectations of this meeting - but also because there is a distinct lack of information on the issue which is our responsibility to overcome.

The following four basic questions came to mind in relation to our statement. Do WTO disciplines in general and the TRIPS Agreement in particular constitute an obstacle to the formulation and implementation of national policies on health and access to medicines? If so, which disciplines or rules could prevent Members from adopting decisions on this matter? In what way would it be possible to amend or improve those disciplines? Who should be taking part in these discussions?

First of all, the answers to these questions, and consequently the conclusions drawn, will depend upon the kind of policy each Member wishes to pursue and the factors taken into consideration in its formulation.

I should like on this occasion to briefly discuss our country's experience in and interpretation of this issue on the basis of the current provisions of the TRIPS Agreement.

The National Medicinal Drug Policy established by the Chilean Government in 1996 not only confirmed the right of the population to access health services, including medicines, but also the Chilean State's responsibility in the matter.

In our opinion, medicines are essential social goods which afford people the opportunity of protecting and recovering their health. The quality, effectiveness, safety and affordability of medicines, *inter alia*, form the basis of a rational medicinal drug policy.

State intervention, through the formulation of a policy and strategic plan in the field of medicine, can be justified by certain national realities which, in the case of Chile, are basically as follows:

(a) unequal access by the population to medicines;

(b) unsuitable prescriptions and a lack of systems to monitor the use of medicines;

(c) widespread uninformed and irresponsible self-medication;

(d) the need for adequate monitoring to guarantee bioequivalence; and

(e) the upward trend in the price of medicines.

Chile has granted patent protection to pharmaceuticals since 1991. Prior to that date, only the right to grant process patents was recognized. This change entailed major efforts on the part of Chile's Industrial Property Office since it had to train specialized staff and earmark greater financial resources for building up its capacity with a view to the technical analysis of these new patent applications.

Even at that time, the conditions for granting patent rights were established on the basis of the three core patentability requirements stipulated in Article 27.1 of the Agreement, i.e. that patents be new, involve an inventive step and be capable of industrial application. We are of the opinion that these three core principles should not merely be upheld, but also reinforced, since coupled with the temporary nature of industrial property rights, they are what allow an appropriate balance between inventors' and creators' rights and benefits on the one hand, and those of society as a whole on the other.

In our opinion, the basic principle applicable to the formulation of laws and regulations with regard to health-related intellectual property is that established in Article 8 of the Agreement, under

which States may adopt the measures necessary to protect public health, *inter alia*, provided they are consistent with the other provisions of the Agreement.

In this sense, Article 27.2 of the TRIPS Agreement authorizes Members to exclude from patentability inventions the prevention within their territory of the commercial exploitation of which is necessary to protect human life or health, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Chilean legislation recognizes the right to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans, pursuant to paragraph 3 of the said Article.

The new legislation currently being reviewed in the National Congress recognizes the principle of exhaustion of intellectual property rights, including patents. In a globalized world, this principle is the basis for avoiding market segmentation and permitting parallel imports, a measure which we consider absolutely crucial for open economies such as Chile's. In our opinion, this situation is fully consistent with Article 6 of the Agreement.

Chile's 1991 Law confirmed the establishment of non-voluntary licensing in the event of the holder of industrial property rights being involved in monopolistic abuse thereof. Such abuses are handled by a special court on a case-by-case basis. Chile recognizes that the granting of this kind of licence is not necessarily contingent on a single factor. On the contrary, there could be other grounds, provided that they comply with the conditions stipulated in Articles 30 and 31 of the Agreement. In all the years that this Law has been in force, Chile has never been asked to grant such a licence.

Apart from these exceptions to holders' rights and pursuant to Article 30, Chile also understands to be legitimate any action taken for private, non-commercial purposes by an individual patient who requests authorization to import a particular drug for personal use. The same applies to research and scientific experiments conducted on the basis of a patented invention and authorization to conduct equivalency tests before the patent expires. Such exceptions must not unreasonably conflict with a normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

In relation to the protection of undisclosed information furnished by companies as a condition for obtaining marketing approval for a product, in Chile this process is bound to absolute secrecy as long as the conditions of Article 39.2 of the Agreement remain, i.e. as long as such information is secret, has commercial value because it is secret and has been subject to reasonable steps under the circumstances, by the person lawfully in charge of the information, to keep it secret. This does not in any way mean that the health authorities must require a third party to repeat the same tests and clinical trials backing the registration of the original product.

To sum up, Chile considers that Article 8 of the TRIPS Agreement encapsulates a basic principle, namely the recognition that Members are entitled, when formulating and amending their laws and regulations, to adopt measures that they themselves consider necessary to protect health, including access to medicines, provided that such measures are consistent with the other provisions of this Agreement, such as those referred to above.

We hope that on the matter at issue some points of interest to Members will have emerged from this meeting and that we will be able to reach a consensus which will enable us to answer the questions we raised earlier on. We hope that this effort will be undertaken jointly and in coordination with other international organizations, such as WIPO and the WHO.

INDIA

India is particularly pleased that the WTO Council for TRIPS is discussing today one of the most important issues facing all our countries, i.e. the issue of public health and access to medicines. The international community has focused recently on a number of possible implications that the TRIPS Agreement might have for adverse impact on access to medicines and thus, on protection of public health. It may be useful to recall here that as many as 11 million people die every year of infectious diseases, the great majority of them women and children living in the third world. Out of these, AIDS claims an estimated 3 million lives, tuberculosis 2 million and malaria 1 million. Affordable access to medicines for what are life-threatening diseases for people in developing countries is a fundamental human right. The governments in these countries therefore have a duty and responsibility to ensure both availability and affordable prices for medicines.

As the Council is aware, India is a co-sponsor of the joint communication submitted by about 50 countries on the subject. So, it is not necessary for me to repeat all the points made therein, to which of course India fully subscribes. In this intervention, India would like to make some observations and raise some questions for further reflection by the TRIPS Council.

We wholeheartedly endorse the statement made by the distinguished delegate of Zimbabwe on behalf of the African Group; we also wholeheartedly endorse all the recommendations made on behalf of the African Group. I would also like to associate myself with the statement made by the distinguished Ambassador of Brazil.

First of all, we need to be clear about the mandate and the objective of this exercise. It goes without saying that the TRIPS Council should be discussing all issues relating to public health and access to medicines as they pertain to the various provisions of the TRIPS Agreement. So, while it is perfectly legitimate to talk about patents and compulsory licencing, for example, and their impact on public health and access to medicines, it is not, in our view, within the mandate of this Council to talk of the infrastructure available in different countries in terms of hospitals, availability of doctors, nurses etc. Equally, it may not be useful for this Council to discuss the global funds being set up in various fora for acquiring medicines and distribution in various countries. The purpose of today's meeting is therefore to examine the relationship between the various provisions of the TRIPS Agreement and issues of public health and access to medicines. I am not trying to underestimate the relevance of factors like availability of medical personnel, infrastructure etc. What all I am trying to say is that the job of this Council is to look at the TRIPS Agreement from the perspective of public health.

At the outset, it needs to be stated that protection and enforcement of intellectual property rights contribute to creative and inventive activity and thus welfare to the society. In the field of pharmaceuticals, intellectual property rights have contributed to large private investments resulting in the development of newer and often better medicines. The exclusive rights conferred by patents provide incentive for further investment in research and development of new and effective medicines, a point some delegations have made today. However, a distinction needs to be made between the exclusive rights of the patent holder for example in the case of medicines for life-threatening diseases on the one hand, and say beauty-enhancing and cosmetic drugs on the other hand. Two observations may be pertinent here. One, not enough research and development would appear to be targeted at tackling diseases afflicting people in poor countries. Two, due to price inelasticity in the pharmaceutical sector, particularly for essential drugs, manufacturers pricing decisions are unrelated to the market. Add to this the market exclusivity that is granted by patents and you have a situation where access to medicines becomes difficult if not altogether impossible for the vast majority of the population. It is therefore this aspect of the TRIPS Agreement, insofar as it impacts on the access to medicines, that needs to be examined in detail by us in today's meeting and in future meetings on this important subject.

Protection of public health and nutrition is a fundamental principle governing the TRIPS Agreement and is reflected in Article 8. The TRIPS Agreement grants WTO Members the right to adopt measures necessary to protect public health and nutrition. But it does add that such measures would have to be consistent with the provisions of the TRIPS Agreement.

This is a rather curious formulation. There is no need for a provision in an Agreement to say that you are "OK" as long as you are consistent with the Agreement. Besides, a principle which, *inter alia*, incorporates an element of exception as well, cannot be tested against the yardstick of consistency with other provisions of the Agreement. Second, in areas like protection of environment (protection of plant and animal life), Article XX of the GATT gives Members the right to deviate from fundamental principles such as MFN and national treatment, provided the requirements in the Chapeau of Article XX which relate to avoidance of arbitrary or unjustifiable discrimination or disguised restriction on international trade are met by the Member. If this is so in the case of environment, it seems strange that for protection of human life which is perhaps equally, if not more, important, the TRIPS Agreement appears to suggest that Members can protect public health only if the measures taken by them are consistent with the TRIPS Agreement. The implication is that, if by any chance the measures taken by a Member are deemed inconsistent with the TRIPS Agreement, then it would not be possible for that Member to have resort to those measures to protect public health. One of the most vehement criticisms against the TRIPS Agreement is by those who perceive it to be placing protection of public health on a lower level of priority and giving utmost pre-eminence to protection of the rights of the right holders. This needs to be remedied. Both protection of the rights of the right holders and protection of public health are important objectives in themselves and one cannot be espoused at the expense of the other.

Secondly, in Article XX of the GATT, protection of human health is considered an exception and hence entitles the Members to be exempt, under some carefully defined circumstances, from the disciplines and obligations of GATT. If this is so in the case of GATT 1994, it seems odd that in the case of the TRIPS Agreement there is a requirement that in all circumstances the measures that a Member takes to protect human health have to be consistent with the TRIPS Agreement. It would appear that in the very same organization, that is WTO, the way in which protection of human health is dealt with in the two Agreements, namely GATT and TRIPS, are different.

Finally, is there a common understanding among all WTO Members as to what constitutes "consistency" with the TRIPS Agreement? Is it possible or conceivable that a measure taken by a WTO Member in good faith to protect public health within its territory is considered "not consistent" with the provisions of the TRIPS Agreement by either another Member or indeed by a dispute settlement panel? It is important that this meeting be considered the beginning of a process which will eventually come up with a clear common understanding among WTO Members as to what constitutes consistency with the TRIPS Agreement. In other words, the TRIPS Agreement should offer every Member a wide and broad range of measures for protecting public health. This issue is too important to be left either to chance or to future panels. This is why all of us here should collectively recognize and confirm the considerable degree of flexibility offered by the TRIPS Agreement in this regard.

Having set out the broad parameters within which this meeting and future meetings on the subject should dwell, let me spell out India's concern and position on some of the issues involved.

It is obvious to my delegation that every provision of the TRIPS Agreement must be read, understood and interpreted in the light of Articles 7 and 8 of the TRIPS Agreement. This is because the objectives and principles of the TRIPS Agreement are contained in these Articles and these are of overarching relevance and importance for the rest of the provisions. Apart from the fact that the Vienna Convention on the Law of Treaties would endorse such a point of view, the fact is that

promotion of intellectual property rights is not an end in itself, and its effectiveness would have to be measured not just in terms of whether or not the rights of the right holder have been protected or not, but also in terms of whether or not public policy objectives based on Articles 7 and 8 have been adequately met or not. We welcome the EC's view on the overarching importance of Articles 7 and 8 as well. After all, this is what the TRIPS Agreement is about, i.e. a balance of rights and obligations, a balance between private rights and public policy objectives and mutual advantage for both producers and users of technological knowledge. The real concern both in the international civil society and in national jurisdictions is that the TRIPS Agreement in its current form may be misinterpreted by some as promoting one at the expense of the other. This concern must be taken seriously by the TRIPS Council.

Any discussion of the relationship between the TRIPS Agreement and public health and access to medicines has to begin by taking a look at the provisions relating to patents and the way in which the existing patent system operates.

As is known to all, patents confer exclusive rights on the owner by essentially preventing any third party not having the owner's consent from making, using or selling the product concerned. In the area of pharmaceutical products, it is widely believed that patents are necessary for rewarding inventions, but also to ensure that there is incentive for further research and development for creating new drugs. This is true and no body is questioning this assumption. The problem, however, is that by conferring a patent on a drug, there are huge implications for its accessibility, especially for the most vulnerable sections of the population. For one thing, a patent generally ensures that there is no other substitute or alternative drug for the period for which the patent protection is made available. For another, because generic competition is generally prevented by a patent, the price of a patented drug tends to be exorbitantly high. And there are any number of studies to prove this. In addition, it needs to be noted that the TRIPS Agreement provides a patent term of 20 years, much more than what used to be provided in national laws before. Moreover, the actual term of patents may even be longer than 20 years because of the practice of "selection patents" or "evergreen patents". All of the above factors have enormous implications for access to such medicines in poor countries where the per capita income is low and per capita expenditure on health is pitifully small.

It has been argued that not all existing essential drugs are on patents. Even assuming this is true, it seems clear that future inventions which are going to be ground-breaking, such as a vaccine for AIDS or indeed even new vaccines for old diseases like malaria, tuberculosis, etc. are going to be on patents. What happens then to countries which simply cannot afford to pay exorbitant prices for medicines which may well decide between life and death for its citizens. This then is the central issue facing the Council today.

In these circumstances, it is important that we explore all options currently available under the TRIPS Agreement to see how we can allow countries the maximum flexibility to take measures for protection of public health.

The most widely discussed provision on the subject is Article 31, which deals with "other use without authorization of the right holder". It is obvious that a broad and flexible interpretation of this provision is critical for allowing Members the fundamental right under the TRIPS Agreement to promote and protect public health. We are informed that there is some flexibility inherent in the TRIPS Agreement on this particular issue. Whether there is adequate flexibility or not will become apparent only when we clarify the existing flexibility to the fullest possible extent, so that Members are clear what they can do to protect public health. It is also important that there be absolute legal certainty in this regard. At this stage, I would like to note that this point was forcefully made by the Ambassador of Brazil. I would also like to thank the representative of Norway for calling upon developed countries to exercise due restraint till the required degree of legal certainty is achieved. Let me also say that this is important from a public relations exercise angle. After all, a number of NGOs

like OXFAM, Médecins Sans Frontières have made valid criticism against the TRIPS Agreement. The Council must demonstrate that such criticism is taken seriously and that the Council is trying to find solutions to the problems and issues posed.

Against this backdrop, it is important that the TRIPS Council reaffirm that a Member can resort to Article 31 on any grounds whatsoever, including of course of protecting public health. Second, it is important that in the context of efforts to obtain authorization from the right holder, the expressions " reasonable commercial terms" and "within a reasonable period of time" are interpreted flexibly and in the light of the practice prevalent within the territory of the Member, taking into account the level of development and socio-economic priorities. Furthermore, the above requirement can be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. A health crisis characterised by pandemics and epidemics of major diseases such as AIDS, malaria, tuberculosis, etc. (the list is obviously not exhaustive) should qualify for an emergency or circumstance of extreme urgency. Similarly, public non-commercial use should cover governmental health care for the poor.

It seems obvious that the TRIPS Agreement does not restrict the possibility that a compulsory licence be executed by means of importation of the patented product. Indeed, in countries where the size of the market does not justify a local drug industry or local manufacturing, this may be the only option.

A related question is the right of the compulsory licensee to import or export. In the case of the former, the compulsory licensee may import from a compulsory licensee in another country. Such importation must be deemed as legal parallel importation. Similarly, a compulsory licensee can export. However, the TRIPS Agreement does stipulate that the compulsory licensee supply "predominantly" for the domestic market. This needs to be interpreted flexibly and broadly. First of all, this limitation does not apply in some developed country markets when the compulsory licence has been granted to remedy anti-competitive behaviour. If that is so, why should the same yardstick not be applicable for compulsory licences issued on grounds of public health? This is something that needs further reflection. Secondly, the condition that compulsory licences should supply predominantly for domestic markets makes productions unviable in small countries with a very small domestic market and poor purchasing power. It is inconceivable that in small countries pharmaceutical companies would set up production facilities for catering exclusively for the domestic market. For such countries to benefit from flexibilities available in the TRIPS Agreement, various options have to be explored. One option is to licence import from the cheapest source. Another is to licence production which allows the right mix of domestic use and export that permits economies of scale. Still another is to encourage regional or global alliances for production by a manufacturer, licensed or otherwise. In this context, the European Communities, in paragraph 13 of their submission, have raised an important issue regarding a possible interpretation of the TRIPS Agreement that would allow a Member to issue a compulsory licence to a manufacturer in another country under certain circumstances. Our view is that this is a correct and legitimate interpretation and therefore cannot be characterized as merely a "possible interpretation". As to the EC's view that such an interpretation may or may not stand scrutiny of a panel or the Appellate Body, our view is that this issue is far too important and should be decided by Members and not through jurisprudence. We appreciate the readiness of the European Communities and their member States to discuss the issue further.

Article 39.3 of the TRIPS Agreement obliges Members to protect undisclosed test or other data against unfair commercial use. It is important to understand what the obligation is in Article 39.3. First of all, it is about protecting certain data against unfair commercial use and not about creating exclusive rights on such data. Second, it applies only to those pharmaceutical products which utilize new chemical entities. We are concerned that there have been suggestions to adopt standards of protection on confidential data that virtually amount to exclusive rights. The adoption of

such standards may lead to a restriction of legitimate generic competition for products which are already in the public domain. Such an approach may also undermine the value of the compulsory licensing system, since the compulsory licensee may face unnecessary obstacles to registration. This issue needs further examination by Members.

Article 6 relating to "exhaustion" in the TRIPS Agreement establishes that each Member has full freedom to incorporate the principle of international exhaustion of rights in its national legislation. Thus, it is clear that the TRIPS Agreement permits parallel imports, i.e. the import and resale in a country, without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the right holder or in any other legitimate manner. It is clear, and the TRIPS Council needs to reaffirm this, that parallel imports is one of the most important measures that a Member can take to protect public health. Thus, it is quite possible that in the market of the exporting country, the product may well be in the public domain or under a compulsory licence. In all these circumstances, it is important to confirm that WTO Members have full freedom to resort to parallel imports, so that access to medicines is achieved in the country of importation.

Article 30 provides for limited exceptions to the exclusive rights conferred by a patent. The exceptions provided in Article 30 are those which do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. These uses could be private and non-commercial use, use for research, experimental or academic purposes and government use, etc. This would mean that the government, as part of public health policy, can use the flexibility under Article 30 for public non-commercial activity. While some jurisprudence in the WTO has already been developed on the issue, it would be the suggestion of my delegation that Article 30 be interpreted as an exception to patents and not read in conjunction with Article 27 as suggested by some. While we agree that the exception should be a narrow one, it is not legally correct to allow an exception to a rule to be trumped by the rule itself! We stand ready to discuss this issue further.

There is yet another issue related to Article 27.3(b) which, in our view, is also relevant for the subject being discussed today. And that is the issue of how biological/genetic resources are dealt with by the TRIPS Agreement. It is no secret that a vast majority of the new drugs and medicines are based on biological/genetic resources which are traditionally found in the South. Patenting of such resources results not only in misappropriation, but also might end up affecting access to medicines based on these biological/genetic resources. Accordingly, it has been suggested by us in a different context that, first, patent applications should reveal the country of origin of the biological/genetic resource; second, that there be prior informed consent of the country concerned; and, third, there be equitable benefit-sharing. Furthermore, the main issue would appear to be the tendency to grant patents on the basis of mere discovery and not invention as also the tendency not to take into account the knowledge of the traditional communities which may not always exist in written form. Since all these issues have to do with medicines and drugs and its access, it would be useful for the Council to look at these issues with a view to finding appropriate solutions.

Article 64.2 provides that the non-violation provisions shall not apply to the TRIPS Agreement for a period of five years from the date of entry into force of the WTO Agreement. Article 64.3 requires the TRIPS Council to examine the scope and modalities and application of non-violation complaints made pursuant to the TRIPS Agreement and submit its recommendations to the Ministerial Conference for approval. Since the scope of non-violation complaints made pursuant to the TRIPS Agreement is not yet clear to the membership and the TRIPS Council has still not made any recommendation, the non-violation clause is not applicable to the TRIPS Agreement. In these circumstances, it would be extraordinary for anyone to suggest that measures taken by Members for protection of public health should somehow be seen through the prism of non-violation!

A number of questions and issues have been raised. This is as it should be. The subject is vital, if I may say so, a matter of life and death! While we may not today find all the answers to the questions raised, it is important that the Council begin the task of looking at the issues raised in right earnest. We know that this is not going to be the last meeting. Indeed, it marks the beginning of a collective effort to find solutions to some of the most burning problems of our time. I call upon our developed country trading partners to engage in all sincerity and seriousness to find ways and means to address the issues and concerns raised by us. By collectively confirming that the TRIPS Agreement does not, should not and need not come in the way of governments dealing effectively with public health concerns and by publicly committing to the position that, even in situations of perceived ambiguity, the TRIPS Agreement will not be allowed to come in the way of achieving public health objectives, our Ministers at the Doha Ministerial Conference can send a powerful message to the world that WTO cares for the people and it is not an organization, as is generally perceived, designed just to serve the business interests of big companies.

SOUTH AFRICA

The South African delegation welcomes the opportunity provided by this meeting, to discuss the relationship between the TRIPS Agreement and public health. We fully associate ourselves with the statements made by Zimbabwe on behalf of the Africa Group and by Brazil on behalf of over 50 countries.

Our intervention is simply to supplement those statements with some additional perspectives.

In our view, the objective of today's discussion is threefold:

- first, to identify the key provisions of the TRIPS Agreement as they relate to the production, trade and affordability of drugs needed to treat serious illnesses prevalent in developing countries;

- second, to re-affirm our common understanding that the TRIPS Agreement strikes a balance between the importance of protecting patents and ensuring that governments are able to take all necessary measures to provide their citizens access to medicines at affordable prices. This common understanding among Members would establish the necessary predictability and certainty without the need to resort to litigation; and

- third, to initiate an ongoing process of discussion amongst WTO Members, leading to the fourth WTO Ministerial Conference in Doha, where Ministers should seek to confirm that the TRIPS Agreement is supportive of all necessary measures to promote public health objectives.

Life-threatening diseases in South Africa, Southern Africa and Africa constitute the most serious developmental challenge confronting our continent, and are beginning to emerge as a serious challenge in other regions. These threaten to obliterate progress on all other fronts. It is an immense challenge that will require a wide-ranging multi-faceted response over many years by Africans themselves, and with the support of the international community.

The central question facing Members of the WTO, given this Organization's particular remit, is: "What will be our contribution to meeting this challenge?"

In making similar points to those contained in the Group's submissions referred to earlier, it may be helpful to draw on South Africa's recent experience.

In 1998, the Pharmaceutical Manufacturers Association of South Africa, together with thirty nine pharmaceutical companies, initiated a three-year legal battle to prevent the South African Government from implementing its 1997 Medicines and Related Substances Act. At issue was the Government's right to utilize the public health safeguards available under the TRIPS Agreement, with the Association charging that the legislation in question violated the Agreement. At virtually the same time, a major trading partner challenged South Africa's proposed health legislation on similar grounds.

Earlier this year, the Pharmaceutical Association and its affiliates unconditionally withdrew the charges and announced that the 1997 Law was framed in a manner consistent with the TRIPS Agreement. In September 1999, South Africa reached an understanding with a major trading partner that clarified that the provisions of the Medicines Act were not inconsistent with the TRIPS Agreement.

The South African Government had always maintained that the legislation in question was indeed consistent with the TRIPS Agreement and that both challenges were tantamount to upsetting the delicate balance that exists in the Agreement. In effect, both challenges were demanding "TRIPS-plus" legislation.

A favourable outcome on both counts was a demonstration of the Government's resolve to ensure a supply of more affordable medicines, since medicines prices in South Africa have often been much higher than in many developed and wealthier countries, both in real and in purchasing power parity terms.

The basic correctness of the policies, technical weaknesses in the challenges to the draft legislation, as well as wide support from domestic and international civil society, combined to ensure that the South African Government position prevailed.

Given that TRIPS was not drafted with current health concerns in mind, and while the outcomes of both of these challenges were favourable, the very fact that the challenges were raised in the first place, suggests the need to confirm, multilaterally, the existing balance in the Agreement.

It is also important to recall that, in May 2000, former President Clinton issued an Executive Order that prohibited the US Government and its agencies from challenging any measure being introduced by Sub-Saharan African countries to address the HIV/AIDS endemic that are consistent with our shared understanding of the safeguard provisions in the TRIPS Agreement.

The earlier statements by Zimbabwe and Brazil have identified the relevant provisions in the Agreement that relate to health policies, and both submissions have asserted a reading of those provisions that supports the introduction of appropriate health measures. We subscribe fully to the reasoning contained in those statements.

In conclusion, WTO Members should consolidate and re-affirm this common understanding by incorporating into the preparatory process leading to the fourth WTO Ministerial Conference in Doha, an ongoing discussion to prepare appropriate recommendations for Ministers' consideration.

BARBADOS

First, I wish to express my delegation's thanks to the African Group for its foresight and initiative in calling for this special session of the Council.

Barbados believes that this special session can make a positive contribution, not only to work within the TRIPS Council, but also in relation to the preparations for the Doha Ministerial Conference.

My delegation is looking forward to concrete results/action coming out of this special session in terms of reaching a common understanding on the principles and objectives of the TRIPS Agreement and the options open to governments to pursue their public health policies. Such a result would have a positive impact on the ongoing "confidence-building" that is necessary if we are to have a successful Ministerial Conference, and if all Members, including developing countries, and in particular LDCs and small economies are to feel that they are part of the ownership of the multilateral trading system, and can maintain their faith in its role as a tool for achieving sustainable development.

My delegation took the floor specifically to express its strong support for the paper tabled by Brazil and co-sponsored by a large number of developing countries, including Barbados.

The Caribbean region, like many others, has experienced the negative impact of the AIDS pandemic on its society and its productive capacity. Within CARICOM, we have devised a regional strategy to try to meet the many challenges which this disease poses. We have also made a positive contribution to discussions on differential pricing, which is an essential issue for Barbados in the implementation of its public health policy. The scale of the problem we face is such that it is clear that we will need creativity, sensitivity and a deep commitment if we are to devise effective, sustainable and long-term solutions.

It must be stressed, however, and the paper makes it quite clear, that the issue before us today in the Council involves much more than the AIDS pandemic. In this regard, my delegation feels that the interpretations advanced in the paper of the various provisions of the TRIPS Agreement strike an appropriate balance between the need to protect private rights and public health concerns.

Permit me to conclude by reiterating the importance my delegation attaches to the issues under consideration. We do not expect that we will resolve all the outstanding problems today, but we do expect and have high hopes that Members, particularly our developed country partners, will take part in these discussions in a positive and constructive manner.

TANZANIA (ON BEHALF OF THE LEAST-DEVELOPED COUNTRIES)

Speaking on behalf of the Least-Developed Countries (LDCs), let me first commend you in your dual capacity as the Coordinator of the African Group and as Chairman of this Council for being instrumental for the convening of this special session devoted to the discussion of such an important issue, that of TRIPS, access to medicines and public health.

Indeed, it was such a great anomaly that while NGOs and other groups were loudly expressing their concern at the negative impact of the TRIPS Agreement on the greatest human tragedy of our times - the millions of deaths due to HIV/AIDS and other killer diseases - the WTO and especially this Council should remain silent. Such silence was harmful to the image of the WTO and indeed can only be disturbing to our collective conscience as members of one human family. The statistics are appalling and revulsing - it is said that more than 17 million lives have so far been lost due to HIV/AIDS in Sub-Saharan Africa alone, and that out of 36 million people infected with the HIV virus worldwide, more than 25 million live in Sub-Saharan Africa, making it quite legitimate for the African Group to be in the forefront on this common concern. For Tanzania, the figures indicate that at least two million people have been infected with the HIV/AIDS virus since it was first reported in 1983 and to date we have more than one million orphaned children as a result of this devastating pandemic. Taking into account that many of the Sub-Saharan African countries are LDCs, this problem is also of particular interest to the LDCs. I would therefore wish to fully support the

statement made by the delegation of Zimbabwe on behalf of the African Group and endorse the proposal that Members of the WTO, through their Ministers at Doha, issue a special declaration on the TRIPS Agreement to facilitate easier access to medicines and ensuring that the TRIPS Agreement should not prevent Members from taking measures to protect public health. We also support the other proposals made by the Group enumerated at the end of that statement. We also endorse the paper which has been presented by the African Group and other delegations which has already been referred to by Zimbabwe and Brazil.

We all agree that Article 7 of the TRIPS Agreement is fundamental as it encapsulates the need for a judicious balance between the need to provide an incentive for invention and research on the one hand and the overriding need to apply the knowledge and technology for the social economic welfare of the wider society. We need to have a humane common interpretation of this Article on the basis of our common commitment to the primacy of human life and decent human values so that, while it remains possible for the inventors to be justly rewarded, private profit must not be allowed to threaten human lives. And yet, over the last six years of the life of the TRIPS Agreement, this is what has been seen to be happening when patented drugs for HIV/AIDS have been priced beyond the ability of HIV victims, most of whom are the poorest of the poor who live below $1 a day. When the life-saving three-drug combination of antiretrovirals for HIV/AIDS is priced at $10,000 - 15,000, this is a coded message to the poor that they may as well die if they cannot pay the price that will make the boardrooms of the pharmaceuticals happy. It should certainly arouse our ethical instincts when we know that such prices have no rational relation with the cost of research and development for such drugs and when it is also known that some of the cost for the research for such drugs has been borne by public funds and not by the funds from the private companies that reap therefore super-profits.

We also believe that Article 8 of TRIPS Agreement should give our countries the maximum flexibility to adopt such measures that are necessary to meet the challenges of the killer diseases without the implied restriction that could be read into the words "provided such measures are consistent with the provisions of this Agreement". This is a point which Ambassador Narayanan from India also referred to more extensively. We believe this Article should be interpreted in the context of the basic need to uphold the primacy of human life as implied in the most sensible interpretation of Article 7 as already referred to above. As statistics show with regard to the lives lost due to HIV/AIDS and other killer diseases, many of our countries are losing more people than we have lost in the two World Wars and other national and regional conflicts put together, and it is only fair to allow governments the flexibility to adopt any measures which seek to ensure the very survival of the nation-states.

For the same reasons as stated above, the same level of flexibility should be accorded for the interpretation to Article 31 with regard to compulsory licensing. The presence of this option is a clear recognition of the fact that, where public interest is at stake, it may be necessary to take measures to override the purely private interest, and in the light of the permanent emergency situation in our countries as evidenced by the stark statistics, the justification for compulsory licensing should not be limited by the strict interpretation of the provisions of the Agreement, but must be flexible enough to enable our countries meet the challenges of preserving human lives. It is also known that LDCs do not have the industrial and technological capacity to manufacture drugs even when they have the right to resort to compulsory licensing and in this case LDCs should be allowed to invoke compulsory licensing in favour of a firm located in another country and then be allowed to import the drugs without being accused of infringing the Agreement.

This will also be an incentive to the firm concerned, if it can be allowed to export to a country other than where it is located and therefore the provisions in Article 31(f) that such products under compulsory licensing "shall be authorized predominantly for the supply of the domestic market" should be interpreted more liberally.

The LDCs also believe that the option of parallel importation is useful, since it allows a poor country to buy drugs that are more affordable than if importation was restricted. In a survey conducted in 1995, it was revealed that 100 tablets of Zantac were sold for $2 in India, $77 in Canada, $150 in South Africa and $97 in Tanzania. Similar situations are in place even now where prices of some tablets are less expensive in richer countries than in Tanzania. The option of parallel importation as implied under Article 6 should therefore be supported and expanded as it will enable more patients in LDCs to have access to cheaper drugs. With regard to differential or tiered pricing arrangements, even if this is a matter which needs to be looked at more closely by the WHO and other competent international bodies, if properly conceived and managed, it could provide yet another possibility for the LDCs to get access to more affordable medicines.

For the LDCs, all this talk of using the options of compulsory licensing or parallel importation means that these countries need to be assisted in enacting the appropriate legislation to put those options in place. This means that there is need for the more developed Members of the WTO to provide more technical assistance to the LDCs, and I take due note of what Ambassador Trojan of the European Communities said earlier this morning. In this regard, we wish to commend the recently launched Joint WTO-WIPO Initiative to assist LDCs in fulfilling their commitments under TRIPS when the transition period expires in 2006. At the same time, we need to remind the more developed WTO Members of their obligations under Article 66.2 to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base". As this matter will be specifically discussed again in the course of this week, I need say no more now than just to flag it for your kind attention.

Let me conclude by agreeing with what others have said before me that this discussion today should not be a one-off event. The human tragedy caused by HIV/AIDS and other mass-killer diseases is real and the potential for humanity to rise to the occasion to at least mitigate the potential holocaust is also real if we are to use the TRIPS Agreement as part of the solution and not allow it to be part of the problem. In the process, we may even address more fundamental questions as to whether the TRIPS Agreement itself, which is basically protectionist in its thrust, is in tune with the rest of the Uruguay Round Agreements and the WTO, which are geared to market liberalization. Even if the TRIPS Agreement remains, we may also ask if we cannot use Article 27.2 to exclude from patentability at least medicines that are vital for saving human lives. Clearly therefore, it is important that we remain engaged with this important issue all the way to Doha, and beyond if need be.

BOLIVIA

I would like to associate myself with all that was said today by the delegations of Zimbabwe, Brazil, Venezuela, India, South Africa and Tanzania.

For the delegation of Bolivia, which presented and endorsed the document "TRIPS and Public Health" together with 17 other delegations and the African Group, it is highly important that the Council for TRIPS should be addressing the issue of the relationship between intellectual property and access to medicines as an agenda item.

The WTO's decision to incorporate this subject into its discussions was a step in the right direction in tackling a problem with worldwide connotations that has led civil society to question the validity of the TRIPS Agreement, and in particular patent protection of pharmaceutical products. While this meeting is providing public opinion with an optimistic message, the WTO must take concrete measures to ensure that the millions of citizens in the developing countries suffering from poverty related diseases have effective access to pharmaceutical products.

Before initiating a discussion on the relationship between intellectual property and access to medicines, we should establish clearly that medicines are not just ordinary goods, and should receive special treatment.

Similarly, these discussions should be conducted in the framework of the Marrakesh Declaration in which Ministers affirmed that the establishment of the WTO must be for the benefit and welfare of their peoples. It should be recalled in this connection that access to medicines is a public health priority which prevails over purely commercial considerations in that it is one of the human rights, i.e. *the right to health*.

In principle, there should not be any conflict between the TRIPS Agreement and public health in view of the different provisions contained therein, in particular Articles 6 (exhaustion of rights), 7 (objectives), 8 (principles), 27 (patentable subject-matter), 30 (exceptions to rights conferred), 31 (compulsory licensing), 34 (reversal of the burden of proof), 40 (anti-competitive practices), 66 (transfer of technology to the least-developed country members) and 67 (technical cooperation). However, in practice, some developing countries have encountered difficulties with the holders of patents for medicines, because profit has prevailed over public health considerations.

The delegation of Bolivia is not questioning the fact that the patent system has served to promote research, develop new medicines and provide profits to inventors and creators. However, the objectives and principles of the Agreement must prevail and the Agreement must be applied in such a way as to protect and promote public health.

In this context, we consider that there are provisions in the TRIPS Agreement that enable the developing countries to face their domestic public health problems, such as the objectives and principles of the Agreement, compulsory licensing, parallel imports, as well as other initiatives such as the use of generic medicines, differential pricing - a concept introduced by the WHO -, dissemination of information on the prices of medicines, and so on.

We conclude by repeating that the fourth WTO Ministerial Conference in Doha must clearly establish that there is no conflict between the TRIPS Agreement and public health and, if necessary, that the existing provisions must be interpreted or a mandate provided to develop other provisions to clarify or amend the existing ones.

THAILAND

General observations

First of all, Thailand would like to thank the African Group for taking the initiative of organizing this meeting to address TRIPS and related health issues. It is time for the WTO/TRIPS Council to take this issue seriously and explore what Members can do to improve/respond to the situation now occurring in developing countries where access to affordable medicines is a serious problem.

Thailand, as one of the co-sponsors of the joint paper on TRIPS and Public Health, supports fully the statement made by Malaysia on behalf of ASEAN and would like to make additional observations as follows.

We think it is clear to everyone that some of the provisions in the TRIPS Agreement, particularly those relating to patent protection for pharmaceutical products, have significant impact on public health.

We are well aware that many essential drugs are not under patent, but that is beside the point today. The TRIPS Council's task is to discuss the problems in making available drugs that are under patent; problems caused by the lack of clarity in the TRIPS provisions. The TRIPS Agreement says nothing about infrastructure or other pressing problems. So the TRIPS Council has no business discussing them at the expense of devoting precious time to the relationship between patents and health.

Our task here is not to attack the patent system. We are aware that the patent system can be an effective mechanism to promote innovation in the area of pharmaceuticals.

We are all aware that TRIPS provides built-in flexibilities regarding measures WTO Members can take to obtain medicines, both patented and non patented, from the best and cheapest sources, both foreign and local.

However, due to lack of clarity of certain provisions of the Agreement, developing countries seem to be reluctant to take measures that they are entitled to under the Agreement. This is very unfortunate, because one of the purposes of the Agreement was to establish an international benchmark for intellectual property protection and to prevent unilateral pressure, as stated in the Preamble.

My delegation would like to suggest that, at this stage, Members attempt to identify and explore whether such flexibilities in the TRIPS Agreement are available in practice. Further, we wonder why developing countries (and least developed countries) facing critical health concerns are not pursuing the options that some Members often claim are open to them in order to address the inadequate access to affordable life-saving drugs.

Specific points

Firstly, we need to confirm that each Member is free to decide for itself the grounds for granting compulsory licences under Article 31. Without trying to embark on a narrow interpretation of the provision, on the contrary, Members should reaffirm that Article 31 should be read in the light of Articles 7 and 8 of the Agreement.

Secondly, Article 27.1 does not restrict the grounds for granting compulsory licences. The obligation to consider applications for compulsory licences on individual merit in Article 31, if properly applied, overrides the non-discrimination provisions under Article 27.1.

Thirdly, due to the mere fact that Article 6 explicitly indicates that the TRIPS Agreement shall not be used to address the issue of exhaustion of intellectual property rights, Members are free to adopt their own scheme of exhaustion of rights. As a result, parallel imports are permitted and do not violate patent rights.

Fourthly, in certain circumstances, Members should be able to grant compulsory licences to producers in another country to produce patented drugs in Members' own markets. This will enable developing country Members with limited industrial capacity to be able to make use of compulsory licensing and gain access to affordable drugs. In this regard, Members could try to explore the flexibility available under Article 31(f).

In conclusion, my delegation finds this special discussion very useful and a good start for substantive discussion. Due to the very nature of the problems involved, we find it necessary to have continued discussions on these issues.

If I correctly judge the sentiment of all of us here today, we will not be satisfied if at the end of the day we end up with a mere statement of recognition of the seriousness of health and access problems while the current flexibilities are still unclear.

Without prejudging the outcome of our discussion, the Council needs to make a recommendation to the General Council for a decision interpreting the relevant TRIPS provisions, putting beyond doubt measures which governments may take to tackle the problem and, if found necessary, amending the TRIPS Agreement.

UNITED STATES

Before I read out my prepared statement, let me first thank Zimbabwe, the African Group and their co-sponsors as well as the European Communities and their member States for their very thoughtful contributions in writing to our discussions today. I also would like to thank all of those speakers who went before me; their interventions will be immensely valuable as we continue this dialogue. I believe Members will see in my statement that we share many of their views.

The HIV/AIDS crisis is a terrible tragedy - for countries, families and individuals. The United States is fully committed to the battle against this disease.

We very much want our discussion in this Council to make a constructive contribution to this effort.

Policy Points

Our discussion today is intended to clarify Members' views of the interpretation and application of relevant provisions of the TRIPS Agreement, particularly with respect to the flexibility Members have under the Agreement in providing access to life-saving drugs.

The United States supports this discussion. We hope that, through this dialogue, Members will come to appreciate the important role the TRIPS Agreement plays in stimulating development and commercialization of new life-saving drugs. We also hope that this dialogue will result in a clearer understanding of existing flexibility in the Agreement which enables Members to ensure that such drugs are available to their citizens, particularly those who are unable to afford basic medical care.

The TRIPS Agreement strikes the proper balance between these two objectives. Some have quite incorrectly blamed the Agreement for health crises or claimed that it stands in the way of resolving such crises. Quite the contrary, Members have the ability under the Agreement to implement their obligations in a way that fully supports their national health care objectives.

On the other hand, without the economic incentives provided by patent systems, there would be far fewer drugs available for the treatment and cure of life-threatening diseases.

My comments first address the United States' broader policy approach to fighting infectious diseases and life-threatening conditions. Strong patent, trademark, and trade secret protection is a key element because of the critical role such protection plays in the rapid innovation, development, and commercialization of safe and effective drugs.

We are equally committed to ensure that Members are able to use the flexibility in the Agreement where necessary to meet their health care objectives. In February, the Bush Administration reaffirmed the commitment of the United States to a flexible approach on health and intellectual property. Under this policy, we have informed WTO Members that, as they take steps to

address major health crises, such as the HIV/AIDS crisis in Sub-Saharan Africa and elsewhere, the United States would raise no objection if Members availed themselves of the flexibility afforded by the WTO TRIPS Agreement.

A comprehensive approach is needed to serious health problems. We believe that participants in our discussion today should keep in mind that the TRIPS Agreement - its obligations and flexibility - is, at most, one element of the equation. To deal with serious health problems, countries need to stress education and prevention as well as care and treatment if health crises are to be eliminated.

Health experts inform us that the cost of drugs is only one of many important issues that must be addressed in any health crises. Effective drug treatment necessitates urgent action to strengthen health management systems particularly directed to drug distribution and patient monitoring. Appropriate drug selection policies and standard treatment guidelines; training of care providers at all levels; adequate laboratory support to diagnose and monitor complex therapies; and systems for ensuring that the right drugs are used for the right purpose and in the right amount are all required to address the HIV/AIDS crisis.

We must recognize that even if enough drugs to treat every single HIV-positive person were provided, free of charge, an adequate infrastructure to deliver them and monitor their use does not appear to exist in many areas most in need. To ensure that health care is available, particularly to those unable to afford basic medical care, health experts tell us that each country must also develop its medical and public health infrastructure, increase the resources allocated to health care, and take other appropriate steps.[2]

That is why the United States will continue to pursue an integrated approach to fighting disease, focusing on prevention of new infections and training medical professionals, as well as on treatment and care.

As tangible evidence of our commitment to this integrated approach to fighting disease around the world, the United States continues to be the largest bilateral donor of HIV/AIDS assistance, providing for nearly 50 per cent of all international HIV/AIDS funding.

Recently, the United States announced a proposal for the creation of a new global fund to fight HIV/AIDS, malaria and tuberculosis. The United States will back this international effort by providing US$200 million in seed money for fiscal year 2002. The United States also will work with other governments, private foundations, corporations, faith-based groups, and other organizations to generate additional support for this global effort. Just today, it was announced that the Gates foundation has made a major contribution of the fund.

In addition to the US$200 million commitment to the new Global Fund, the United States budget for FY 2001 increases funding to fight the international HIV/AIDS epidemic to

[2] At the Norway conference, Dr. Brundtland closed with the following statements:

'We have heard quite clearly that the price of drugs matters, it matters to poor people, and it matters to poor countries. But little progress will be possible without a significant investment in building effective health systems", and

"There were other important lessons that came out of our review of current experience. It reinforced the point that just making drugs available - even at no cost - does not guarantee that they will be utilized. All other pieces of the picture have to be in place as well: the distribution systems, the partnerships between public and private providers; the agreements between governments and development agencies; and clear and explicit goals and objectives."

US$480 million, increases to US$10.2 billion the budget of the Department of Health and Human Services, and US$2.5 billion for the National Institutes of Health for HIV/AIDS research.

My Government invites the participation of other nations and other partners in securing the necessary funding to address the global HIV/AIDS pandemic.

Role of IPRs in developing new health care-related technologies

Recognizing that it is but one part of a much larger equation, let me focus on the role of intellectual property, particularly patents, in supporting effective health care.

There is no question that patent systems serve public health objectives by stimulating discovery, development and commercialization of new products to prevent, treat, or cure illness.

Specifically, the experience of the United States has been that a period of market exclusivity for innovated products and processes - whether provided by a patent, data exclusivity, trade secrets or a combination of these legal protections - is essential to ensure development and commercialization of new health care products, including pharmaceuticals, diagnostic products and medical devices.

Without this period, during which unauthorized parties cannot sell copies of the protected invention, the private sector may be unwilling to take the immense risks associated with development of significant new healthcare products. Market exclusivity for the results of innovation, and not simply the possibility of a royalty, provides the necessary incentive for companies to invest in research to discover, develop and commercialize new products.

Contrary to what many have asserted, this exclusivity does not give right holders a monopoly. In fact, the scope of the exclusivity provided by a patent is quite narrow. Based in part on the disclosure associated with the patent application, even during the patent term, competitive manufacturers are able to develop and market their own competing drugs to treat the same illness, thus ensuring price competition and a wide choice of effective treatments for both doctors and patients.

We understand that in the United States alone there are presently more than 100 new drugs for the treatment of HIV/AIDS in development, more than 120 new drugs to treat heart disease and stroke, more than 135 new drugs for treating or preventing infectious diseases, more than 400 new drugs for treating or curing cancers, and more than 700 new drugs to address diseases associated with aging.

These are in addition to the revolutionary treatments that have been marketed in recent years that, every day, are saving lives that would have been lost just a few short years ago.

Many thousands of initially promising drugs never reach the market because they have been found to be ineffective or too toxic. It is the prospect of market exclusivity that continues to spur the development and commercialization of new products despite the high number of unsuccessful compounds.

Simply put, intellectual property protection systems, particularly patents and trade secrets, under the TRIPS model must be available to create the environment necessary for new drug development. This is significantly different from an environment that merely promotes copying of existing drugs.

UN Secretary General Annan pointed this out recently, when he said, "Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the

health of the world's poorest people. The United Nations fully supports the TRIPS Agreement the safeguards incorporated within it."

We also note that the Resolutions approved by at the 21 May World Health Assembly clearly recognize the importance of intellectual property in urging members to support, encourage and provide incentives for increased investment in research related to HIV/AIDS, including in the development of new preventive and therapeutic approaches and technologies, including in particular HIV/AIDS vaccines and microbicides.

Apart from stimulating innovation, however, a strong IPR regime - particularly a strong patent regime - can also produce other benefits for countries, regardless of whether the countries are developed or developing.

For example, countries that have strong patent regimes are more effective in attracting investments and market entry by innovative companies. The reasons for this are fairly simple - patents provide a greater capacity for the innovator to compete based on the innovation. If the innovator cannot use the innovation to provide a market advantage, there is a disincentive to enter the market, particularly where others in that market can charge lower prices because they do not need to recover the costs of research and development, nor do they need to invest in new research and development.

As I have already noted, another important benefit of a patent regime is that, in order to obtain a patent, an innovator must disclose all the technical details of the invention, a requirement embodied in Article 29 of the TRIPS Agreement. This disclosure stimulates a significant flow of information to the public, including competing manufactures, that might otherwise be kept secret. Therefore, patent systems do not impede research and development activities nor do they discourage competition. Patent systems encourage this activity.

Thus, patent regimes actually promote the objective of Article 7 of the TRIPS Agreement by contributing to the promotion of technological innovation and to the transfer and dissemination of technology.

The TRIPS Agreement Reflects the Proper Balance Between Innovation and Access to Health Care

In establishing standards for patent regimes, and in providing certain flexibilities, the TRIPS Agreement has struck a proper balance between offering incentives for innovation and ensuring that there is access to needed medicines.

Indeed, two documents available on the WTO website, the "WTO Fact Sheet: TRIPS and Pharmaceutical Patents", and the "Technical Note: Pharmaceutical Patents and the TRIPS Agreement", highlight how this balance is struck by the Agreement. We encourage Members to refer to these documents as useful explanations of the Agreement and to avoid documents circulated by other individuals and organizations that lack the WTO's expertise.

We also want to note the European Communities' thoughtful paper on the relationship between the provisions of the TRIPS Agreement and access to pharmaceuticals. We find many areas of agreement with them and note with interest some of the questions raised about "permissive" readings of Article 31.

Before discussing the specific articles of the Agreement most commonly associated with access to medicines, I would like to remind delegations that among the most significant flexibilities contained in the TRIPS Agreement are the transition periods provided to developing and

least-developed country Members, especially the specific transition period provided to Members which had not established patent protection for pharmaceuticals and agricultural chemicals at the time the Agreement entered into force.

We would like to understand better what impact the TRIPS Agreement could be having on the health care regimes of least-developed country Members given that these Members are not currently obligated to implement the Agreement, including its patent provisions. We are particularly interested because certain Members have suggested that these transition periods be further extended, even before these Members have had any experience implementing the Agreement.

Article 30 of the TRIPS Agreement

Article 30 of the TRIPS Agreement allows Members to provide for limited exceptions to exclusive patent rights so long as the exceptions do not unreasonably conflict with the normal exploitation of the patent or prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

Earlier drafts of the Article reveal that negotiators had in mind exceptions for such things as so-called prior user rights; acts done privately and for non-commercial purposes; acts done for experimental purposes; and similar activities.

We note that a WTO panel considered Article 30 in a dispute between the European Communities and Canada, regarding the provision of Canada's patent law allowing generic manufacturers to make use of patented drugs during the patent term solely for the purpose of developing data to obtain marketing approval for a generic equivalent. This policy was designed to allow introduction of generic drugs on the market quickly after the expiration of the patent. The panel found that the exception in Canada's law, with one exception, was sufficiently limited to fall within the scope of Article 30.

That means that exceptions for pre-expiration testing similar to those provided in Canada and the United States which significantly accelerate the availability of lower cost generic drugs can be included in Members' patent laws without violating the Members' obligations under the TRIPS Agreement. This is an important flexibility in the Agreement that enhances access to drugs.

Article 31 of the TRIPS Agreement

It is apparent that Article 31 creates obligations for Members only when a particular pharmaceutical is protected by a patent within its territory. It should be obvious that Members have no TRIPS obligations with respect to products that are not protected by patents within their territories, even though those products are patented elsewhere.

Therefore, it is not necessary for a Member to grant a compulsory licence to produce a pharmaceutical product within its territory if patent protection for that pharmaceutical product does not exist in its territory.

As has been noted by the European Communities and others, Article 31 does not itemize the purposes for which compulsory licences may be granted. Instead, the Article establishes conditions that must be met with respect to compulsory licences, conditions that are modified, in some instances, depending upon the purpose for which the compulsory licence was granted.

Of course, Article 31 must be read in light of the other provisions of the TRIPS Agreement, including Article 27.1. The latter provision prohibits discrimination in the enjoyment of patent rights

based on whether products are imported or domestically produced. In other words, importation of a product, rather than domestic production, cannot justify the grant of a compulsory licence.

Because Article 31 does not specify the circumstances under which compulsory licences may be granted, it is understandable that it does not make express reference to public health. Article 8.1 makes it clear, however, that public health is one concern Members may take measures to address, so long as the measures are consistent with the TRIPS Agreement's provisions.

While I will not discuss in detail each of the conditions established by Article 31, I would like to highlight those that seem most relevant for our discussion today.

The second condition under Article 31 establishes an obligation, then provides circumstances in which that obligation may be waived. The obligation is that unauthorized use may be permitted only if the party seeking a compulsory licence has been unable, within a reasonable period of time, to obtain a voluntary licence on reasonable commercial terms and conditions.

That obligation may be waived in a national emergency or other circumstances of extreme urgency or in the case of public non-commercial use. This waiver authority is, of course, very important for our discussion today.

The possibility of such a waiver recognizes that, in the case of a national emergency or other circumstances of extreme urgency, there isn't time to enter into negotiations with a patent owner to obtain a voluntary licence. Certainly, epidemics such as HIV/AIDS within a Member's territory are as much a national emergency or a circumstance of extreme urgency as war, civil strife, or natural disasters for purposes of exercising the waiver authority. The United Nations Security Council made this point last year, and I believe most speakers in the room have also made that point.

Paragraph (b) also permits a waiver of the requirement to seek a voluntary licence first in the case of public non-commercial use, recognizing that requiring governments to do patent searches and seek voluntary licences before every procurement of goods or services for the government's own use would unnecessary delay the procurement of those goods or services and would add to their costs.

Paragraph (b) also makes clear, however, that in cases in which the requirement to seek a voluntary licence is waived, the patentees must be notified as soon as reasonably practicable. In addition, paragraph (h) of Article 31 makes it clear that the patentees must be paid adequate remuneration for the use of their patents, taking into account the value of the authorization.

Paragraph (c) specifies that the scope of a compulsory licence and its duration are to be limited to the purpose for which the licence was authorized. Obviously, were such a licence granted on a patented drug in order to address a condition of extreme urgency, such as an epidemic, the use should be limited to providing the pharmaceutical to treat those suffering from the disease or to prevent contraction of the disease, if that is the purpose of the pharmaceutical. The duration would likely depend upon the duration of the epidemic. Related to this, paragraph (g) provides for the termination of a compulsory licence when the circumstances that led to its issuance cease to exist and are unlikely to recur.

Paragraph (f) is also very important for our discussion today, because questions have been raised about whether a compulsory licence can be granted under a patent to a supplier from another country. Paragraph (f) states that compulsory licences should be authorized predominantly for supply of the domestic market of the Member authorizing the use.

In our view, the nationality of the recipient of a compulsory licence is not relevant for the purposes of Article 31. What is relevant, in such a case, would be whether the licence results in an infringement of a patent for the same product in the licensee's country.

Obviously, if no patent for the drug has been granted in the licensee's country, no infringement would occur. If such protection does exist, however, and the compulsory licensee chooses to manufacture the drug in its country for export to the country that granted the compulsory licence, a problem is created. If the patentee successfully sued the producer in the other country, the compulsory licence originally granted would be ineffective in supplying the needed pharmaceutical.

For this reason, one must consider whether it would be appropriate to limit eligibility for compulsory licences to those parties that can assure the government granting the licence that they will be able to supply the market without interruption that might result from infringement of a patent in their own country.

The non-national could make such assurances either because no patent existed in its home country, because it had obtained a voluntary licence from the patentee in its home country that allowed it to produce the patented pharmaceutical for the supply of the other market, or because it planned to produce the patented pharmaceutical in the territory of the country granting the compulsory licence.

The EC has identified a possible interpretation of the Agreement with respect to whether a compulsory licence can be granted under a patent to a supplier from another country even where patent infringement might otherwise be considered to have occurred. This proposal raises questions that should be addressed if there is further discussion of this concept.

Lastly, I would like to address two misconceptions regarding compulsory licensing. First, contrary to what some have asserted, compulsory licences under the TRIPS Agreement are not intended to be a mechanism for directing industrial development, protecting domestic industries against foreign competitors, or for promoting the now widely discredited economic policy of import substitution.

The foundation of free trade embodied in the WTO system is the removal of conditions that lead to inefficiencies in global trade. The WTO has long recognized the trade-distorting nature of local content, import substitution and local production requirements. We note that the non-discrimination clause of Article 27.1 of the TRIPS Agreement is built on this foundation.

Pharmaceuticals are among the best examples of products where these principles are true. Pharmaceuticals can be efficiently produced in a small number of locations and transported through international trade to markets needing those products. Such efficiencies in production and distribution lead to lower prices and faster supply of products to meet demands, including those caused by public health emergencies.

Indeed, recent studies have shown that local production does not necessarily result in lower prices.

Second, some have observed that certain Members employ compulsory licences to remedy anti-competitive practices, as the TRIPS Agreement clearly provides, with no ill effect to their patent system.

Certainly the United States has never suggested that compulsory licences are not a fully appropriate and TRIPS-consistent way to remedy anti-competitive behaviour. However, we would point out that compulsory licences are used in this manner to remedy an abuse, and not in the normal

course of doing business. Therefore, it is inaccurate to suggest that US practice would support the conclusion that there would be no negative implications for patent systems, and more importantly incentives for developing future life-saving drugs if Members were to permit widespread use of compulsory licences for any purpose.

Parallel Import

So-called "parallel imports" are also sometimes raised in discussions regarding access to drugs. To be clear, we define that term to mean legitimate goods produced by a patent owner or with the patent owner's authorization that are purchased in one market where the price is attractive, whether as the result of differential pricing by the patentee in recognition of the economic development of a country, of currency differences, of price controls, etc., and imported into another country where a patent exists, without the authorization of the patent owner.

There is no question that Article 6 denies Members the ability to avail themselves of dispute settlement in relation to questions involving parallel imports, except when those questions involve national or most-favoured-nation treatment. However, Article 6 of the TRIPS Agreement does not, in our view, authorize parallel imports. Members must remember that Article 6 does not alter the substantive obligations of the TRIPS Agreement, particularly those contained in Part II of the Agreement.

In our view, advocates of parallel importation overlook the fact that permitting such imports discourages patent owners from pricing their products differently in different markets based upon the level of economic development because of the likelihood that, for example, products sold for a low prices in a poor country will be bought up by middle men and sent to wealthiest country markets and sold at higher prices, for the benefit primarily of the middle men.

The lack of parallel import protection can also have significant health and safety implications. Our law enforcement and regulatory agencies, especially the Food and Drug Administration, have commented on how very difficult it is for them to keep counterfeit and unapproved drugs out of our country even with the strong parallel import protection provided in the United States.

Advocating parallel imports, therefore, could work to the disadvantage of the very people on behalf of whom the advocates purport to be speaking. As Dr. Brundtland in Oslo recently noted, "For differential pricing to work on a large scale, I think we can all agree that there must be watertight ways of preventing lower priced drugs from finding their way back into rich country markets".

Article 39.3 of the TRIPS Agreement

With respect to Article 39.3, we concur with the EC's observation that the most effective way of protecting test data against "unfair commercial use" in a manner consistent with the TRIPS Agreement is to ensure that regulatory authorities do not rely on such data for a reasonable period of time, such as five years, as is the case in the United States.

Conclusion

To conclude, I believe it is universally agreed that we must provide incentives for investment in research and development of new and more effective life-saving drugs. Effective patent systems, therefore, are crucial if we are to find better treatments and ultimately cures for HIV/AIDS and the many other diseases and health conditions that afflict the world's population.

The TRIPS Agreement appropriately requires that an effective patent system be provided within every WTO Member. It also provides sufficient flexibility by allowing certain limitations on patent rights to, among other things, address public health issues, including diseases and conditions that are epidemic and endemic.

We look forward to the interventions of other delegations, the in depth analysis behind such interventions, particularly in those cases where it is being asserted that the TRIPS Agreement is not already sufficiently flexible. We also look forward to continuing this discussion in future meetings and to all Members' substantive contributions.

EGYPT

In this intervention, which I hope will be quite brief, the intention is to touch upon only a limited number of provisions in the TRIPS Agreement.

But, at the outset, let me thank the coordinator of our Group, Zimbabwe, for the statement delivered on behalf of the African Group, which we fully subscribe to. We also wish to express our appreciation for the paper produced and presented by the European Communities (IP/C/W/280) which contributes positively to our discussions today.

The particular case of medicines is very significant and the stories behind it are very many and also very telling. Indeed, the developing countries have the right to use a transitional period of up to 10 years before they become obliged to apply all the provisions of the TRIPS Agreement on equal footing with any other country.

The question that looms in many minds is whether a 10-year period of transition is reasonably sufficient for the transformation of a typical developing country to a status reasonably close to that of a typical developed country in a manner that reasonably allows equal application of the same rules to obtain reasonably similar results.

Given the realities of differences in capacities and needs, one must look to the set of rights and obligations as explicitly pronounced or implicitly to be understood in their international legal instrument which all member countries must respect, namely the TRIPS Agreement. In that instrument there are, to be sure, certain inflexibilities, but there are also certain flexibilities.

We can find the flexibilities presenting themselves in some of the horizontal general provisions and basic principles of Part I of the Agreement. Most importantly among these are Articles 7 and 8, which allow governments to adopt measures necessary to protect public health and nutrition, and to prevent the abuse of IPR's including the resort to anti-competitive practices. These flexibilities, however, are restricted - but not totally neutralized - by the requirements that they must be consistent with the provisions of the Agreement. I wish to recall here the fact that the crucially significant language in Articles 7 and 8 summarizes the whole drive and purpose of the Agreement, by stating that it aims at balancing rights and obligations to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare.

We have also Article 6 on the exhaustion of IPRs, which consequently allows parallel imports. The same effect is reflected in Article 28 on the title-holder's exclusive rights where the footnote to this Article confirms the same kind of flexibility. In the field of medicines, this spells much relief in many adverse health situations. We have thus some useful permissibles which somewhat counterbalance the pressures imposed in other places in the Agreement.

Let me also make mention of Article 30 on exceptions, which allows developing and developed countries alike to resort to limited exceptions that may be used carefully and judiciously to

produce beneficial effects without infringing the legitimate rights of other parties. A set of selected exceptions can thus provide a breathing space and some degree of freedom of action, which would necessarily differ from country to country. On this point, I may make mention of the Canadian experience in the area of medicines where a single exception, the so-called springboarding-Bolar exception, was applied with notable success. Of course, the exceptions are not *carte blanche*. They are again restricted, since their application can encroach on other parties' rights.

Before leaving this point and having alluded at the experience of Canada in the pharmaceuticals fields, I allow myself to make mention of a remarkable drug pricing mechanism which is operational in Canada, namely the Patented Medicines Prices Review Board. This, I believe, deserves study, since it is a mechanism of a highly developed economy, a wealthy country, yet a country, which harbours concern about the prices of medicines available to the average citizen.

What looms in many minds during this Special Discussion on intellectual property and access to medicines, is the need to explore the permissible exceptions, both candidly and in depth, and how they can prudently be conceived.

Compulsory Licensing (Article 31 of the TRIPS Agreement) is another area where a degree of flexibility is available for application whenever necessary, such as in difficult and harsh times. I guess no times can be more difficult or harsh than when a life-saving medicine is denied or when the price is prohibitive. In this connection, attention has already been drawn in many quarters to paragraph (f) of Article 31 concerning the obligation to supply "predominantly" the domestic market. A human reading or a re-reading of the language in Article 31(f) would also lead to permitting the use of a locally produced medicine to alleviate adverse health situations in another country.

Let me turn, from hinting at some of the flexibilities that are pronounced in the TRIPS Agreement, to hinting at other flexibilities that deserve to be given attention, although they are <u>not</u> straight-forwardly pronounced in the Agreement, but have roots in its provisions.

Of all practices that can now be highlighted as pertinent morally and useful to all countries, and fair to all peoples and eventually to all businesses including the pharmaceutical manufacturers themselves, are the following:

(1) Differential pricing policies and practices, where drug selling prices are influenced by the *per capita* income in different countries.

(2) Refraining from the practices of requiring expansions or extensions to the exclusive rights of the right holder, such as demanding prolongation of the patent term, pipeline protection, and evergreening of patents.

(3) Refraining from those restrictive forms of patenting in the area of pharmaceutical products, that are either useless or harmful, such as what has come to be known as broad-blocking patents and sleeping patents.

(4) Noting that a strict, but a fair reading of TRIPS Article 27.1 together with Article 27.3(a) would not mean that the *use*, even if it is a new use of a known pharmaceutical product, is in itself patentable. Such new use is certainly a valuable scientific finding, maybe a genuine discovery, that deserves every appreciation and needs to be brought to the attention of the medical profession. Such new use would more appropriately be seen as a *method* of therapy of the kind indicated in Article 27.3(a).

(5) The historical role of R&D in the health area, particularly the area of fighting against or protecting from communicable diseases, cannot be over-emphasized. What needs now to be emphasized, however, is the need to persuade R&D – most of which is conducted in the developed countries and particularly in the laboratories of the MNCs – to pay greater attention to the health problems of the poor in the developing world. Such contributions will pay great dividends in the long run and will certainly help in dismantling the wall of fear and suspicion that is sometimes visible.

(6) The principle of working a patent locally is historically cardinal in the general philosophy of the patent system. What is meant by working of a patent is its actual implementation to produce the patent-protected product or the actual use of the patent-protected process. This is what the WIPO Model Law for Developing Countries says. Working is the reward that the society deservedly receives in exchange for conferring complete and strict protection of the IPRs. This lofty goal will be defeated if working occurs only through importation of the patented product. It is to be remembered also that, to the Paris Convention, non-working is a kind of abuse of the exclusive rights enjoyed by the title-holder, which can be a ground for a compulsory licence.

(7) Major manufacturers of those medicines that have fallen into the *public domain* can do a lot of good to the peoples of developing countries. Encouraged by their governments, such as through the award of incentives (remember TRIPS Article 66.2), these manufacturers can transfer technology and manufacturing know-how relevant to medicines of importance to receiving developing countries against reduced prices, or perhaps at no cost at all.

(8) My own country, Egypt, provides a package of generous incentives which, in addition to a favourable IPR-protective environment, is aimed at attracting foreign enterprises to establish in the country a base for their manufacturing operations. The message is directed with a particular appeal to manufacturers of medicines and *pharmaceutical chemicals* that have relevance to the local health problems.

Finally, there is a special message that needs to be directed to the WHO. The presence of this critically important organization is very much needed in all future review or revision functions as related to or as affecting the area of medicines. There is dire need to evoke the question of essential drugs and how the list is constructed and updated, and how best it can be utilized, in the context of today's deliberations, to provide real and effective relief for the poor in the developing world. Towering above all issues is the Organization's role in the implementation (or helping in the implementation) of the resolutions recently adopted by the 54th World Health Assembly, including the much needed WHO Medicines Strategy.

In conclusion, there is a general, and perceptible, feeling that deserves to be given due consideration in respect of two procedural-substantive issues. The first is the proposal to approve a moratorium on dispute settlement actions in matters related to medicines, the duration of which can be discussed and decided by general agreement. The other issue concerns the outcome of the present special discussion, which would in all probability need to be pursued for further elaboration during at least one more meeting focussing on the same subject matter, namely access to medicines as related to and influenced by the TRIPS provisions.

In this intervention, it is clear that only a few provisions of the TRIPS Agreement have been touched upon by our delegation. But a broader coverage and a more in-depth treatment of several other TRIPS Articles will be attempted in any future meeting for follow-up on today's proceedings. I am specifically referring to the TRIPS medicines–relevant Articles: 27.1, 27.3(a) and (b), 28.1,

28.2, 29.1, 30, 31, 32, 33, 34, 39.3, 40, 70.8 and 70.9. In each one of these Articles or paragraphs, there are comments that we wish to put for your consideration, and for the consideration of this distinguished Council. It is also in several of them that certain *inflexibilities* reside which need to be candidly addressed. But for now and for the sake of brevity, this delegation has limited itself to a treatment of the most direct flexibilities subject-matter of TRIPS.

We trust, that the forthcoming WTO Doha Ministerial Conference will have the subject matter of today's deliberations featuring high on its agenda, and that it will engage the interest and concern of participating Ministers.

SWITZERLAND

The question of intellectual property and access to medicines is a question of utmost importance in the context of the pandemics of HIV/AIDS which, in some parts of the world have taken or are taking extremely worrying dimensions. That is why at the TRIPS Council's last meeting in April, Switzerland welcomed and supported the request of Zimbabwe on behalf of the African Group, that this Council should set aside a full day for a special discussion on the issue of "intellectual property and access to medicines".

We would like to thank all those delegations that enable us to come to a structured and result oriented discussion by having provided this Council with written communications for today's meeting.

First of all, I would like to stress what the distinguished ambassador of the EC has stated this morning: the TRIPS Agreement should not be looked at as part of the problem but as part of the solution.

This is, because intellectual property protection and in particular patent protection are an important instrument in favour of research and development which again is in favour of development, especially in the field of health care.

Making drugs available at affordable prices includes as a *prerequisite, that drugs have to be available per se.* If no drugs were available at all, how could we then discuss to make them available at lower costs?

We therefore have to make sure that enough incentives will continue to be given to the private sector, which is responsible for research and development of new medicines which will result - hopefully - one day to a vaccine against such a terrible illness like HIV/AIDS. These incentives are assured in the TRIPS Agreement, in particular by *Articles 27 and 28* which define the patentable subject-matter and the rights conferred to the patent holder. We therefore must resist to any temptation to downgrade these rights, or else we take the risk, to have far less medicines to distribute in the end.

While addressing the issues of flexibility offered by the TRIPS Agreement, we also should bear in mind that any move we make, could finally lead to a reaction from right holders. In other words: any so-called flexibility on which we agree to be in the TRIPS Agreement should have to be construed in such a way, that it does not take away the incentive to research for new drugs and vaccines, if we do not want to face at the end of the exercise a so-called "loose-loose" situation - something which cannot be in the interest of anybody.

A delicate balance between these interests has been achieved by limiting the exclusive right of the right holder to a specific term of protection, by determining the definition of protectable subject-matter, and by the obligation to disclose, already during the term of protection, the invention

in order to disseminate new technology and therewith to encourage new research and development and thus ensure faster progress of technology.

Beyond this balance, parties to the TRIPS Agreement have agreed to include even further scope for flexibility on the range of which we have started to discuss by today. This flexibility should enable Members to implement their TRIPS obligations in balance with their public health considerations.

As for the price of medicines, like intellectual property rights, we agree it is an important issue in the access to health discussion. However, even if such medicines were offered at half of their actual price or as low as at one tenth of that price, they would probably still not be affordable for many people. So price is a core problem that has to be addressed. In that respect, we can only encourage discussions between governments and the private sector in order to agree on prices and UN Secretary General Annan's call for a fund raised to finance the access to and distribution of essential drugs in those countries which desperately are in need of such drugs. It is, however, important to mention that patents are only partly responsible for the price of a patented product:

First, a patent does not give the right to charge a specific price for a pharmaceutical.

Second, a patent does not prevent prices for patented pharmaceuticals from being adjusted to take into account the capacity to pay of different countries and their population.

And third, the market of pharmaceutical products is one of the most regulated in the world and the influence of patents is hence very much reduced.

As to the flexibility of the relevant provisions of the TRIPS Agreement, 1 would like to cut a long story short: My delegation would like to support what has been said by the European Communities and their member States in document *IP/C/W/280 in paragraphs 6-9 and 17-19*. We also fully agree with *what* has been said in the same communication by the EC/MS in the bold typed conclusions at the end of paragraphs 11-16 concerning Articles 7, 8, 30, 31 and 39 of the TRIPS Agreement.

Since the said communication of the European Communities and their member States does not address the issue of parallel imports and local working, we would like to focus on these two points which in our view are of crucial importance to the problem of "access to drugs":

While in the view of this delegation, the TRIPS Agreement in its substantive provisions supports the notion of national exhaustion (Article 28), it is recognized that *Article 6* of the Agreement prevents Members from taking action against Members that do permit parallel imports (and let me be clear, when talking of parallel imports, I mean imports of original products put on the market with the consent of the right holder at a cheaper price in another country than the one offered in the country considering parallel importation). Although this delegation still has some doubts whether parallel importation is really for the benefit of the consumer and not rather the trader, we recognize that Article 6 offers flexibility to developing countries in the search for patented medicines offered at a cheaper price elsewhere in the world.

However, the concept of exhaustion and parallel import need particular scrutiny when talking about *differential pricing*, which has been put forward from various sides as a possible option to increasing accessibility to drugs in developing countries: When considering differential pricing, my delegation would like to emphasize that if such a pricing system should get the support of all the stakeholders necessarily involved in its implementation, one of the main prerequisite would be to ensure that products which are sold at a lower price to developing countries are not re-exported to industrialized countries. Effective safeguards in that respect would be necessary and in place as soon

as large quantities of price-reduced pharmaceutical products would be delivered to developing countries facing a health crisis. The risk of re-exportation would not only undermine research and development of new products, but would also divert the products from those so urgently in need of them, the people, who are the reason why we are having today's special discussion, that is, those suffering from HIV/AIDS, malaria, tuberculosis or other epidemics in the developing world. In our view, *Article 6* of the TRIPS Agreement would provide for the necessary flexibility to find an appropriate solution for this problem, but may be this would have to be expressed by this Council in a more explicit way, for example in a joint declaration.

As regards compulsory licensing and the requirement of *local working of patents* as suggested by some delegations, I have to say that my delegation does not see how such a requirement could be brought into harmony with the wording of Articles 27 and 28 of the TRIPS Agreement, which respectively prohibit discrimination between locally and imported products, and considers *importation* as the working of a patent. But may be we get further clarity on this issue during the continuation of our discussion in this Council.

Having said this, I would like to say that Switzerland is ready to continue in this Council the technical discussion on the issues of flexibility offered by the TRIPS Agreement when facing a health crisis and an "access to medicines" problem.

We are sure that the TRIPS Agreement provides us with enough flexibility in this regard.

We simply would like to recall that in this discussion the TRIPS Council should not forget the crucial importance of intellectual property protection and in particular patent protection as the core incentive for the development of new, more effective medicines in our battle against health problems.

JAPAN

Japan's contribution and commitment

Japan has been consistently insisting on the importance and necessity of measures for combating against life-threatening infectious and parasitic diseases, such as HIV/AIDS, malaria, tuberculosis and polio.

Based on its recognition of serious epidemic situations in many regions of the world, Japan has been committed to taking Actions to combat those deadly infectious and parasitic diseases. For example, at the occasion of the G-8 Summit last year, Japan announced the "Okinawa Infectious Disease Initiative", which is targeted to allocate a total of 3 billion US dollars over five years in order to enhance Japan's assistance for measures against those infectious and parasitic diseases.[3]

In the framework of this three billion-dollar Initiative, Japan has accelerated its formulation and implementation of a variety of projects, programmes and schemes. These actions are directed not only to cooperation in the framework of intergovernmental fora such as the UN and non-governmental international cooperation, but also to individual developing countries and regions all over the world. For example, Japan's initiative is directed to those countries, such as Viet Nam, Cambodia, Thailand, the Philippines, Sri Lanka, Bangladesh, India, Mongolia, Tajikistan, South Yemen and China, in the Asian region. Japan's commitment also covers countries in the African region, such as the Democratic Republic of Congo, Kenya, Zambia, Tanzania, the Republic of South Africa, Ethiopia, Ghana, Nigeria, Sudan and Burkina Faso, as well as Haiti in the Central American region.

[3] (http://www.mofa.go.jp/policy/economy/summit/2000/genoa/infection3.html)

My delegation would like to stress that Japan is, and will continue to be, committed to efforts to combating against those terrible infectious and parasitic diseases, including HIV/AIDS, which is a terrible tragedy to countries, families and individuals.

Needs of comprehensive approach

Having said that, however, my delegation must admit that the combat against those infectious and parasitic diseases is not an easy task. The most important and difficult part of the problem is that we need to address a wide range of comprehensive measures to combat against those diseases. My delegation is well aware of the importance and necessity of improving the accessibility and affordability of key pharmaceuticals for those diseases. In addition to those measures, however, we need improvements in public health infrastructure, including building medical institutions, as well as education and training of medical staffs at all level. Measures for strengthening health management systems and enhanced prevention are also needed. Research and development of new drugs and new therapies are also essential for the solution to the problem. In the view of my delegation, those issues could be achieved only if we have a partnership with all relevant stake-holders.

Because of this very reason, the Okinawa Initiative of Japan covers a wide range of fields of activities, such as direct assistance for control measures against those infectious and parasitic diseases, assistance for improvement of public health infrastructure, development of research network, assistance in basic education for preventive measures, and access to safe water. Because of this reason, the Okinawa Initiative calls for a partnership with governments of other countries, international organizations, such as WHO, industries, particularly the pharmaceutical industry, academic institutions, NGOs and other relevant actors in civil society.

Japan is ready to discuss the accessibility of key pharmaceuticals for those major infectious and parasitic diseases. However, my delegation would like to point out that the most difficult part of the problem is that, again, many factors are related to the issue of drug access. With respect to the accessibility of drugs, for example, one of the important issues would be the method of delivery, and medical/paramedical staffs who must ensure that the right drugs are used in the right amount for the right time to the right patients. With respect to the affordability of drugs, it should be noted that the prices of drugs are determined depending on many factors, including governmental price control, insurance system, taxes and tariffs, demand-supply situation in the market, and costs for transportation and delivery.

In the view of my delegation, therefore, IP protection to drugs is only a part of the complicated issues which are to be tackled in a comprehensive manner. If we want to solve this problem, a comprehensive and holistic approach should be taken. When we discuss the issue of IP protection in the context of accessibility and affordability of pharmaceuticals, we should always keep that in mind.

IP protection in the context of drug access - in general

It is needless to say that ensuring an adequate access to drugs is important from the perspective of public health. At the same time, development of new drugs and new therapies are equally important to improve public health. Viruses and bacteria are becoming more and more resistant to the existing drugs. Particularly, the HIV virus has a quite mutable nature, so that a new AIDS therapy must be developed in a continuous manner. Without continuous R&D of new drugs and new therapies, we would be unable to ensure public health in the future.

The development of new drugs requires a quite large amount of costs. On the other hand, the drugs are very easy to copy. This is the reason why IP protection is essential for the area of

pharmaceuticals. If unauthorized copies of patented drugs were to be freely made, it would be difficult for research-oriented pharmaceutical companies to recoup the costs for R&D of new drugs. Less likelihood of cost recovery would mean less incentive for drug companies to develop new drugs. Less incentive for R&D in a certain area of drugs could lead to a sift of R&D efforts to other areas of drugs. Therefore, my delegation takes the view that appropriate IP protection is one of the key factors for promoting R&D of new drugs for those major infectious diseases. It should be noted that IP protection gives an incentive for developing new drugs for infectious diseases, including HIV/AIDS. Therefore, my delegation is not in favor of attempts to downgrade the level of protection set out in the current provisions of the TRIPS Agreement.

My delegation would not deny that patent protection could have an impact on the accessibility of drugs, because patent protection gives to the patent owners the limited monopoly right within the certain time period over the manufacture, sale and importation of the patented drugs. However, the relevant provisions of the current TRIPS Agreement provide for the appropriate balance between the protection of inventions and the use of the inventions. For example, Article 31 which stipulates "other use without authorization of the patent owner" provides measures to secure an appropriate balance between patent protection of inventions and use of the patented inventions by third parties. Article 31 of the TRIPS Agreement provides for other use without authorization of the patent owner (i.e., compulsory licence), and Members could legitimately allow the use of patented drugs to the extent that it complies with this provision.

Also, it should be noted that some of the private sector pharmaceutical companies have already launched a voluntary price differentiation scheme, in which they provide anti-HIV drugs (ARV) to certain developing countries at a preferential discounted price.

Therefore, my delegation is of the view that the public health concern could be accommodated with patent protection of new drugs, and in a long-term perspective, patent protection of new drugs would contribute to the improvement of public health.

In the view of my delegation, relevant provisions of the TRIPS Agreement have some flexibility. And, they could be interpreted so as to implement an appropriate balance of patent owners and users of the patent. In this regard, Japan is willing to enter into the discussion aiming at clarifying Members' views regarding the interpretation and application of the relevant provisions of the TRIPS Agreement.

Therefore, now I would like to touch upon the views and interpretation which Japan takes regarding some of the TRIPS provisions.

Exhaustion/parallel import - Article 6

My delegation takes the view that Article 6 allows Members' discretion as to whether national or international exhaustion is to be taken in their national jurisdiction. It is widely accepted that "international exhaustion of patent rights" means that a patent right is exhausted and cannot be exercised over a patented product, once the patented product is put on the market somewhere in the world either by the patentee himself or by another person with the patentee's consent. Therefore, Members have a freedom to adopt national legislation by which a patentee can no longer claim his patent right over his patented product, if that product has been put on the market of another country either by the patentee or another person with the consent of the patentee. On the other hand, my delegation takes the view that, if a patented product has been produced under compulsory licence, and has been put on the market of another country, international exhaustion should not apply. This is because such a circulation in the market has not been made with the consent of the patentee. Rather, such a circulation has been made under the compulsory licence.

Another point to be noted is the implication of international exhaustion in the context of voluntary tiered pricing arrangements. There are many pharmaceutical companies which have launched voluntary price differentiation by which they voluntarily provide key drugs to developing countries at a special preferential price. If the drugs provided in such a developing country at a preferential price are re-exported to a third country-market, those drug companies would be discouraged to continue the tiered pricing policy. In order to encourage the tiered pricing arrangement, measures should be examined to prevent re-exportation from such developing countries to third-country markets. Tiered pricing is primarily a contractual issue between a drug company and the government of a developing country which is a recipient of tiered-priced drugs. Nevertheless, it might be worth discussing to take appropriate measures. Such measures would include that: (1) the recipient developing country takes measures to prevent re-exportation of tiered-priced drugs to third countries; and (2) third countries take measures to prevent the importation of tiered-priced drugs from the recipient developing country.

Other use without authorization of the right holder - Article 31

(1) Condition of compulsory licence

Article 31 does not specify the grounds for compulsory licences. My delegation takes the view that public health consideration could be a legitimate ground for a compulsory licence, and Members have a right to issue compulsory licences in accordance with the relevant TRIPS provisions.

Subparagraph (a) of Article 31 provides that a compulsory licence should be considered on its individual merits. This would imply that compulsory licences should be primarily decided on a case-by-case basis. Nevertheless, some observations could be made regarding the terms and phrases provided in the subparagraphs of Article 31.

For example, subparagraph (b) provides the "fast-track", in which the requirement of prior negotiation is waived by a Member either in the case of a "national emergency or other circumstance of extreme urgency" or in cases of "public non-commercial use".

Regarding the terms "national emergency" or "extreme urgency", my delegation takes the view that, for some countries, HIV/AIDS epidemics are certainly situations of national emergency or circumstances of extreme urgency.

Regarding the term "public non-commercial use", my delegation takes the view that free-of-charge distribution of drugs by governments could amount to "public non-commercial use".

(2) Non-capacity country

There are countries which do not have sufficient production capacity in their territory to manufacture the patented drugs. For those countries, it has been argued whether or not a compulsory licence can be granted to a supplier of a third country which has sufficient production capacity. In relation to this question, subparagraph (f) provides that a compulsory licence should be authorized predominantly for the supply of the domestic market of the Member authorizing the use. If a compulsory licensee is to manufacture the patented product in the third country for the sole purpose of export to the country which does not have sufficient production capacity, the literal conflict with subparagraph (f) would likely to take place.

In our view, however, it would not be appropriate if the drugs produced under the compulsory licence cannot be imported to the country which does not have sufficient production capacity and which is in a status of national emergency of HIV/AIDS epidemic. Otherwise, the right given to

Members under Article 31 to issue a compulsory licence in the case of national emergency would be meaningless for those countries which have no production capacity.

Therefore, we should explore ways to justify the third-country production under a compulsory licence, without prejudicing the provision of subparagraph (f). Japan is ready to address this issue in a positive and constructive manner in order to reach consensus among Members.

Undisclosed information - Article 39.3

My delegation agrees with the EC/MS that Article 39.3 neither obliges Members to have marketing approval procedures, nor does it prescribe what those procedures should be.

In conclusion, I would like to stress once again that Japan is ready to join the international efforts regarding drug access and intellectual property which we have started today in a positive and constructive manner.

CUBA

Considering that the right to life of thousands of disadvantaged human beings is constantly dependent, minute by minute, upon legal interpretations which determine government action, interpretations which, in their turn, are subordinated to the pace of negotiations as determined or governed by the financial power of private holders of the rights to basic medicines on which lives depend; and *considering* that the debate which commenced today in this Council, in accordance with the proposal presented by the African Group at the meeting of 2 to 6 April 2001 and endorsed by virtually all Members, aims to clarify the flexibility available to Members when implementing the provisions of the TRIPS Agreement on real and effective access to medicines; *my country hereby wishes to contribute to the discussion by presenting its own interpretation of the issue*.

In the light of the Agreement's objectives as set forth in Articles 7 and 8 and given the ambiguity of some of the relevant provisions, Members can fully accommodate their personal interpretations to their own individual social - and in particular public health - requirements and objectives and thus strike a balance between the public and private interests at stake.

One way of doing this is through compulsory licensing, not only in the event of a national emergency and other circumstances of extreme urgency or public non-commercial use, but also to ensure that patents are not used to make access to medicines solely dependent upon imports at prohibitive prices. In accordance with these objectives, the economic value of authorization should be analysed in the light of the individual circumstances of each case and should rest on prices that are in keeping with each Member's social requirements and objectives.

In special situations such as these and whenever medicines are intended for people with zero or very low income, payment would be according to special, differentiated prices, respecting a reasonable mark-up and preventing smoke screens from concealing the real costs.

Patent owners' rights should be subject to international exhaustion, so that access to medicines through parallel imports from countries where prices are lower can constitute an alternative. This means of access cannot give rise to a dispute settlement proceeding within this organization. Neither is recourse to unilateral pressure to prevent a Member from making use of a measure which is authorized within the framework of this Agreement a legitimate move, since it undermines legal certainty and confidence in multilateral commitments and is detrimental to the protection and interests of public health.

The implementation of the TRIPS Agreement in relation to protectable subject matter allows therapeutic methods, *inter alia*, to be excluded from patentability to ensure that such applications, being in the interests of society and public health, are not subordinated to private interests. This equally controversial issue goes hand in hand with the need to protect second uses of already known and patented medicines.

In this sense, inventions whose commercial exploitation must be prevented to protect the life or health of populations, *inter alia*, should be excluded from patentability, once again in order to balance public interests with the interests of private right holders.

Other uses without the authorization of the right holder must be possible; compulsory licensing for exports from countries where they are granted is necessary for effectively promoting the protection of public interests, taking into consideration the small economies which are unable to acquire and hence take advantage of such licences.

The provision on the protection of undisclosed information should not be interpreted in such a way as to override Members' rights under other Articles of the Agreement. Such information must at least be available in the event of a national emergency or other circumstances of extreme urgency.

The opinions stated herein do not even begin to cover the wide range of unsatisfied needs and provisions of dubious application, whether or not available, in the TRIPS Agreement. Consequently, this exercise must be considered merely as the first step in discussions leading to the analysis and negotiation of means to ensure the effective implementation of the Agreement to the mutual advantage of right holders and consumers, and conducive to a balance of rights and obligations and to the social and economic welfare of the broad strata of society lacking an economic livelihood or minimum income, who must be the first beneficiaries of social and public health objectives.

Ongoing research into new medicines for both longstanding and new diseases must not be the cause of, or effectively result in, the side-lining of the most sacred of all human rights, the right to life, because the considerable expense involved, mentioned constantly but never proven, has to produce returns.

The advocacy of a system for the protection of intellectual property rights that guarantees general public policy objectives should not in practice result in a system which, while calling for the recognition of the need for such guarantees, gives priority to the removal of trade barriers and distortions with the result of nullifying or impairing the right of access to the means of protecting and prolonging life.

This is why the discussions initiated today in this body must continue to form part of this Council's regular work and feature on the agenda of the fourth Ministerial Conference, so that Ministers can ensure that the results of this work are available as soon as possible for the immediate benefit of all WTO Members, in particular the most disadvantaged.

KENYA

On behalf of the Kenyan delegation, we would like to support the statement made by Zimbabwe on behalf of the African Group on the crisis arising from the effects of patents on prices and affordability of pharmaceutical drugs. We also would like to associate ourselves with the paper that has been presented by Brazil on behalf of a number of developing countries including Kenya. Allow me to preface my remarks by stating that this Council cannot afford to ignore the debate raging across the world about the role of intellectual property rights protection in dealing with health emergencies, and pandemics such as HIV/AIDS and other life-threatening diseases. This heated debate is based on the demand for a balance of rights and obligations of the patent holders *vis-à-vis*

the right of access to health by the poor. Specifically, we must address directly the sensitive issue of a patient's right to access essential, life-saving and vitally needed drugs.

A human tragedy of shattering proportions is already at hand. In Kenya, as in many other Sub-Saharan African countries, a significant proportion of the population is infected with HIV and life expectancy is projected to decline drastically in the next five to ten years. Besides the AIDS pandemic, the cumulative human suffering and economic damage caused by malaria is immense. Each year, an estimated 26,000 children die from malaria infection, about 170 million working days lost to the malaria war, pregnant women suffer severe anaemia, have low birth-weight babies and run higher risk of death from the disease-conditions aggravated by the problem of drug resistance to conventional malaria drugs. The crisis is compounded by the poverty facing our people. According to 1994 statistics, 12.6 million Kenyans lived below the absolute poverty line, 47 per cent of the rural population and 29 per cent of the urban population below the poverty line. Governmental, non-governmental, private sector and donor community sources indicate that the incidence of poverty in Kenya has increased in recent years.

In Kenya, like in most other low-income developing countries, public spending on medicines is less than two dollars per capita per year. In such circumstances, the cost of care falls to the individual and the family. Since poor people do not have access to health insurance, they have to pay for drugs when they fall ill. Out-of-pocket payments account for up to 90 per cent of total health care spending. No matter what time of the year, no matter what the state of family finances, the situation for many is stark: no cash, no cure. And the result is very high mortality rates. The ethical and financial stakes are very high. These issues are also very emotive and complex. There are definitely different and deeply held opinions as to the way forward, but let us be clear about the objective of our meeting today: achieving greater clarity about strategies that will make the prices paid for key pharmaceuticals more closely in line with the economic circumstances of the purchasing countries.

It is noteworthy that the access debate has been aroused by the extremely high cost of some essential, life-saving and vitally needed drugs. Very few anti-retroviral drugs are among the essential drugs in the WHO Model List of Essential Drugs. Essential drugs are those that satisfy the health care needs of the majority of the population and should therefore be available at an times in adequate amounts and appropriate dosage forms.

Though anti-retroviral medications in the treatment of AIDS is an easy example, there are many other cases of patented drugs used in the treatment of serious diseases that are out of reach of millions of people especially in low-income developing countries. The national drug policies of these nations are, as a result, undermined by the high cost of drugs. These policies seek to ensure the constant availability of safe, effective and affordable drugs to all segments of the population and to encourage self-sufficiency through local manufacture of drugs for consumption and export.

Prior to the coming into force of the TRIPS Agreement, Kenya was able to decide whether or not to exclude pharmaceutical products from patentability on the ground that medicines are essential in saving lives, treating diseases, and in the promotion of health. The TRIPS Agreement now requires the protection of intellectual property rights, including those of pharmaceutical products and processes. The WHO has argued that such protection would strengthen the monopoly of working conferred on the right owner, a situation that leads to an increase in drug prices. The Agreement, however, leaves certain margins of freedom that can be used to limit the adverse effects on prices and access to technology. The WHO position is that the national laws should cover the possibility of authorizing parallel importation of patented drugs sold at lower prices in another country, and to establish compulsory licence provisions, to enable developing countries to meet their for public health needs.

It is, therefore, worrying that obstacles have been placed in the way of developing countries wishing to use these provisions mainly because of different interpretation. Attempts to restrict the use of parallel import and compulsory licensing measures, through restrictive interpretations of the TRIPS provisions, will only further reduce access of poor people to vitally needed and life-saving medicines, and thereby endanger more lives. Such attempts will also add fuel to the growing public perception that the TRIPS Agreement favours the protection of private rights over the public interest and public health.

It is our understanding that the TRIPS Agreement does not stand in the way of countries taking measures to protect public health and to promote public interests.

Article 7 of the TRIPS Agreement embodies the commitments in these words, and I quote:

> "The protection and enforcement of IPR should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

It is also our understanding that the objectives in Article 7 and the principles in Article 8 clearly indicate the subordination of the protection of intellectual property rights to public policy objectives. The TRIPS Agreement stresses the need to promote adequate and effective protection of IPRs, but to do so as part of a series of broader economic objectives and not as an absolute and exclusive obligation. This means that the protection of IPRs has a role to play in relation the priority objectives of public policy for which these rights were created. It should be harnessed to the service of development, and this is the purport of the principles expressed in Article 8.1. This makes for a balance between the rights of patent holders and their obligations to mankind. The application of these provisions, however, has left a lot to be desired. It is this gap between provision and application, which makes us question the working of the Agreement.

The compliance dates of 2000 and 2005/6 are not sensitive to the developmental needs of low-income developing countries and are contrary to the Article 7 commitments. Patent protection ought to contribute to development. By the year 2005, all developing countries will have to grant legal protection of patents including pharmaceutical products. Member states have an obligation to integrate into their patent legislation the minimum standards established by the TRIPS Agreement, i.e. patents for a minimum of 20 years, applicability of the "most-favoured-nation" clause, and reversal of the burden of proof. The question is, against what developmental measures were the compliance dates computed? What is the commercial sense of the 20-year term of protection? Moreover, the protection span does not seem to take into account the medical reality of possible drug resistance and obsolescence of drugs, or the possible development of more efficacious drugs that supersede earlier patented drugs.

WTO Members should agree on longer transition periods based on developmental milestones in keeping with the TRIPS commitments I have just referred to. We need time as a nation to industrialize, to develop our own local manufacturing and quality control capacity, time to train the human capital, time to revamp our depleted healthcare infrastructures, time to put in place the proper framework that would support the smooth operation of a rules-based international trading regime. We simply need time. These compliance dates therefore need urgent review, if the fight against life-threatening diseases in poor nations is to be won.

The developing countries need fundamentally different IPR regimes from the ones that developed countries have now. They should be allowed to grant weaker protection of IPRs. These should include shorter patent life, easier compulsory licensing, compulsory working and easier

parallel imports in the absence of local production. These countries should also be allowed to pay lower licensing royalty rates, graduated to a country's ability to pay.

We recognize the importance of investment in research and development, especially given the extremely mutative nature of the HIV virus, the drug resistant strains of tuberculosis, malaria, and other common infections. New and effective drugs are clearly a life necessity. Our challenge, however, is to address the TRIPS principle of striking a balance between the question of affordable access to drugs and industrial commercial concerns, and to avoid abuse of patent protection through recourse to non-competitive practices.

We conclude by asserting that pharmaceutical products cannot be regarded as ordinary goods or products, because access to essential, life-saving and vitally needed drugs are an integral part of the realization of a fundamental human right, i.e. the right to health. It means that policies pursued by all concerned in the sector must aim to make drugs available for all who need to have them and at affordable prices. Patents affect prices by creating market monopolies, greatly hindering access to the patented products by those who need them, most predominantly poor people who lack health insurance. Price is a key factor to health delivery, and it becomes to us a health concern when it impedes access to health care. This special impediment must be overcome as a priority in order to reverse the human suffering we are faced with. We envision a very near future in which people, particularly poor people, are not excluded from healthcare by virtue of their poverty.

We, therefore, request the Council to recommend:

That the Qatar Ministerial Conference shall adopt a declaration on the TRIPS Agreement and access to medicines, affirming the following:

- That Article 7 be immediately operationalized in the spirit of commitments embodied therein, so that the protection and enforcement of intellectual property rights should contribute to development and transfer of technology. In the context of public health and access to medicines, patent protection should encourage research and development of new medicines and the international transfer of technology to promote the development of manufacturing capacities of developing countries, without prejudice to national policies for the protection of public health and promoting access to affordable medicines.

- That Article 8 explicitly recognizes the right of members to adopt measures to protect public health, among a range of other interest objectives. In the context of public health and access to medicines, it is understood that the TRIPS Agreement does not limit the grounds on which Members may issue compulsory licences, nor does it prevent Members from applying the principles of international exhaustion to allow them to exercise their right to parallel importation.

- That consistent with international human rights obligations, it is agreed that the health crisis in many poor countries constitutes a national emergency entitling them to operationalize the exceptions on protection enshrined in the TRIPS Agreement.

- That WTO Members agree on longer transition periods for introducing new industrial property laws, based on development milestones, and that developing countries should retain the right to produce, market, import and export affordable medicines.

- That Members observe an immediate moratorium on the dispute settlement action against developing country Members to enable them to adopt measures to promote

public health and human rights considerations, as well as international developmental objectives.

We have only touched on a few important flexibilities provided for in the TRIPS Agreement. There are others, such as those provided for in Articles 30, 39.3 and 40, which are equally important. We, therefore, reserve our rights to come back to this matter at a later stage.

HUNGARY

Hungary welcomes the special session in the TRIPS Council on intellectual property and the access to medicines, which was initiated by the African Group and supported by the entire WTO membership.

We welcome today's discussion in particular, because we recognize that the access to affordable pharmaceutical products is a vital problem particularly and in strictu sensu of the word vital for millions of suffering people in vary many developing countries. In our view, it is of crucial importance that the international community helps affected countries effectively combat preventable and treatable infectious diseases and that the WTO, in the sphere of its competence, contributes to this effort.

We believe that the issue at hand is very complex in nature and only concerted international efforts can bring, tangible positive results. This is reflected in the fact that different aspects of this issue are discussed in different relevant international organisations, like the UN and its specialized agencies like WHO or WIPO. We believe that our Council is best placed to discuss the TRIPS implications, including the flexibilities in the relevant provisions of the TRIPS Agreement and should not duplicate work that is going on elsewhere. To sum it up, the WTO does have a role to play, but it should concentrate on issues within its competence.

Against this background let me offer a few specific remarks regarding some of the TRIPS provisions relevant to the access to drugs (but before doing so I would like to use this opportunity to thank those delegations, which submitted their views on the relevant issues in writing, in particular the paper presented by Zimbabwe on behalf nearly 50 developing countries and the paper presented by our friends of the European Communities and its member States.

On the *objectives and principles of the TRIPS Agreement*, as Article 7 makes clear, the purpose of the TRIPS Agreement is to promote technological innovation and the transfer and dissemination of technology to the mutual advantage of producers and users of it. In other words, the protection of intellectual property rights is supposed to serve the society as a whole by striking a balance between the interest of private right holders (inventors, authors and manufacturers) and the users of their inventions. Article 8 in turn makes clear that Members may adopt measures necessary to protect public health, provided that those are not inconsistent with the provisions of the TRIPS Agreement. *We share the view that all the provisions of the TRIPS Agreement should be read in light of the principles and objectives as set forth in Articles 7 and 8*.

On *compulsory licenses*, we share the view expressed in the papers submitted to the Council that *Article 31 does not specify the grounds on the basis of which compulsory licences can legitimately be granted*. Article 31 simply lays out extensive procedural safeguards to prevent abuse. Some of these safeguards however may be waived, including in cases of national emergency or other circumstances of extreme urgency, as well as in cases of public non-commercial use. We believe that situations such as created by the AIDS/HIV pandemics in the seriously affected countries could definitely be considered to fall under these categories. We share the view that the absence of an explicit reference to public health in Article 31(f) cannot be interpreted as preventing WTO Members from invoking public health concerns, when granting compulsory licences.

It is not clear whether, under Article 31(f), a WTO Member which does not have sufficient domestic manufacturing capacities is allowed to grant a compulsory licence to manufacturers in another country where the product is under patent protection. This is a real problem and an issue that deserves attention and further discussion in the Council. We are ready to engage in such a discussion and believe that when seeking a solution - preferably in the form of interpretation - the Council should be guided by the objective of ensuring access to reliable and most cost-effective supplies of medicines in question. The interpretation suggested by the EC in their paper (IP/C/W/280, paragraph 13) is certainly one of the options the Council should look at.

On *exceptions to patent rights*, Article 30 allows WTO Members to maintain limited exceptions regarding the exclusive rights conferred by a patent, including for the purposes of research. We believe that this particular exception is of great importance for improving, on the longer run, the access of all to cheaper medicines. It has to be noted though, that such exceptions can have a relatively limited short term effect, at least so far as the current health crisis warranting rapid action is concerned.

Let me finish by indicating Hungary's willingness to discuss further these issues and others raised by delegations in the Council and I would like to assure you that we will treat these problems with the due seriousness and responsibility commensurate with the dramatic dimension of the problem we are dealing with.

NIGERIA

Like other delegations who spoke before me, I would like to fully associate my delegation with the statement made by Zimbabwe on behalf of the African Group on the relationship between TRIPS and public health. It is a positive and constructive way and a basis for addressing and finding solutions to the problems of increased and affordable access to essential medicines or treating diseases and saving lives.

This delegation regards this discussion as an important one, necessary in clarifying the provisions of the TRIPS Agreement of relevance to access to medicines, to ensure that the TRIPS Agreement does not in any way undermine the legitimate rights of WTO Members to formulate public health policies and implement them in a manner to promote and protect public health. Nothing in the TRIPS Agreement should prevent Members from achieving this goal.

We are of the view that each provision of the TRIPS Agreement should be read in the light of Articles 7 and 8 dealing with the objectives and principles. Our view is that nothing in the TRIPS Agreement should inhibit or restrict the range of options available to governments to promote and protect their public health and other overarching public policy objectives. The TRIPS Council should confirm this understanding.

Finally, we hope that the discussion should not be a one-off event. Indeed, it should be the beginning of a process or a more substantive discussion. The momentum should be sustained until a solution is found. The matter should be pursued further in the context of the ongoing preparatory process for the fourth session of the Ministerial Conference of the WTO, and Ministers should take action in Doha that will ensure that the TRIPS Agreement does not in any way undermine Members' ability to take appropriate measures to protect their public health. A satisfactory resolution of the issue will send a positive signal and improve the image of the WTO and enhance confidence in the system.

CANADA

Canada is pleased to also participate in this discussion on the various issues related to intellectual property rights and access to medicines. We certainly share many of the views that have already been expressed and for that reason offer only a few remarks.

The provision of HIV/AIDS drug therapies is a complex question. It involves patent rights, the establishment of adequate systems to deliver and monitor drug usage, as well as direct and alternate mechanisms to finance drug purchases.

Access to essential medicines encompasses broader issues than simply cost.

Developing and least-developed countries are in need of assistance to develop their health systems and infrastructure capacity for the delivery and monitoring of complex drug regimes.

Last fall, the Canadian International Development Agency released a new HIV/AIDS Action Plan which quadrupled the HIV/AIDS budget to a total of $270 million from Canada for over the next five years.

As we all know, attempts to address additional funding measures are being discussed at the UN General Assembly Special Session on HIV/AIDS on 25-27 June in New York, and through relevant UN agencies, including the WHO and UNAIDS, as well as through the G-8. Canada is fully supportive of all of these international initiatives.

However, given the scale and complexity of the HIV/AIDS problem, we recognize that it will be difficult to see results easily or quickly. But we must do what we can and certainly this discussion today is an important step in reviewing the role of intellectual property rights and, in particular, patent protection.

Although over 90 per cent of drugs on the World Health Organization's List of Essential Drugs are not covered by patents, most HIV/AIDS therapies still are.

Discussions have therefore included reducing the price of patented medicines as one part of the solution.

Many of the pharmaceutical companies, both brand-name and generic, supplying these medications have agreed to lower their prices for HIV/AIDS drugs in developing and least-developed countries as part of the solution. This is a very positive step and Canada applauds this effort.

However, to work effectively, we must ensure that prices for these medicines adequately reflect the cost-of-living differences between developed, developing and least-developed countries.

We must ensure that differential or tiered pricing, which takes into account the ability to pay for the drugs at whatever price, works to assist those most in need in least-developed and developing countries.

Work should proceed quickly to further the idea of differential or tiered pricing under the global health fund which is now under development.

It will also be important to ensure lower-cost HIV/AIDS drugs are not re-directed and sold in more affluent markets, such as those in Europe and North America. Fortunately, Canada already has mechanisms in place to monitor drug imports into the country.

To be effective, the patent system must be allowed to play its role of providing effective patent protection so that research and development into new and better drugs will continue. In Canada, we also offer tax incentives to encourage research and development.

Another issue raised here is compulsory licensing. As stated in Article 31 of the TRIPS Agreement, there are special rules in place for "national emergencies or other circumstances of extreme urgency" that do not require prior agreement with the patent owner.

Cooperation with the company owning the patent may be an efficient and effective means of addressing a health crisis, but we recognize that Members should have sufficient flexibility to use the option granted in the TRIPS Agreement.

We recognize that some Members have doubts about the value of the compulsory licensing provisions. Only through discussions will we be able to explore the true merits of the TRIPS provisions.

As already mentioned by the US and Egypt, we believe that in the EU case against Canada – Patent Protection of Pharmaceutical Products – the Panel came to a balanced and sensible decision in favour of Canada's "regulatory review exception". The Panel clearly determined that there is scope for flexibility in the TRIPS Agreement. Certainly in arguing our defence, Canada called upon the balance that exists between the rights of those creating the inventions and health and social priorities.

The TRIPS Agreement attempts to provide the necessary balance between encouraging innovation and development of new products, and the needs of those requiring access to such products. That balance, and the flexibility in the TRIPS Agreement, plays an important part in finding a solution to the HIV/AIDS health crisis. But we must also note that without effective patent protection we will not have research and development and new medicines and solutions to help solve with health crises/pandemics.

ECUADOR

It is a source of concern to Ecuador that many factors that affect the development of countries are being aggravated by positions that go beyond the legitimate trade interests that all Members of this Organization should logically be defending.

Let us drop these positions and revert to principles such as those agreed upon when the WTO was established, to which Ecuador reiterates its commitment. According to these principles, "relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development".

Similarly, the Preamble to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) recognizes the "underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives".

Consequently, the implementation of the TRIPS Agreement should not impede the development of countries or constitute a barrier to free trade as a driving force behind economic development.

In this context, Ecuador repeats that it considers health to be a basic human right which must be recognized and applied without any conditions or limitations. In other words, the protection of the right to health cannot be made contingent on the protection of intellectual property rights or, to put it another way, the application of intellectual property rights must be of benefit to society as a whole and cannot aim merely to protect private rights.

Access to medicines is a prerequisite to the full exercise of the right to health. This access must be general, and not limited to a certain type of medicines. Arrangements for such access must aim at resolving or alleviating health problems as a whole: not only one major disease, such as HIV/AIDS, but all endemic diseases affecting above all the poorest populations, such as malaria and dengue fever in their various forms.

If we do not deal with these diseases in a comprehensive and general way, the development of trade, which is one of the pillars of growth in our societies, will suffer considerably. A disease-stricken population is not good for trade or, ultimately, for development.

The development of health policy is the sovereign right of each country, and cannot be limited by international measures that prevent or restrict governments in their efforts to resolve the problems caused by disease among their populations.

The granting of discounts or the donation of medicines should not be seen as a substitute for domestic legal provisions; nor should they be seen as an alternative to the legitimate recourse under the TRIPS Agreement to parallel imports and compulsory licensing, legal remedies available to all the WTO Members. These mechanisms ensure that public institutions have the invaluable possibility of obtaining access to cheaper medicines and stimulating the necessary price competition.

Ecuador is neither denying nor minimizing the importance and complete legitimacy of the rights of those who invest their efforts and money in the research and development of medicines. Indeed, it is important to ensure that the commitments and international agreements are properly applied so that they do not cause injury to intellectual property right holders. But it is just as important to strike a proper balance in order to protect the health of populations, especially the poorest populations.

In this connection, Ecuador also reaffirms the principles and objectives of the TRIPS Agreement as set forth in Articles 7 and 8, i.e. that 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 (Article 8), so that intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations (Article 7).[4]

[4] Article 7: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in an manner conducive to social and economic welfare, and to a balance of rights and obligations".

Article 8: "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…".

Ecuador has endorsed the understanding discussed by a large number of developing countries on the relationship between the TRIPS Agreement and public health, as set forth in the document presented to Members in connection with this meeting.

The urgent public health problems of the developing countries cannot be sidelined until the Council for TRIPS has resolved the various lacunae of the Agreement. In Ecuador's view, the document of the Doha Ministerial Conference in November should contain such clarifications of the TRIPS Agreement as are needed to ensure that priority is given to health, in particular among the poorest populations, and to the development of economically stronger societies.

These clarifications should ensure that patent holders are able to exercise their rights within the limits set forth in various TRIPS provisions, such as those relating to compulsory licensing and parallel imports, and hence in such a way as to ensure the balance between the rights and obligations of producers and users of technological knowledge.

Definitive agreement must therefore be reached to prevent Members from taking action against others merely because they have obtained the appropriate means to resolve their problems related to endemic diseases and to protect the health of their populations.

NEW ZEALAND

New Zealand would like to take the opportunity today to formally welcome this special discussion on intellectual property issues relevant to access to medicines. This is an important development in the range of efforts being undertaken by a number of fora to address the current HIV/AIDS pandemic and other public health emergencies. We welcome the high level of positive support that Members have shown today.

We also welcome efforts here in the TRIPS Council to contribute to better clarity in ensuring that current disciplines can make their maximum contribution to public health responses on this issue. We believe this contribution can, and must, be a positive and significant one.

We share interpretations of TRIPS which recognize that the gravity of the current situation is enough to trigger the Agreement's current, but sometimes obscured, flexibilities in order to meet public health objectives. For example, in the context of Article 31 on compulsory licensing, there should be no doubt that what many Members are facing a national or extreme emergencies.

We encourage Members to seriously consider proposed interpretations which help smooth the way for affected Members to implement health pricing policies with confidence, and also with appropriate safeguards against deterrence of future drug development. In this respect, we welcome the contributions made to date, particularly the paper from the European Communities and the focus they help bring to our discussion.

Many of these contributions indicate that Members can think creatively within the TRIPS Agreement to focus on practical solutions. They also highlight the need to keep in perspective the TRIPS aspect of this issue with respect to broader and complementary efforts on disease eradication and poverty reduction. We look forward to further discussions on this basis.

JAMAICA

The delegation of Jamaica expresses appreciation to the African Group for proposing a special session of the TRIPS Council to address the issue of TRIPS and public health. The convening of this special session is particularly timely given the public interest, indeed the acute public concern,

that has been aroused on the question of affordable access to medicines, and the critical role that the TRIPS Agreement can evidently play in this area of predominant interest to all humanity.

We would hope that this TRIPS Council, meeting in special session, will recognize the obligation that is placed on it. Million across the globe, and particularly in the developing world, look to enlightened leadership on the question of affordable access to medicines and, notwithstanding valuable and important bilateral and multilateral initiatives, there is growing public awareness that there is an inextricable linkage between this issue and the TRIPS Agreement. We certainly hope that this Council can respond clearly and unambiguously to the urgent need for a common understanding – for a common recognition of the flexibilities contained in the TRIPS Agreement, and that these provide a basis for Members to take measures for the protection of public health.

It is in this context that I would wish to make reference to the paper circulated by a group of countries. Jamaica has joined a number of developing countries in co-sponsoring this paper. The document is pertinent. It addresses a number of important issues which this Council must take into account. And even so it is not exhaustive. Fundamentally, it underscores how important it is for the provisions of the TRIPS Agreement to be read in the context of the objectives and principles of the Agreement as contained in Articles 7 and 8. This of necessity should be our starting-point in the Council - the premise for our discourse in this special session. And if this is the starting-point, we would hope that the outcome will be the common understanding that nothing in the TRIPS Agreement should be construed to prevent Members from adopting policies to protect public health.

Article 31 of the TRIPS Agreement is, in our view, instructive, and reflective of this flexibility. The Article lays down procedural requirements for the grant of compulsory licences but does not limit the right of countries to establish compulsory licences on grounds not explicitly mentioned in the Agreement. The TRIPS Council should give due recognition to this.

As a small economy, Jamaica has limited capacity to manufacture pharmaceutical products to respond to the needs of our population. We are faced with serious constraints in seeking to provide affordable access to medicines. It is estimated that, for example, comprehensive care and treatment for HIV patients would cost more annually than the entire health budget. One approach being pursued is discussions with supplying companies in an effort to benefit from reduced prices. But we believe also that the flexibility provided under Article 31 is vital for affording governments scope to deal with circumstances of extreme urgency that may arise. We thus believe that it is important to agree on an interpretation of Article 31 that does not deny small economies with limited domestic capacity any real flexibility in regard to compulsory licensing should the need for this measure arise.

Jamaica affirms the importance of striking a healthy balance between the interest of right holders and the wider society. It is our considered view that appropriate balance requires, among other factors, that the interpretation and application of the TRIPS Agreement full scope is provided for measures that facilitate generic competition without undue delay. In this respect, amongst the relevant key articles of the Agreement are those relating to exceptions (Article 30) term of protection (Article 33), data protection and exclusivity (Article 39) and transfer of technology and technical cooperation (Articles 66 and 67).

Yet other measures can assist in improving access to medicines and, in this context, there should be recognition and acceptance of the latitude provided to undertake parallel importation in accordance with the principle of exhaustion of rights.

Jamaica recognizes the important role that the protection of intellectual property plays in stimulating creativity, inventiveness, and in research and development. This is particularly important to the pharmaceutical industry, although we must note that many countries, both developed and developing, until relatively recently excluded pharmaceutical products from patentability. In the past

two or three decades, and especially since the adoption of the Uruguay Round Agreements, that situation has changed. But the protection provided to private right holders can have no logic if it does not thereby lead to social benefits. Let me emphasize that we certainly do not believe that we are engaged in a zero sum game. In our view, there is ample scope for all to benefit – right holders and the public at large. Furthermore, an important contribution to this objective would be the forging of common understanding regarding the flexibilities inherent in the TRIPS Agreement. This would provide both the juridical and political support for Members to take appropriate measures to address their grave public health concerns, and would give hope to millions in the developing world.

Finally, this course of action would also send a definitive signal to all regarding the responsiveness of this Organization to the fundamental challenges and concerns of development and of developing countries.

DOMINICAN REPUBLIC

The delegation of the Dominican Republic fully endorses the statement made by the delegation of Zimbabwe on behalf of the African Group. We also fully support the statements made by Argentina, Brazil, India, Malaysia and South Africa, and would like to thank the delegations of the European Communities and Norway for their constructive contributions. Other developed countries, unfortunately, spoke in less generous terms, and we seem to be heading towards a situation in which the law that rules will be the law of the jungle. Our delegation is particularly eager to ensure that this discussion does not turn into a mere public relations exercise aimed at "demonstrating" our solidarity with the poor people of this earth, whose human rights are at issue when doubts are expressed on the way in which our countries have exercised their multilateral intellectual property rights. And I speak of human rights because, as the distinguished Ambassador of Bolivia rightly pointed out, human rights include the right to health.

The Dominican Republic, together with the group of countries that support the statement by Zimbabwe, would like this discussion to lead to a statement, perhaps by the Council for TRIPS, or, why not, by the Ministerial Conference, reaffirming the unlimited right of our countries to grant compulsory licences and to permit parallel imports of any kind covered by the international exhaustion of rights. We heard some very interesting arguments as to why certain parallel imports can be permitted while others cannot. It is amusing that the countries that put forward these arguments are the same ones that have been pushing for negotiations on competition policy in the WTO. I wonder whether these two stances are mutually consistent.

As regards the protection of test data mentioned in Article 39.3 of the TRIPS Agreement, the Dominican Republic considers that one of the objectives of the health policy applied by WTO Members, particularly the developing country Members, is to ensure an adequate supply of medicines at affordable prices for populations such as ours with limited purchasing power. This means that both the industries manufacturing generic medicines and those involved in research and development must be able to play their proper roles in our economies. Otherwise, we would be in a situation where what is sown by fax is reaped by customs. No viable and sustainable public health policy will be possible unless both segments of the pharmaceutical industry compete on an equal footing. It is not a matter of import substitution, of performance requirements, of anything that was discussed this afternoon - all we are talking about is the right to compete in equal conditions. In particular, the disappearance of independent industries manufacturing generic medicines will seriously undermine the possibility of ensuring that market forces determine the price levels of medicines.

To safeguard our economic development possibilities, it is of the utmost importance that we avoid an interpretation of the TRIPS Agreement that would result in a restriction of competition in the application of new technologies beyond what the patent system permits. This would be contrary to the basic principles of the multilateral trading system - to encourage the progressive opening up of

trade and liberalization of markets at the national and international levels. These basic principles form part of the WTO agreements, and ever since the great liberal revolutions of the eighteenth century have been firmly enshrined in our constitutions. The patent system was considered a useful and valid exception to these principles for a limited period of time and subject to a number of specific conditions. However, it is understood that, if a particular technology that is patentable (such as a chemical molecule that could be used for therapeutic purposes) has not been patented in a particular jurisdiction, the commercial use of that technology would be open to free competition. In other words, that technology, as long as it has not been patented, could be copied perfectly freely. Any attempt to undermine the possibility of free copying of unpatented technology through too broad and anti-competitive an interpretation of the TRIPS Agreement would in fact be contrary to the economic development policies of the great majority of WTO Members.

Thus, it is important that Article 39.3 of the TRIPS Agreement should not be interpreted in a way which would prevent or affect the entry into the market of competitive medicines. In particular, the interpretation must not result in the creation of a circumvention of the patent system to block or restrict the free manufacture and distribution of pharmaceutical or agro-chemical products. An unjustifiably broad interpretation of Article 39.3 would severely affect or even permanently impede the operation of our independent industries producing generic medicines, whose activities play a fundamental role in maintaining the prices of medicines within limits that are affordable for a population with limited purchasing power.

Article 39.3 of the TRIPS Agreement should be interpreted in the context in which it was drafted and in the light of the Agreement's objectives and principles, which have been repeatedly mentioned by delegations (Articles 7 and 8). Article 39.3 only applies to cases in which the approval of the marketing of products which utilize new chemical entities requires the submission of undisclosed test or other data, the origination of which involves a considerable effort. This implies that any procedure for the approval of the marketing of products that does not require the submission of such data would fall *de jure* outside the scope of Article 39.3. In particular, any interpretation of this Article that restricted or limited the possibility of applying accelerated approval procedures (which do not require the submission of the said data) would go beyond the obligations contained in the TRIPS Agreement and should therefore be questioned by WTO Members.

For cases in which marketing approval procedures require the submission of test data, the only obligations under Article 39.3 are the following: (a) to protect the data against unfair commercial use; (b) to protect the data against disclosure. It should be stressed that the TRIPS Agreement does not establish any obligation to prohibit persons from requesting and obtaining marketing authorizations from third persons to produce their own versions of the medicines previously approved. This allows any person to benefit, without discrimination, from the marketing approval procedures for products established by WTO Members in their respective countries. Moreover, requiring the repeated submission of data obtained through considerable research and testing involving a large number of live and healthy human beings and animals raises the sensitive issue of ethics governing the protection of public health, particularly in view of the fact that it does not contribute to improving the quality and effectiveness of the medicines and represents an unjustified waste of our meagre resources.

I would like to stress a point made in the document we submitted together with the African Group, Brazil and other countries. Paragraph 9 of that document calls the attention of WTO Members to the adoption by the United Nations Commission on Human Rights of Resolution 2001/33, which was accepted unanimously with only one abstention. This Resolution establishes a mechanism for follow-up by the United Nations Committee on Economic, Social and Cultural Rights, involving, *inter alia*, an assessment of the use by States of trade regulations to ensure access to essential medicines. Any attempt to use trade regulations to impede such access will be duly condemned by

the said Committee. I think that this is an important point, and one which should be fully borne in mind by all WTO Members.

PERU

Peru is a co-sponsor of the paper on TRIPS and Health submitted by the African Group, Brazil, India and other countries.

Because of this, and in view of the statements already made on this matter, I shall not be discussing the technical and commercial aspects of the said paper in any great detail.

My intention, is rather to say that this special session of the TRIPS Council is not just another meeting: it marks the beginning of a process designed to ensure that the TRIPS Agreement does not in any way affect or restrict the legitimate right of WTO Members to formulate their health policies and protect the lives of their citizens.

This meeting is attracting a great deal of media coverage and capturing international public attention since, for the first time ever, the man in the street has realized that the relationship between intellectual property and health is neither a commercial nor an economic problem but an ethical concern.

It is an ethical concern since the majority of people wonder why health and the lives of millions of men, women and children ravaged by AIDS and other infectious diseases carry less weight than private intellectual property rights and multinational pharmaceutical companies. The problem, which exists the world over, came to the fore with the legal action which was taken (and which backfired) by such companies in South Africa.

AIDS, tuberculosis, malaria and other infectious and contagious diseases are spreading steadily in the developing world since, according to various different studies, the national health services of a large number of developing countries have collapsed, not as a result of TRIPS, but of the continual adjustments made to scale down their fiscal deficit, largely in an endeavour to repay external debt.

This problem is exacerbated by excessive and abusive protection of intellectual property rights to the detriment of public health in the poor countries.

The Council for TRIPS therefore faces the ethical problem of making the TRIPS Agreement legally compatible with public health. This is feasible, if there is both the political will to do so and an awareness of the possible harm to both the WTO and the TRIPS Agreement if these provisions are not brought into line with domestic public health systems.

This means permitting the discretionary application of compulsory licensing and parallel imports and preventing new forms of protectionism, such as the attempt by transnational pharmaceutical corporations to influence public health authorities under Article 39.3 of the TRIPS Agreement.

In particular, and as suggested by the African Group, the Dispute Settlement Body should adopt a moratorium on serious cases involving public health and intellectual property.

The WTO today faces a major challenge; but it has also been afforded a wonderful opportunity to prove to international public opinion that it is an Organization which works for the majority of mankind and not, as is often claimed, for multinationals and developed countries alone.

I shudder to think, what would happen were we to be unable to successfully overcome the ethical challenge raised by the relationship between TRIPS and public health. We do not need a crystal ball to be aware of the dire consequences that this would have on international public opinion.

SRI LANKA

The Sri Lankan delegation welcomes the opportunity provided by the TRIPS Council to discuss today one of the most important issues facing all our countries – the issue of public health and access to medicines.

Sri Lanka fully supports the two statements made by Zimbabwe on behalf of the African Group and by Brazil on behalf of over 50 countries, to which my delegation belongs as a co-sponsor of the joint paper.

As the joint paper highlights comprehensively, the issues and points, it is not for my delegation to repeat all the points contained therein. My delegation's intervention therefore only focuses on some additional perspectives.

First, on the mandate and objective of the exercise. A number of delegations dealt with this issue in great detail during the morning session. Most of those interventions highlighted the fact that the TRIPS Council should discuss all issues relating to public health and access to medicines as they relate to the provisions of the TRIPS Agreement. The delegation of South Africa in its intervention identified three such objectives and they do merit careful examination by the Council.

Second, the relationship between the concept of a patent and its subject-matter. In its present context, the TRIPS Agreement does not differentiate between patenting of public goods versus private goods. Article 27 of the TRIPS Agreement identifies the patentable subject-matter but does not make a difference between what are public or private goods. Pharmaceuticals, particularly the essential drugs, included in it are not simply another commodity, those are recognized as public goods.

Hence the society, as a whole, need to be very mindful of this situation, when dealing with protection and enforcement of intellectual property rights related to such products. My delegation therefore fully supports the proposal that all essential drugs as identified by WHO should be excluded from the patentable subject-matter.

Third, the concept that access to essential drugs is part of human rights to health. Access to essential drugs basically depends on:

(a) rational selection and use of medicine;
(b) affordable prices;
(c) sustainable adequate financing;
(d) reliable health and supply systems.

Since access to medicines is importantly sensitive and connected to their cost and affordability, the Members of the TRIPS Council, as a whole, have a vital role and responsibility in identifying the most needed relationship between the TRIPS Agreement and access to medicines. The impact of the TRIPS Agreement is primarily felt on the prices of patented products. It is avidly believed that the prices of existing patented drugs and new patented drugs would remain high, because of the restraints which the Agreement imposes on bringing out generic versions during the 20-year period of patent protection.

Fourth, my delegation particularly thanks the Ambassador of India for reminding us how the fundamental principle of the protection of public health and nutrition is dealt with in two WTO agreements, namely the TRIPS Agreement and GATT 1994 in different ways.

Fifth, the provisions of the TRIPS Agreement should be interpreted in the backdrop of Articles 7 and 8 of the TRIPS Agreement. A number of delegations referred to this point in their interventions. My delegation also welcomes the European Communities' view on the overarching importance of Articles 7 and 8.

Finally, it has been identified and also referred to by a number of delegations who spoke before, the remedies available to developing countries to deal with the situation under the WTO in three areas, namely compulsory licensing, parallel imports and differential pricing. Various proposals concerning each area, as to how their effectiveness can be improved, are before the Council. As the Ambassador of India said, we may not find all the answers to the questions raised today, but it is important for the Council to commence the task of analysing the issues raised and exploring the possible avenues to address them. My delegation appreciates very much the European Communities' statement that they are open and ready to examine a number of provisions that are relevant to the debate. Likewise, we urge all developed country trading partners to engage in a serious discussion with a view to addressing and finding solutions to issues and concerns raised by the developing countries.

HONG KONG CHINA

Today is the first time the TRIPS Council discusses this important subject of intellectual property and access to essential medicines. We see it as the start of a process, the objective of which is to clarify the scope of the flexibilities under the TRIPS Agreement for Members to pursue policy options to address public health concerns. I would like to thank those delegations which have prepared papers on the subject.

Hong Kong, China is of the view that the TRIPS Agreement has been drafted with a view to promoting effective and adequate protection of IP rights, at the same time allowing Members flexibilities to pursue policy options to address public health concerns. The recent events in South Africa have not changed our views. In this connection, we welcome the two papers on the table today as useful starting points to facilitate and focus further discussions. The objective is to achieve common understanding and bring clarity regarding the interpretation and the application of the relevant provisions of the TRIPS Agreement, and the scope for Members to address legitimate public health concerns.

The papers by the EC and by the African Group and other co-sponsors as well as many of the delegations who have spoken before me have indeed raised a number of pertinent issues, such as the objectives and principles of the TRIPS Agreement; interpretation of Article 31 relating to compulsory licensing, including its scope in dealing with national emergencies, other circumstances of extreme urgency, or in cases of public non-commercial use, and the circumstances under which a Member can confer compulsory licences to a foreign country manufacturer. We look forward to engaging in further substantive discussion by this Council.

HONDURAS

As a co-sponsor of the proposal presented by Zimbabwe, my delegation would like to take this opportunity to reiterate and give its full support to the statement made by the Zimbabwean delegation on behalf of all of the sponsoring countries.

We consider that the TRIPS Agreement should be interpreted and studied in good faith within the context of its objectives and from the point of view of its purpose.

Honduras has always been mindful of the objectives of the TRIPS Agreement, fully confident that the protection of all intellectual property rights would favour technology transfer in our country. However, there has been little or no discussion to date on technology transfer and dissemination in our country, with the result that innovation has not been promoted and there have been no incentives to public health.

Honduras feels that there is a need for these objectives to be fulfilled, since this would pave the way for the development and production in each of our countries of pharmaceutical products that would benefit society as a whole.

Likewise, we feel that the interpretation of the provisions of the Agreement that allow safeguard measures, such as those related to parallel imports and compulsory licensing, to be applied to public health, is a priority since these are both particularly useful instruments which could improve access to medicines and dampen the negative social impact of the privileges enjoyed by some transnational companies.

The Council should explore effective means of solving public health problems and of interpreting the provisions of Articles 6, 7, 8, 31, 39, 66 and 67 in such a way as to render them truly operative and applicable in favour of developing countries. They should not be restricted, nor the small degree of flexibility afforded by some of these Articles reduced in any way.

We consider the establishment of differential pricing agreements to be a very positive initiative in terms of improving access to medicines, but they should not under any circumstances be used to restrict the flexibility or safeguards provided for in the Agreement.

My delegation is of the opinion that, since differential pricing does not fall within the sphere of our discussions on intellectual property rights, it should not be discussed by the Council for TRIPS, but rather, by intergovernmental organizations such as the WHO.

Finally, we believe that the forthcoming Qatar Ministerial Meeting will prove the best occasion for ensuring that the Agreement is not interpreted or applied in a way as to prevent Members from protecting and promoting public health policies.

CZECH REPUBLIC

At the outset, I would like to join previous speakers in congratulating you for your role in organizing today's meeting. Our delegation welcome and support the Agenda of the TRIPS Council where one day is devoted to the discussion on the relationship between intellectual property and access to medicines. As it is for the first time the TRIPS Council discusses intellectual property issues in the context of public health, we see this as a milestone in our work and as a positive message coming from this Organization. We associated with those who considered this issue very urgent and it is our understanding that contradictions taken in this regard, for example, program for action adopted by European Commission, is a step in the right direction.

Access to medicines is an issue which presents a challenge to the human race at the beginning of the 21st century. As such, it contains political, humanitarian as well as technical elements and fingerprints all of these elements we can find in trade. Having said that, it is our understanding that only comprehensive solutions may be operational and acceptable for all participants on this two-way road traffic.

We are of the view that the TRIPS Council shall concentrate on intellectual property aspects. We also support the proposal to promote discussion within other organizations. The discussion may be helpful in addressing the link between the Agreement and public health protection and in identifying components for necessary balance between access to medicine and intellectual property protection. It is a wide-ranging task, requesting further intensive work.

We thank delegations who presented documents for the TRIPS Council. We consider it an excellent contribution facilitating today's discussion. Our delegation, while remaining constructive and positive in further work, will use opportunities to address specific elements later.

PANAMA

The delegation of Panama would also like to associate itself with the praise expressed for your initiative of holding this special meeting to discuss this issue which transcends the realm of the WTO, being very much in the public eye. We all await the results of this meeting and are eager to know how the topic will be followed up.

The delegation of Panama listened carefully to the various statements made today and is encouraged by what the different delegations have said, in particular its partners from the developed countries most active in protecting the intellectual property rights of their citizens that have identified possible room for flexibility and interpretation in the TRIPS Agreement that could be important in finding solutions to the concerns that this very important issue has raised, such as the impact of the TRIPS Agreement and other WTO Agreements on the scope of action of governments in developing policies and operationalizing programmes in areas that are critical to social and economic development, for example the public health sector. At the same time, we are somewhat disappointed that many of these same partners, having examined the possible room for interpretation or flexibility, have merely stated that they are ready to continue the dialogue. We had hoped that they would be prepared, in view of the special and differential treatment provisions of the WTO Agreements and the principles set forth in Article 7 and 8 of the TRIPS Agreement, to adopt, or at least not to oppose, these interpretations when the developing countries tried to operationalize their critical social policy in respect of access to medicines in case of emergency.

Indeed, the delegation of Panama urges these delegations to take the next critical step in the processes we have begun here today and in other WTO fora, and commit themselves to respecting the flexibility and the interpretations that they themselves have identified as possible and which meet the particular concerns of the developing countries.

Finally, we have heard the different delegations say that nothing in the TRIPS Agreement prevents the developing countries from attending to their development needs. On the basis of past experience, it is important that we should hear from our partners that they will not act in such a way as to shed any doubt on these statements.

SINGAPORE

This debate is very timely and we thank the African Group for bringing up this issue and helping the TRIPS Council to focus on the issue. We also thank our colleagues from the EC, Brazil, Malaysia (on behalf of ASEAN) and the many other delegations who are helping us to try and get a clearer picture in terms of TRIPS as far as access to medicines is concerned.

While the question of the cost of medicines is a much more critical problem as far as developing countries and LDCs are concerned, to us, it seems that it is a problem for all countries. Let me just mention the case of Singapore. Medicines concern an area which causes a lot of passion, because people are very concerned when it comes to treatment. In fact, in Singapore, the rising cost

of treatment, health care and so on is such that the Government has found it necessary to put aside a part of the centre provident fund of citizens, purely for the issue of health care, because it is something which is rising all the time. And in that context, drugs of course play a large part.

So we treat this particular exercise as one to see how countries across the world can benefit from the terms of TRIPS to try and ensure to their citizens, affordable medicines and affordable treatment.

As regards the provisions of the TRIPS Agreement, let me stress at the outset that none of our colleagues who have intervened has said that we should abolish the patent system. Neither has anyone said that there should be no reasonable return for the right holders. Nobody is saying that we should not have a system providing for incentives for the big multinationals to invest and do research in this area.

Having such a system, we are looking at how we can have reasonable cost of medicines. In this connection, one needs to look at the various provisions in the TRIPS Agreement. Articles 7 and 8 are important provisions, but they are not easy provisions to deal with. They are to be interpreted in the context of each specific TRIPS provisions and in the context of the facts at hand. There can be no one interpretation cast in stone.

Singapore joins with many colleagues who have referred to parallel imports as an important way of trying to ensure a reasonable cost of medicine for their citizens. As to the concern that if you allow parallel imports there could be problems of safety of medicines, I do not think that parallel import drugs escape checks by regulatory authorities.

Article 30 is one of those provisions which, of course, like other parts of the IP regime, deal with what we may briefly summarize as "fair use" and certainly we ought to look at it to see whether there are any alternatives available there in terms of medicines.

The question of compulsory licensing has been referred to by many colleagues. Certainly there are some factors there, whether in terms of the grounds on which you can provide compulsory licensing; and in terms of adequate remuneration. We should look for flexibility in this area and the extent of the flexibility. However, flexibility is not the ultimate solution, because even if you give a compulsory licence to another multinational of another country producing for your country, ultimately there is bound to be a commercial division. But it is important to see how these provisions are to operate; how we can operationalize them in terms of the problems that we face today relating to the cost of medicines.

We would also like to refer to two interesting points brought up in the EC paper, in relation to Article 39.3 and the use of test data for marketing approval. We note with interest the two issues; one is whether test data should continue to be protected even after a patent has expired and, second, whether such protection could interfere with compulsory licences that you could grant.

Differential pricing may offer some solutions, but it cannot provide *the* answer. It cannot prevent us from analysing the possible flexibilities under the TRIPS Agreement.

INDONESIA

First of all, we also would like to mention that Indonesia fully associates with the statement of ASEAN as delivered by Malaysia. We would also like to remind Members that Indonesia is also a co-sponsor of a joint paper on this subject presented by Zimbabwe. Nonetheless, we are asking for the floor to make some additional comments. Indonesia appreciates the fact that the WTO Council for

TRIPS gives notable attention with regard to access to medicines and thanks the African Group for its initiative to hold this special session.

As a matter of fact, the accessibility of needed drugs remains unresolved concerns in many developing countries due to the high price of patented drugs. In over 30 countries public spending on medicines is less than two dollars per capita per year. Particularly as an impact of depreciation of the local currency government spending on drugs had reduced drastically, *for example in Indonesia only less than 50 cents per head per year.* In addition to that, few people have access to health insurance, in *Indonesia only, 15 per cent of the total 200 million population are covered by health insurance.* This means that the majority of the population have to pay for drugs out-of-pocket. Therefore, access to medicines is particularly price sensitive.

In our view, patents enable prices of medicines to be sold at levels that are artificially high due to the curbing of competition. Indonesia have evidence to show that the prices of branded patented products are far higher than the prices of similar medicines produced by generic. *For example, according to the survey, the price of patented Diazepan is 45 times higher that the generic one; Glibenclamid, needed to - treat Diabetic patient 13x; Propanolol for Hipertension pasient 15 x: and Cotrimoxazol, antibiotic to treat serious diseases is 10x. Out of 50 items of the most fast moving drugs which are being surveyed, in average price of patent drug is about seven times higher than the generic one.*

In order to obtain "discounts" governments need to negotiate bilaterally with individual companies, drug by drug. Just recently, Indonesia negotiated price reductions with 4 companies to make antiretrovirals available at lower prices. Eventually, the companies agreed to provide 90 per cent reduction, so it is priced around US$420 per person per year. Despite the price reduction, however, assessing the data available, it is still higher in comparison to the generic products in other countries. While "differential pricing" is one of the alternatives to solve the problem, however, it should not be a substitute to the rights available in the TRIPS Agreement in particular "compulsory licensing" and "parallel imports" as suggested in the paper mentioned earlier.

Experiences showed that drug prices decrease when there is competition from a generic one. Lower prices enabled governments to provide free drugs to the poor population while at the same time help relieve the majority of the people from the burden of high drug prices. Unfortunately, the items of generic drugs is limited to those which are already off patent. *In Indonesia for example, active ingredients for generic drugs is about 232 in comparison to 1,300 available on the market. Moreover, market share of generic drugs in terms of value is still very low. It is only about 10 per cent (US$100 million) of the total pharmaceutical market which is about US$1 billion in the year 2000 in Indonesia (this is equivalent to drug consumption of US$5 per capita per year). On the other hand, the generic market covers more than 65 per cent of the population who need health care.*

To prevent the negative impact of TRIPS, implementation which could worsened the existing situation, we are of the view that prompt introduction of new generic drugs is vital. Therefore, we believe that options available under the TRIPS Agreement, in particular the exception to exclusive right which permit early testing and approval of generics known as "Bolar" provision should be clarified in such a way so that avoid countries interpret differently. Besides this, to ensure that the needed medicines can be made available at affordable prices, adequate provision for the granting of compulsory licences is crucial. *To give you a better illustration of the manufacturing capacities of pharmaceuticals in Indonesia, from the total 198 pharmaceutical industries, around 60 per cent of the total pharmaceutical market is held by only 20 companies, of which 15 companies are multinationals.* Many countries now provide for compulsory licensing through national legislation, however, since the TRIPS Agreement provides for non-discrimination between locally produced and imported products, a compulsory licence should also be provided for importation to satisfy local needs.

Surveys on retail prices of essential drugs have reported wide price variations between countries. The retail prices of several essential drugs have been found to be higher in developing countries than in the wealthy industrialized countries. This findings showed that companies setting different prices in different markets in order to maximize profits rather than according to the purchasing power of the community. This makes medicines even less affordable. For this reason, Indonesia delegation shares the position that countries should have their rights to import equivalent patented drugs marketed at lower prices in other countries.

We are fully aware that the TRIPS Agreement can stimulate generic competition and reduce the prices for off-patents drugs, but the TRIPS Agreement may also significantly delay the introduction of new generic drugs, depending on the way in which national legislation is designed and implemented.

Based on experience, developing countries have been hindered in applying legal options to increase access because of intense economic and political pressure placed upon them by a number of powerful related business interest. Countries with least capacity for interpreting and acting on international trade agreement have most at risk in terms of access to medicines.

Recognizing the importance of patent in stimulating research and development, Members must find a balance between assuring the right of individual to have access to medicine and protecting IPRs.

Against this background, it is very crucial for the WTO as an international trade organization to take a strategic role in ensuring the accessibility of needed medicine and preventing countries from TRIPS-plus requirements. WTO has to ensure that national legislation should be consistent and must not be more stringent than the TRIPS requirement.

Indonesia is of view that some clarifications and where appropriate some amendments of the TRIPS Agreement are needed in order to promote public health and ensure access to affordable medicines. To enable developing countries to exercise their rights, they must be allowed the maximum flexibility in interpreting and implementing the TRIPS Agreement's provisions.

TURKEY

First of all, I would like to express our satisfaction for the initiation of this debate at the TRIPS Council. Turkey is one of the many countries that had supported this initiative from the very beginning. Needless to say, the relationship between the relevant provisions of the TRIPS Agreement and access to medicines is an important issue and therefore it has to be addressed accordingly at the WTO, as well as at other related international forums, namely WHO, UN and others.

This issue also has other humanitarian, social, political, ethic and medical aspects. Needless to say, here at the TRIPS Council our primary focus should be on TRIPS-related and trade-related aspects of this issue. At this stage, we regard TRIPS Council as the appropriate organ to carry out these discussions. However, as our work progresses, other organs may also be involved in this process. We also consider the fourth Ministerial Conference to be held in Doha in November, as a good opportunity to give us guidance.

Especially, in this period during which WTO and the multilateral trading system are bitterly and unjustly criticized on humanitarian and social grounds, this issue cannot be excluded from our work agenda. It has to be discussed thoroughly and according to the conclusions of our discussions, in our view, Members should take the necessary action, in order to find a satisfactory solution to the problems necessitating this and further meeting.

This can also be in the form of a mandate given by the Ministerial Conference for future work in this field.

Our discussions on trade-related aspects of access to medicines should not exclude any relevant issue and be open ended in nature.

On the other hand, we welcome the written submissions of the European Union and the African Group and some other Members, which provide us with a good starting-point for our discussions. We wish to come back to them with more substantial comments, after having carefully studied these papers in detail.

Nevertheless, having followed the general observations, we wish to make some preliminary comments on both papers.

In the knowledge-based global economy in which we live, intellectual creativity is the main asset of individuals and societies to find means to increase their productivity in order to achieve better living standards. Increased productivity and scientific development can be achieved in a stable environment, where individuals and societies are given sufficient opportunities to use their creativity and being aware of the fact that they will benefit from their innovations, which have a trade value. If the stability concerning the protection of intellectual property is carried on to the international level, this increased productivity and new innovations can spread further as well. This is especially the case for pharmaceutical industry.

However, the health of individuals and public health are such sensitive issues that they cannot be left to merely trade-oriented concerns and one's life cannot be directly connected to the trade concerns and commercial considerations.

Therefore, at this junction we do not intend to discuss the validity of the patent protection provisions. We are not discussing or revisiting the TRIPS Agreement itself either. We are rather interested in the possibility of some flexibility within the TRIPS system itself. In our view, the TRIPS system and especially Articles 7 and 8 of the Agreement give us enough space to manoeuvre in this context.

We support the points made by the EU in their recent paper. We believe that the starting-point of our discussion should be the interpretation of the relevant articles of the TRIPS Agreement. While doing so we believe that an overall balance of the Agreement and the established system should be preserved.

As for the paper of the African Group, we support many points raised by the sponsors in their paper. However, we also believe that we need more discussion on some concepts such as the extent of accommodation of national policy objectives in the TRIPS system, the benefits of the society, extension of transitional arrangements, granting compulsory licence to third countries and moratorium. We have no preliminary objection to the discussion of any issue raised by the African Group and other co-sponsors.

KOREA

My delegation would like to join the other delegations in appreciating the initiative by the African Group and other countries for submitting their papers and their contributions to this meeting.

We believe it is quite appropriate for the TRIPS Council to deal with this very important and urgent issue.

My delegation sincerely hopes that this special session will be result-oriented on the basis of balancing two objectives enshrined in Articles 7 and 8 of the TRIPS Agreement. The first objective related to providing essential medicines at affordable prices to people in need and the second, to promoting technological innovations on new medicines.

First, with regard to interpretation and application of relevant provisions of the TRIPS Agreement, it is our view that some flexibility is already provided in the relevant provisions to ensure balance between socio-economic policies and patents. For example, as I have already mentioned, Articles 7 and 8 clearly refer to this balance. We have other provisions at our disposal to tackle this issue. My delegation does not wish to go into a technical discussion on these provisions at this stage, however, we would like to point out that provisions like Article 31 (compulsory licensing) and Article 30 (exception to exclusive rights) are relevant to this issue. Article 31 could be interpreted to allow Members to alleviate conditions for compulsory licences on essential drugs. However, safeguards measures should be in place against the possible abuse of this clause. Regarding Article 30, it is our view that the notion of the third parties in this article is understood to include general public and their legitimate interest of consumers should be taking into account to purchase medicines at affordable price.

Relationship between the TRIPS Agreement and affordable access to medicines

By stipulating that Members may adopt measures necessary to promote public interest in sectors of vital importance to their socio-economic development, Article 8 can be interpreted to allow for discretionary room for policy on price and reimbursement. In this connection, we would like to note that the possibility of introducing a differential pricing system was discussed at the international level. We think that it would represent a positive step forward to talk about differential pricing among countries, rather than to restrict patent protection on the grounds of access to essential drugs.

Future work programme

Apart from intellectual property rights and pricing, this issue comprises price-sharing of medicines and strengthening the supply and distribution system of medical services.

Therefore, it is important to seek a solution in cooperation with the WHO while paying due attention to the proper competence of the TRIPS Council.

COLOMBIA

In view of the numerous contributions that have already been made to these discussions, I shall be very brief.

My delegation considers that the process we have initiated today is of the utmost importance. While it involves a number of technical issues, it also has a moral and ethical dimension. We would like to give our special thanks to the Members that submitted documents to this meeting. Regarding the document submitted by the European Union, we share the view that public health issues must be addressed on the basis of a comprehensive approach. The most important, although not the only element of this comprehensive strategy for a country like Colombia is the price of medicines, and this is the element which falls within our competence in this forum. As regards the document submitted by India, Brazil and other countries, we agree with certain elements that would be worth analysing, such as parallel imports and compulsory licensing, on the understanding that the TRIPS Agreement leaves considerable latitude for the development of domestic policies aimed at improving access to medicines. At the same time, we think that the extension of the period for non-violation complaints will play a central role in policy-making.

We have also heard different proposals for our future work. Some have referred to collective interpretation, and others to a political statement confirming a margin of manoeuvre to be applied to each particular case. We would be inclined to favour a balanced interpretation of the TRIPS Agreement as a result of our discussions.

We continue to be interested in participating constructively in this effort to define the scope of obligations under the TRIPS Agreement in the hope that we can help to come up with the solution that the multilateral trading system must provide to an issue on which we cannot remain indifferent.

PAKISTAN

Pakistan welcomes this special session of the TRIPS Council to discuss intellectual property and access to medicines issues.

Pakistan is one of the sponsors of the paper contained in document IP/C/W/296 introduced by my colleague from Zimbabwe in the morning session today. Therefore, I will avoid making a long intervention.

In Pakistan's view, the existing model for protecting intellectual property rights is heavily tilted in favour of right holders and is against the public interest. Due to the monopoly exercised by patent holders, drug prices have gone much beyond the access of those who really need them.

Every day, infectious diseases kill 30,000 in the developing world. The HIV/AIDS pandemic has claimed more than 17 million lives in Sub-Saharan Africa.

To say that the TRIPS Agreement strikes a carefully negotiated balance between private rights and public policy objectives, seems, at least to this delegation, much of a rhetoric, especially when the existing flexibilities in the relevant provision hardly do much to provide space to manoeuvre due to the fact that either the relevant provisions have been drafted in a manner which takes away the possible flexibility or these countries lack at the moment in technical expertise and also entrepreneurial skills to undertake production of generic drugs:

- The World Health Organization defines the meaning of "equitable availability and affordability of essential drugs with an emphasis on disease of poverty".

- It therefore follows from the above definition that price is a crucial factor in having access.

- Patents affect the price of a drug and therefore accessibility.

Under the TRIPS Agreement, the Members are required to provide exclusive marketing rights to holders of patents on pharmaceutical products for a period of at least 20 years. This imposes restrictions on what governments can do in regard to production, marketing and import of low-cost generic drugs.

The effect of these restrictions are two-fold:

(a) reduced competition;

(b) increased prices for drugs essential in the treatment of HIV/AIDS and other common diseases.

This creates a situation where accessibility to life-saving drugs virtually becomes an impossibility for a large number of the world's population.

This situation, in the creation of which the TRIPS Agreement certainly has a role, needs to be the focus of our attention.

In Pakistan's view, all provisions of the TRIPS Agreement must be interpreted in line with the objectives and principles set out in Articles 7 and 8 of the Agreement. These Articles attempt to strike a balance between private rights and public policy objectives. The apprehensions that the existing provisions lend priority to private rights over public policy objectives needs to be viewed seriously.

The Ambassador of India has rightly pointed out the need to explore all options currently available under the TRIPS Agreement to see how developing countries could be allowed to have maximum flexibility to adopt measures for protection of public health.

Pakistan therefore shares the views expressed by the Ambassador of Brazil that:

(a) the TRIPS Agreement should not run counter to the public health interests; and

(b) the need to evaluate and interpret the provisions of the TRIPS Agreement in the public health context to ensure accessibility of medicines which is a fundamental human right.

I will avoid, as I said, making reference to various provisions in the TRIPS Agreement because most of the Members have already explained these provisions in great detail and in a much more comprehensive and lucid manner.

The benefits of the WHO and the UN proposals for differential pricing of pharmaceutical products are likely to be marginal. Particularly in relation to HIV and AIDS Drugs, almost all of each can still claim patent protection for more than 10 years from now.

Another issue that may have to be addressed is how far the rules permit exports of generic versions produced under compulsory licences during the validity of the patent protection period.

The issue we are discussing today brings to focus the concerns most of the developing countries are voicing in the context of the implications of the TRIPS Agreement has for them.

It underpins the fact that there is a development deficit in the existing disciplines.

Pakistan is of the view that the public health issue highlights the need for a substantive review of the Agreements to ensure how developmental objectives can be taken into account in the TRIPS Agreement.

GUINEA

My delegation would like to begin by congratulating the delegation of Zimbabwe, which spoke on behalf of the African Group, and expressing its support for a statement which reflects the concerns felt by a number of countries in which millions suffer from HIV/AIDS and other pandemic diseases that impede social, and, in particular, economic development.

In 1999, at the ministerial round table entitled "HIV/AIDS: Strategies for sustaining an adequate response to the epidemic", the WHO informed us that in urban areas of highly affected countries in the developing world, 50 per cent to 70 per cent of hospital beds were occupied by

HIV/AIDS patients, increasing the risk of spreading infections such as tuberculosis, malaria and other diseases affecting public health.

These figures are highly disturbing. This is why the developing countries need parameters that enable them to combine trade policy with policies aimed to improve individual welfare. The developing countries should be able to have recourse to the public health safeguard measures contained in the TRIPS Agreement.

It is impossible to ensure economic stability without establishing a guaranteed threshold for certain minimum rights, beginning with access to essential medicines.

On the question of public health, my Government's objective is to introduce a health system that is accessible to all and that is able to respond to the health needs of its poor populations.

This means creating conditions in which it is possible to reduce public health complications, which, in turn, inevitably implies access to medicines at affordable prices.

The role of WTO Members in this debate is unique. This is why it is essential and appropriate that the fourth Ministerial Conference in Doha should play an active role in the discussions on access to medicines at affordable prices. This would add a human dimension to the TRIPS Agreement, and would be further evidence of the commitment of the international community to the combat against pandemic diseases affecting the poor populations of our countries.

URUGUAY

We welcome the opportunity for this Council to discuss, at this meeting, the TRIPS Agreement and access to medicines.

The document prepared by the Secretariat is of great value and reveals the importance of this issue at the international level, reflecting concerns at the national level with respect to intellectual property protection and public health, a matter of legitimate interest of our governments.

Uruguay shares these concerns, which involve weighing public health interests against the commercial aspects of intellectual property.

In our view, the TRIPS Agreement provides for a considerable margin of flexibility, enabling Members to conciliate the protection of intellectual property rights with public interests which, in this particular case, means access to medicines. Indeed, the Agreement enables a number of relevant instruments to be considered in domestic legislation, such as the exhaustion of rights, compulsory licensing and interpretation of the provisions of the Agreement in the light of its guiding principles and objectives set forth in Articles 7 and 8.

The African Group, Brazil and a group of other countries have made an important contribution to the consideration of this topic, which will be studied in-depth in our capital, since this is the beginning of a discussion process leading up to the next Ministerial Meeting.

Finally, these discussions should enable the Council to reach a common understanding that will clarify the balance between intellectual property rights and such highly sensitive areas as the life and health of our populations, basic human rights which we should all be able to enjoy.

AUSTRALIA

Australia welcomes all the contributions that are made to this very important debate today and I think it's a debate that will be significant for the rest of the time that we have, for the rest of this year. Australia's understanding of the TRIPS Agreement is that it provides sufficient scope and flexibility to address health emergency situations. The TRIPS provides a balance of benefits for the public and right holders, which enables us to deal with the very serious health situation we have been discussing today and we look forward to discussing these issues in more depth at future meetings.

It may be appropriate for this Council to encourage, for example, WIPO, to ensure that as the expert body providing technical assistance to inform countries in the drawing up of their TRIPS-consistent legislation, that significant care is taken to enable Members to enact all the provisions of the TRIPS Agreement.

Given the very detailed and substantive discussion that has taken place, it will assist our future discussions if the Secretariat could find a way to ensure that Members are provided with either copies of the statements or early delivery of their records. I think that if we can take this message back to capital, it would really help future discussions.

UGANDA

Permit me to start by fully associating myself with the statement made by Zimbabwe on behalf of the African Group. The Ugandan delegation also endorses the statement made by Tanzania on behalf of the LDCs.

The Ugandan delegation fully recognizes the need and the importance of having this special session to discuss the TRIPS Agreement and access to drugs and public health. At a time when millions of people in poor countries are unable to afford essential medicines and when public health is being threatened by a combination of new diseases and drug-resistant variants of killers, it is only reasonable and understandable to examine the TRIPS Agreement to see how it can be interpreted if at all in a manner which would not have adverse effects nor further reduce access to new medicines by effectively extending the monopolies of drug companies and restricting generic competition.

Many delegations have spoken in detail on the various aspects of the importance of access to drugs and public health. My delegation will not repeat some of the technical and legal arguments advance to which we subscribe. However, my delegation will try to highlight only a few areas and make a detailed written submission to the Secretariat.

Uganda is no stranger to the horrors and tragedies inflicted by the HIV/AIDS pandemic nor the effects of Malaria. The HIV/AIDS pandemic is a human tragedy of horrific dimensions. I cannot but agree with the statement made by the Ambassador of India earlier that the cry for affordable access to medicines for what are life-threatening diseases for people in developing countries is a cry of a fundamental human right of nature. Statistics show that more than a quarter of the adult population in some countries in Africa are infected with HIV. Those victims, I believe, deserve being given hope. Hope that they to can have access to those very vital drugs at affordable prices. My delegation agrees with previous speakers that the TRIPS Agreement should be part of the solution and not the problem. We believe that this can be done through affirming and confirming that the Agreement has clear and sufficient flexibility which allows governments to adopt appropriate measures to protect the health and lives of their people. Governments need the assurance that they can adopt such measures without fear of litigation through the WTO or other bilateral pressures.

Regarding the intellectual property aspect, my delegation is convinced that IPRs are intended as a means to benefit society as a whole rather than as an end in itself. The mere existence and

protection IPRs such as patents does not necessarily result in the fulfilment of the objective of the TRIPS Agreement. A case is the example of the recent controversy around the excessive price of patented HIV/AIDS medicines in South Africa. This case graphically illustrated the negative impact of the TRIPS Agreement on access to medicines.

As has been stated by other delegates before me, Article 8 explicitly recognizes that Members may adopt measures to protect public health among other overreaching public policy objectives such as nutrition and socio-economic and technological developments. We agree with this approach. My delegation concurs with the African Group that each provision of the TRIPS Agreement should be interpreted in the light of objectives and principles set forth in Articles 7 and 8 as has been stated by other delegations previously.

My delegation believes that parallel importation is an important tool to ensure adequate access to medicines. Parallel importation of a patented medicine from a country where it is sold at a lower price will save the lives of thousands in an importing country like Uganda by giving them access to that very much-needed medicine.

Regarding differential pricing, my delegation favours this arrangement, provided it is done in a fair manner and within a comprehensive and multilateral framework. My delegation believes that this should be part of a bigger set of initiatives to improve access to medicines.

On the way forward, my delegation fully endorses the call of observing, with immediate effect, a moratorium on dispute settlement action against developing country Members hinder their ability to promote access to medicines and protect public health.

And finally, I would like to say that my delegation agrees with the many speakers that this dialogue, and this Council that we have been backed on today is just the beginning and the subject should not end here. This dialogue, we believe, should serve as a basis for a further debate on the matter in the coming months, indoor and beyond.

PHILIPPINES

Being one of the co-sponsors of document IP/C/W/196, we welcome this discussion and similar future discussions, particularly in light of the objective of rendering more clarity to the provisions of the TRIPS Agreement as those provisions impact on the ability of Members to formulate and implement measures to promote public health.

Absence of clarity or insufficient clarity causes uncertainty. In other fora in the WTO, the phrase "chilling effect" has been applied to trade, referring to an adverse effect of uncertainty. In this instance, uncertainty could have worse consequences, as it could have a "chilling effect" on the formulation and implementation of measures to promote public health, a paramount concern.

In associating ourselves with the objective of rendering clarity, we are not necessarily taking the position that the TRIPS Agreement is so unclear and so ambiguous as to cast doubt on the ability of Members to formulate and implement measures to promote public health. We believe that the TRIPS Agreement does authorize these measures.

Uncertainty is not necessarily a function of the perceived clarity – or lack of clarity – of the relevant provisions. Indeed, uncertainty could also arise from extrinsic factors such as the widely disparate negotiating positions of Members, each seeking to assert their respective rights as they perceive it.

We may all be legally equal as Members, but there are intrinsic advantages to being economically dominant, and the temptation to act on the basis of an economically dominant position is always there. And if such temptation is yielded to, the most clear of rights could be – to borrow a phrase used by New Zealand in a slightly different context earlier– rendered obscured. In short, rendered uncertain.

We should endeavour to minimize unclarity, uncertainty.

Rendering more clarity to the relevant provisions of the TRIPS Agreement is a significant step in this regard.

That process means listening, in order that one may truly understand the position of other Members. At the same time, it also means that we must render ourselves capable of being understood by other Members.

Having listened to others the whole day, we now focus on the need to render ourselves capable of being understood by other Members. It is in this context that we present to you in an abbreviated form our understanding of certain relevant provisions of the TRIPS Agreement.

Article 30 of the TRIPS Agreement provides that Members may provide limited exceptions to the exclusive rights conferred by a patent, provided, among others, that such exceptions do not unreasonably conflict with a normal exploitation of the patent. We take this to mean that Members may provide exceptions which reasonably conflict with a normal exploitation of the patent. It also state that such exceptions must not unreasonably prejudice the legitimate interests of the patent owner.

In respect of Article 31, we are gratified to note, based on the interventions we have heard, that no one expresses serious doubt on the ability of Members to provide, to authorize, to grant a compulsory licence, subject only to the essentially procedural requirements specified in that Article.

It is the prerogative of each Member to decide for itself whether or not it would have the ability to resort to parallel imports. This is based on footnote no. 6 to Article 28, in relation to Article 6 of the TRIPS Agreement. In this regard, there is no need for the Member concerned to require the issuance of a compulsory licence to import as a condition to such importation. This is because the rights of the patent holder over the products which are to be imported have already been exhausted. And "exhausted" means just that.

We look forward to further discussions on this matter, with the end in view of minimizing the "chilling effect" on the formulation and implementation of measures to promote public health.

HOLY SEE

The Holy See, as an observer state, has prepared a short note which, I hope, with the permission of the Council can be made available to all.

I will limit myself here to briefly explain the reasons why the Holy See addresses the question.

The first reason is the gravity of the HIV/AIDS pandemic as well as the re-emergence of other infectious diseases, with the consequent disastrous effects on the lives of people of developing countries, especially in Africa.

We cannot overlook the fact that a heavy burden of disease has serious negative effects on economic development. An improvement in health enhances those human resources which are the

driving force of development and economic growth. WTO cannot ignore the link between health and economic development.

The second reason why the Holy See addresses the question, is it challenges the very credibility of this body today. Public opinion is watching how this Council will address the question of access to essential medicines.

The credibility of the WTO is linked with its ability to use flexibility in interpreting TRIPS rules, other way in which it will not show that ability but public opinion will judge how we behave. The manner it can interpret its rules in such a way as to achieve the pro-development stance of the whole legal body.

Availability of medicines is not the only aspect of access to health. It is, however, an essential aspect. Accessible price always remains a determinant factor.

The tension between the duty of solidarity with victims of disease and the need to protect intellectual property.

A broad-based commitment of solidarity is the best way to prevent poor countries from falling into any temptation of weakening the intellectual property rights framework.

The solution to the problem of access to basic medicines is far beyond the mandate and the means of the Council for TRIPS. However, the Council for TRIPS could make a fundamental contribution, by means of an authoritative interpretation of the TRIPS rules:

- consistent with a unified vision of law;
- based on respect for human rights;
- and especially applying those articles of the WTO treaty that call for a pro-development interpretation of the whole legal body.

Such a legal interpretation might affirm:

- that any TRIPS clause should not be understood in a way that becomes a practical obstacle to rapid, efficient and universal access to basic medicines, for those who are the victims of the actual dramatic health emergency; and
- that nothing in the TRIPS Agreement should prevent countries, including small countries with limited domestic manufacturing ability, from implementing sound health policies.

This would contribute to a broad rather than a restrictive interpretation of Articles 30 and 31, which allow that licensing fees may be fixed in accordance with the real purchasing capacity of the poorest country, balanced with a system that blocks the re-exports of the licensed products to the original markets.

We have talked a lot about private property but private property has a fundamental social function, indeed we can say that a "social mortgage" on all private property, which requires to be directed to the benefit of the common good.

Today, that "social mortgage" must be applied today to "intellectual property" and to "knowledge".[5] The law of profit alone cannot be applied to that which is essential for the fight against hunger, disease and poverty.

WIPO

The World Intellectual Property Organization (WIPO) welcomes the opportunity offered by this special TRIPS Council to clarifying discuss the relationship between public health issues, the patent system and the TRIPS Agreement.

The delegation of WIPO notes a general support today on an essential role of the patent system in stimulating the development of essential drugs, including anti-AIDS drugs. Without the patent system, existing anti-AIDS drugs would not have been produced. Without the patent system, new and better drugs needed to overcome the increasing resistance of the AIDS virus would not be developed. Without the patent system, key technical information on new drugs would be kept secret, and drug manufacturers would have to reinvent the wheel. Given the severity of the crisis, no one can afford to spare such resources and time.

WIPO considers it important to strike a proper balance between public health concerns and the interest of the patent owner. This balance exists within the patent system. The delegation of WIPO notes that, in the meeting today, a number of delegations agreed that the TRIPS Agreement provides the necessary flexibility to achieve that balance and to accommodate the needs of the countries deeply affected by HIV/AIDS.

WIPO has no mandate to interpret the TRIPS provisions. However, within its mandate, WIPO will continue to provide legal-technical assistance to countries on the implementation of the TRIPS Agreement. In fact, within the framework of the WIPO-WTO cooperation agreement concluded in 1995 and technical assistance programmes for developing countries launched in 1998, more than 100 developing countries have received a wide range of assistance regarding the TRIPS implementation. As the Ambassador of Tanzania on behalf of the LDCs stated in the morning session, on 14 June last week, WIPO and WTO launched another initiative and signed a joint communication to assist LDCs in implementing TRIPS Agreement and in using intellectual property as a tool for technological advancement, economic growth, knowledge and wealth creation. WIPO is convinced that LDCs should be able to stimulate local research activities and make joint efforts, through effective use of the patent system, to develop and produce anti-AIDS drugs.

WIPO is ready to share with you its expertise and experience gained through WIPO's assistance programmes and to contribute to this important exercise and the discussions on the issues before us.

Council action on further work

5. Following these statements and on the basis of subsequent consultations, the Chairperson proposed that the Council proceed with its work on this matter as follows:

- that the Secretariat prepare a checklist of all Articles of the Agreement that Members made reference to in their interventions and all matters that delegations raised in relation thereto, in which the Articles be listed in the order in which they appear in the Agreement.

[5] JOHN PAUL II, Message to the "Jubilee 2000 Debt Campaign" Group, 23 September 1999.

- that this checklist be circulated to Members as soon as it is compiled and be the basis of an informal meeting to be held on 25 July.

- that Members extend the formal meeting of the Council in September 2001, presently scheduled for two days, to three days and set aside a full day at that formal meeting to deal with the issue of the TRIPS Agreement and access to medicines.

6. The Council so agreed.