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TRIPS, Biological Resources and Public Health:

Documents and Discussion Papers Presented at the ICTSD - Africa Group Roundtable on 12 June 2001

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TRIPS, Biological Resources and Public Health: Documents and Discussion Papers Presented at the ICTSD - Africa Group Roundtable

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Introduction

Following a request by the Chair of the Africa Group, ICTSD on 12 June 2001 held an Informal Roundtable on *TRIPS, Biological Resources and Public Health*. The Dialogue aimed to provide support to the Africa Group for the preparation of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the fourth WTO Ministerial Conference. In addition to African negotiators based in Geneva, the meeting mobilised four experts, including Prof. Johnson Ekpere from the University of Ibadan and consultant for the drafting of the Organization of African Unity (OAU) *Model Law on Access to Genetic Resources and Community Rights*; Dr. Tewolde Egziabher, General Manger of the Ethiopian Environmental Protection Authority; Prof. Thomas Cottier, former trade negotiator and Director of the World Trade Institute (Switzerland); and Cecilia Oh from the Third World Network (Malaysia).

As a follow-up to the Roundtable, the present collection of reference documents and discussion papers is designed as a reference tool on the TRIPs Agreement as it relates to biological resources and public health. The document is primarily aimed at African trade negotiators, but will also provide a valuable resource for other stakeholders interested in this debate. By providing a combination of information and perspectives, our aim is to support and facilitate fruitful discussion on the issues in particular among members of the Africa Group, with the ultimate goal of enhancing the African and other developing countries' capacity to advance their public policy objectives in future negotiations.

Following the structure of the Roundtable, the document is divided into two sections. The first section focuses on the concerns raised by the Africa Group in the review of TRIPs Article 27.3 (b) including the patenting of life forms; *sui generis* options for plant variety protection, and the harmonisation of TRIPs provisions with the CBD and the IU, and evaluates how these are dealt with in the OAU Model Law. The second section addresses the relationship between TRIPs and access to medicines, in particular the use of compulsory licences and parallel imports as means to facilitate access. Each section contains a selection of reference documents reflecting the Africa Group's present position, as well as discussion articles that highlight some of the relevant issues. The discussion articles are comprised of contributions from speakers who participated in the Roundtable, and articles previously published in ICTSD's *BRIDGES Monthly Review*. We would like to thank all the authors for their generous contributions. The views presented in the articles are those of the authors and do not necessarily reflect the views of ICTSD.

Context

As we move towards the next WTO Ministerial Conference in Doha, Qatar, the implementation of the TRIPs Agreement and the review process under Article 71.1 and Article 27.3(b) remain among the most controversial topics in ongoing WTO negotiations. Article 27.3(b) of the TRIPs Agreement allows countries to exclude plants and animals (other than micro-organisms) and certain biological process from patentability as long as plant varieties are protected by patents, *sui generis* systems (i.e. systems to protect plant varieties different from the patenting system, but with the same effect) or both.

The Article is currently under review in the TRIPs Council where discussions have focused on whether to extend the scope of 27.3(b) to include issues such as biodiversity, traditional knowledge, benefit sharing, and the ethics of patenting of life forms; whether and how to harmonise the TRIPs Agreement and the Convention on Biological Diversity (CBD); and the extent of flexibility to create *sui generis* plant variety protection. In two communications to the TRIPs Council dated 29 July 1999 (See pp 22, WT/GC/W/302) and 20 September 2000 (see pp 27, IP/C/W/206), the African Group has raised many of these concerns. To a large extend, these communications reflect the OAU position on TRIPs and the Review of Article 27.3(b) and in particular the provisions of the OAU Model Law on Access to Genetic Resources and Community Rights (See Ekpere, pp 13). While this Model Law is often considered as a viable alternative to the UPOV model for the implementation of TRIPS, concerns have been raised with regard to its compatibility with Article 27.3(b), as it clearly rejects patenting of life forms and biological processes.

In the context of the debate on the HIV/AIDS Pandemic and its impact on human development and economic growth, some WTO Members have expressed serious concerns related to the high cost of essential medicines. Following a request by the Africa Group, Delegates at the TRIPs Council on 20 June 2001 devoted a full day of discussion to IPRs and access to medicines to combat diseases such as HIV/AIDS, tuberculosis, and malaria. In what one delegate referred to as a "historic" event, Members generally acknowledged the importance of patent protection as an incentive for new pharmaceuticals and agreed that the TRIPs Agreement contained flexibilities that allowed governments to deal with public health.

Specifically, discussions focused on the general principles of the TRIPs Agreement, in particular the extent to which Articles 7 (Objectives) and 8 (Principles) of the Agreement allowed countries to meet their public health objectives. Members furthermore addressed the degree of countries' flexibility in relation to parallel imports and compulsory licences including for import rather than local production by smaller developing countries. Submissions addressing access to medicines were received from the European Communities (IP/C/W/280) and a group of around 50 developing countries, including the Africa Group (IP/C/W/296, see pp. 51).

TRIPS, BIOLOGICAL RESOURCES AND COMMUNITY RIGHTS

Developing Countries and TRIPs: A Case for a Full-fledged Review of Article 27.3(b)

Genetic Resources Action International
Reprinted from BRIDGES, Year 4 No 2, March 2000 [1]

When developing countries reluctantly signed on to the Agreement of Trade-related Aspects of Intellectual Property Rights (TRIPs) as part of the overall package of the Uruguay Round Agreements, they expected to revisit the TRIPs provision on "patentable subject matter" during a substantial review scheduled for 1999. TRIPs Article 27.3(b) states that WTO Member must provide patent protection over micro-organisms and microbiological processes, such as those used in biotechnology today, but countries are free to exclude plants and animals from their patent laws. However, all nations must provide intellectual property titles over plant varieties, either through patents or through an "effective *sui generis* system".

The review of Article 27.3(b) got underway one year before developing countries were obliged to implement the provision. This was important because the provision itself was a source of tremendous uncertainty in the South. Many people hoped that TRIPs could be clarified through the review and, if possible, amended to better suit the development interests of the South.

Up to now, the review has been a disappointment. It was only in July 1999 that discussions started on the substance of Article 27.3(b) rather than its implementation by WTO Members. India highlighted the need to focus on two complementary dimensions: The fundamentally political question of whether patenting life is acceptable in terms of ethics, and the need to recognise not only formal systems of innovation but informal systems as well, especially with regard to biodiversity. In particular, India insisted on the need to reconcile TRIPs with the Convention on Biological Diversity (CBD). Malaysia took the discussion a step further by asking the WTO Secretariat to prepare a list of other *sui generis* options than that offered by the Union for the Protection of New Varieties of Plants (UPOV).

It is important to note that around this time, the preparations for the Seattle Ministerial Conference entered a critical phase. Between the July and October sessions of the TRIPs Council, almost 100 developing countries signed onto nearly a dozen proposals to reform TRIPs as far as biodiversity and indigenous knowledge were concerned. These proposals were tabled in the WTO's General Council for negotiation at the Ministerial.

The Africa Group's position was the first and the most comprehensive from the South[2]. It proposed an extension of the deadline to implement TRIPs 27.3(b) for developing countries so that the review may proceed and conclude properly. It also spelled out that the Africa Group would like the review to clarify that patents on life should be prohibited, including those on microbiological processes. In the eyes of many, these two suggestions amounted to a proposal for a moratorium on implementation of the current text.

In subsequent TRIPs Council meetings, the South continued to proactively shape the frame for a review of the provisions of Art. 27.3(b), and the North also finally addressed issues of substance. The United States, for instance, argued that patenting of life forms had tremendous advantages; that UPOV 91 was what Washington would consider an effective *sui generis* system; and that there was no conflict between TRIPs and the CBD[3].

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[1] This article is adapted from a longer, fully footnoted, paper entitled *"For a Full Review of TRIPs 27.3(b) - An Update on Where Developing Countries Stand with the Push to Patent Life at the WTO"*, produced by Genetic Resources Action International (GRAIN), based in Barcelona, Spain. The report is available at: http://www.grain.org/adhoc.htm

[2] *Preparations for the 1999 Ministerial Conference: The TRIPs Agreement. Communication from Kenya on behalf of the AfricanGroup.* WTO, Geneva, WT/GC/W/302, 6 August 1999.

[3] *Article 27.3(b): Views of the United States of America*, paper presented at the TRIPs Council, WTO, Geneva, 20 October 1999.

Europe supported the US perspective, although it indicated that it was prepared to take into account the need to deal with ethics and, by way of example, provide protection for traditional knowledge systems. However, the January 2000 deadline for implementation of Article 27.3(b) in developing countries arrived before any conclusions could be drawn from the mandated re-examination of the text.

Then came Seattle. Beyond the tear gas, a negotiating text reflecting proposals on TRIPs from the Africa Group and the Like-Minded Group of developing countries was on the table. One "Green Room" session, involving a limited number of participants, looked at the TRIPs chapter but did not conclude anything. As the Conference was "suspended" without any agreement on where negotiations stood or how they would proceed, the status of these demands is unclear, and confusion reigns at present about the obligations and opportunities generated by the review. (See page 6 for a report on the TRIPs Council's discussion on Article 27.3(b) at its March 2000 session, *ed*).

Problems embedded in TRIPs Article 27.3(b)

- No parameters for what a *"sui generis"* system can amount to.
- No parameters for what is "effective".
- Many WTO members have expressed their view that genes and microbiological processes are not inventions and therefore are not patentable subject matter.
- With its lack of any benefit-sharing mechanism, TRIPs offers no remedy for the ongoing wave of biopiracy and is perceived as exacerbating the problem.
- There is a bias ingrained in TRIPs to protect breeders and biotechnologists at the expense of farmers and local communities.
- Many countries perceive a conflict between TRIPs and the rights and obligations countries previously acquired under the Convention on Biological Diversity (CBD).

In addition, there is evidence that plant variety laws inspired by the Union for the Protection of New Varieties of Plants (UPOV) have no positive impact on food security[4], a matter that the TRIPS Council has not looked into.

Implementation of Article 27.3(b) in the South: State of Play

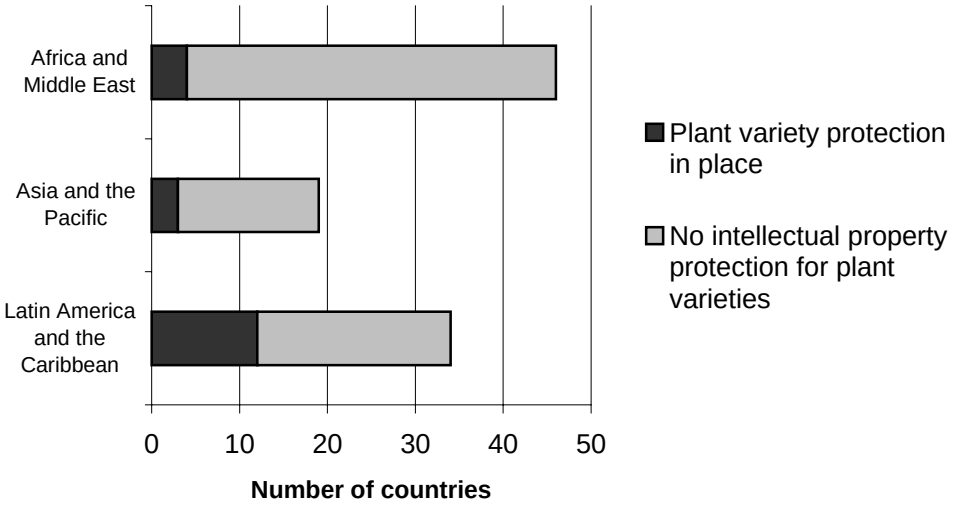
The vast majority of developing country WTO Members have approached their obligation to grant intellectual property rights over plant varieties through "an effective *sui generis* system" - whatever that means - rather than patenting[5]. The deadline to have such legislation in place [5] was 1 January 2000.

Despite the threat of possible trade sanctions, only a few developing countries managed to adopt such legislation in the final hour. To our knowledge, only 21 of them currently have plant variety protection (PVP) legislation in place (see chart above). Leaving out the 29 "least-developed" WTO Members, whose transition period ends 1 January 2006, we now face a situation where 47 Third World countries which are party to TRIPs have not enacted IPR protection for plant varieties. This means that 70 percent of the (non-LDC) developing countries that participate in the WTO system are presently in arrears of their obligations regarding TRIPs Article 27.3(b), and could be considered targets for dispute settlement proceedings on grounds of non-compliance with their WTO obligations.

[4] GRAIN (1999). *Plant variety protection to feed Africa? Rhetoric versus reality*, Barcelona, October. http://www.grain.org/publications/reports/variety.htm

[5] At present, only the United States and the Republic of Korea explicitly provide patent protection for plant varieties.

TRIPS ARTICLE 27.3(b) IMPLEMENTATION STATUS IN THE SOUTH (LDCs included)



This does not mean that developing countries are inactive on the legislative front. Far from it. India, Egypt and the Philippines have final drafts under scrutiny by their national assemblies right now. Costa Rica, Malaysia, Pakistan and Egypt are either discussing drafts or have them awaiting Cabinet approval for submission to Parliament. Many other countries are still drafting. For example, most of the member states of the Organisation of African Unity are deeply engaged in a process to develop national legislation based on a regional Model Law, which was only finalised last November. The OAU Model Law covers not only breeders' rights but also farmers' rights, benefit-sharing and rules on access to genetic resources. The 15 members of the Organisation Africaine de la Propriété Intellectuelle revised the Bangui Agreement in February 1999, incorporating a UPOV-based system of intellectual property rights for plant varieties. But to the best of our knowledge, national PVP laws drawn from the revised Bangui Agreement are not yet in force.

Nevertheless, the message is that despite four-year transition periods, despite best intentions to bear the cost of inclusion in the WTO trade system, as well as the pressure and countless workshops organised by the industrialised world, including UPOV, *developing countries are not ready to implement TRIPs Article 27.3(b*). They have good reason to be in this state: since the mid-1990s, they have been under intense, often unilateral, pressure from industrialised countries to follow the UPOV model of plant variety protection as a means of implementation - something which many developing countries strongly feel is not in their interest. The WTO itself joined in this campaign by sponsoring a series of workshops for developing countries on UPOV-as-*sui-generis*-solution even while hosting a review, which was supposed to revisit the very provision. Then, proposals from developing countries to clarify what the Article means, not only through the TRIPs Council review but a Ministerial Conference, were not dealt with. Finally, commitments to other treaties that TRIPs overlaps with, *viz.* the CBD and the International Undertaking at FAO, have inclined many developing countries to want to ensure that community rights and farmers' rights are not torpedoed by rash legislation favouring industrial plant breeders. The developing countries that did adopt UPOV-based PVP laws reacted understandably to all these conflicting pressures. But they did so in most cases - not all - without meaningful consultation or debate with those who will be most affected: the farming and indigenous communities. They certainly did not, in any case, resolve the underlying conflicts.

For a Full-fledged Review

It is hard to escape the conclusion that a full and thorough review of Article 27.3(b) is imperative. The current text is the result of a compromise between Europe and the US, with no proper consideration of the interests of developing countries or of the principles embedded in the Convention on Biological Diversity and other international agreements. In addition, the text as it stands is of full of dangerous ambiguities. Rather than bulldoze ahead and force inappropriate legislation upon developing countries and their farmers, it is important to seriously review the Article as originally agreed, and clarify its scope, meaning and objectives taking into account all these interests and concerns.

In that context, the Africa Group has offered the most comprehensive proposal on how to move forward and it merits full support - and active implementation - without further delay. It can be seen as leading to a moratorium since it demands a thorough review procedure, an extension of the transition periods and specific clarifications, which would result in amendment of the treaty. However one designates it, this in no way means that countries should abandon their efforts to develop balanced national systems of rights in the meantime. On the contrary, putting the African proposal into action should provide the appropriate time and space for developing countries to elaborate, in a more integrated and consultative way, legislation that properly meets their needs. Protecting biodiversity, promoting its sustainable use and giving fair recognition to the rights and interests of local communities and indigenous peoples cannot be sidelined from implementation of TRIPs. These objectives and issues go far beyond the scope of any world trade system, but they stand directly in the way of the current WTO TRIPs Agreement.

The collapse of the Seattle process could very well mark the start of a new era in which developing countries increasingly and successfully challenge the over-expanding reach and undemocratic functioning of the WTO, and the way it has served the interests of the industrialised world and its corporations. In that context, these are times to review and rebuild - not to rush ahead and adopt inappropriate IPR laws.

The Inappropriateness of the Patent System for Life Forms and Processes

Tewolde Berhan Gebre Egziabher[1]

1. Introduction

Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) allows the patenting of all life forms and life processes, and makes it compulsory for World Trade Organization (WTO) Members to patent micro-organisms and microbiological processes. It also makes it compulsory for them to either patent plant varieties, or to protect them through "an effective *sui generis* system," or both through patent and through "an effective *sui generis* system".

TRIPs gives absolutely no reason why useful human interventions in machines and living things, which everybody knows are different, should be rewarded through the same system. A "patent" is only a document authorising the monopoly control of an object or a process. My problem is, therefore, not with the use of the term "patent", but with the criteria for granting patents, which were developed as appropriate for tools and machines, being extended blindly into the realm of living things.

This is complicated by the fact that TRIPs uses many of the important terms without defining them. The problems that arise from the differences between machines and living organisms are thus exacerbated by this lack of precision in the provisions.

2. The TRIPs Criteria for Patenting

Article 27.1 of TRIPs states: "...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application."

The use of the phrase, "inventive step", to qualify "invention" immediately strikes one as tautological. This tautology is rectified by a footnote which states that "inventive step" means "non-obvious". The use of the phrase, "capable of industrial application" also suggests that only those technologies that can be applied in factories can be patented. This restrictive interpretation is also dispelled by a footnote which states that "capable of industrial application" means "useful".

In this TRIPs provision on "Patentable Subject Matter", the term "invention" and the distinction between "product" and "process" make the patenting system inappropriate for life forms and life processes. This claim that I am making has obviously to be substantiated. I will try to do that.

3. Invention and Discovery

Article 27.1 of TRIPs states that it is inventions that are patentable. By implication, this means that discoveries are not. The word "invent" is not defined. We have thus to resort to a dictionary definition of the term.

The Oxford Shorter Dictionary gives the word "discover" and the phrase "expose to view" as one set of optional meanings. I do not think that this is the intended meaning in TRIPs. Otherwise the whole Agreement is in serious trouble. For example, a child is born with a blank mind. As it grows up, it discovers everything. Everything could then be everybody's "patentable subject matter". WTO could not be established to enforce such an absurdity!

[1] Dr. Tewolde Egziabher is the former chair of the OAU Task Force that prepared the draft *Model Legislation on Community Right and Access to Biological Resources*. He now works as the General Manger of the Ethiopian Environmental Protection Authority.

Another meaning is given as "devise as an untruth". This would make patenting a system of falsification. I am sure that this is not the sense intended by TRIPs.

A third meaning is "found" or "institute". Since institutions are not patentable, and since, even after the establishment of WTO, there has been no move in that direction, I can discount also this meaning. Otherwise, who would patent the WTO?

There are also three interrelated meanings: "devise by means of the intellect or imagination", "create, produce or construct by original thought or ingenuity" and "devise or originate a new art, instrument, process, etc." All these three nuances of "invent" can apply as a requirement for patenting. They all have "devise" or "create" as the operative word. Both "devise" and "create" imply the making of something that did not exist, and in the context of Article 27.1, "something" means technology. Therefore, they exclude the sense of "discover", even if what is discovered is a technology, e.g. an implement buried with some Egyptian Pharaoh of 7000 years ago.

4. Are we Inventing Life?

Living things are made of only some of the elements that constitute the non-living world. It is, therefore, possible that life could be "invented". Whether we believe this is possible or not is of little relevance to our present discussion. It is, however, important to note that no living thing has been obtained by human agency constructing it solely out of the non-living world. If someone invented a living organism in that manner, she/he would definitely be entitled to patent the invention, and perhaps revel in being a god (God?).

What, then, are the claims for inventing life?

Finding a hitherto "unknown"[2] trait or traits is said to be a patentable technology in some countries. Obviously, these countries accept that "discovery" is "invention".

Determining the nucleic acid sequence of a gene is also said to enable patenting. Whether the nucleic acid sequence is known to anyone or even everyone or not at all will not make the slightest difference to the traits of the organism. Such sequencing is, therefore, merely a discovery. It should not be patentable.

In any case, many of the genes are the same across species. A given gene is, therefore, the same for many species. If I determine the nucleic acid sequence of a gene from a bacterium and patent it because of this fact, what would happen if another person determined the nucleic acid sequence of the same gene from a tree, whose patent should "protect" the gene? If I were to determine the nucleic acid sequence of the same gene in two different species, could I have two patents on the same gene? Or, will the first patent prevent further patents?

Even assuming that I have sequenced a gene from a bacterium and it has not been sequenced in any other species, does that make it unique? No. This is because, to claim that, all other forms of life have to be examined. So far, scientists know all the nucleic acid sequences only for the bacterium *Escherschia coli*. And yet estimates of the number of species in the biosphere range from 10 to 60 million. Would we ever be certain that a gene is unique?

When a specific gene (a nucleic acid sequence) is introduced into an organism, the introduced gene may be expressed (i.e. it may result in a trait new to that receiving organism). But, just as the gene existed in another organism, so did the trait it determines. Obviously, anyone who introduces a gene in this manner deserves to be rewarded for the technique used in introducing that gene or genes, and/or for the skill for doing so. The invention of the technique should be patentable, but neither the introduced gene nor the

[2] even "unknown" refers only to the "modern" sector; it is likely to be known to some local or indigenous communities.

expressed trait are inventions and they should thus not be patentable. The particular skill is presumably rewarded through the salary payment system.

Box 1 - Of Genes and Traits

Genes determine traits. A stringing together of chemicals known as "nucleic acids" into strands, and a twisting together as in a rope of two counterpart strands, makes up a chromosome. The substance of chromosomes, which is thus made of nucleic acids, is called Deoxyribonucleic Acid (DNA). Chromosomes are found in the nucleus of a cell, but organelles, e.g. plasmids, which are outside of the nucleus, may also contain DNA. Points on a strand of a chromosome have specific nucleic acid sequences which, together, make up a gene. A gene in one strand has the same function as that opposite it in the counterpart strand. The nucleic acid sequence in two opposite genes (known as alleles) may be the same, in which case they reinforce each other in producing a trait. We then say that the organism is homozygous with respect to that gene. They may also be different, in which case one of the pair of sequences determines the traits, and the effect of the other is eclipsed. When this happens, the trait of the homozygous state with regards to the dominant allele and this heterozygous state are similar. The alleles may also be equally dominant and the compromise trait is different from that of the homozygous state.

Genes are responsible for the presence of specific enzymes in the cell. These enzymes influence the complex chemical reactions that are constantly taking place in the cell. Specific traits are, therefore, the outcomes of the interactions among many molecules. The individual steps of the interactions are directed by specific enzymes.

In genetic engineering, we introduce specific genes into the cell. An introduced gene may get inside an organelle or inside the nucleus. It may thus attach itself to any part of the chromosomes in the nucleus, or to DNA bodies in an organelle.

The physical relationship among genes may influence "gene expression", or a trait.

If the new gene attaches itself to the DNA in an organelle, its amount in the cell will vary. This is because the numbers of a particular organelle (e.g. plasmid) in a cell is variable as the organelle divides and multiplies unrelated to the mother-cell division.

It is perhaps for these reasons that the impacts of genes introduced through genetic engineering cannot be predicted before hand with any certainty, that it is usual to encounter many unexpected traits.

For this and other complex reasons, the number of individual organisms without the introduced gene increases with increases in the generations coming forth from a genetically engineered

But of course, to make the effort of patenting worthwhile, the technique will have to be one that can be used often enough, e.g. the gene gun, with differing genes and differing recipient organisms. If it were a once off technique, nobody would bother to patent it.

The expression of the introduced gene is not always as predicted *a priori*. Its expression in its new host organism may be different from its expression in its parent organism. Should it then be patentable? In other words, would it then be a discovery or an invention? I maintain that it would be a discovery.

A comparison with the behaviour of water would help clarify this issue. Water, like all substances, reduces in volume as it cools down. However, when it turns to ice, it suddenly expands. That is why many a wine bottle put in the freezer and forgotten shatters. Simply because icy water at freezing behaves

differently from liquid water at room temperature, can we say it is natural in one state, but invented in another? No. We can only say that, by freezing it, we discover additional properties of water. Similarly, the fact that one gene, when in the cell environment of one type of organism behaves differently from that when it is in the cell environment of another type of organism does not make its new behaviour an invention, only a discovery of an additional property. Besides, if a trait that is expressed were different from the one that had been expected *a priori*, it would only show a weakness in the prediction, not an invention. I do not believe that the patent system is aimed at rewarding weaknesses!

5. Some Problems Associated with Patenting Life

If we ignore the biological objections to treating what is now being done with molecular biology (which studies, among others the physics and chemistry of nucleic acid sequences) and genetic engineering as "inventions" and, consequently support Article 27.3 of TRIPs, we create problems for the system of patenting. We will now look at some of these problems.

5.1. Product or Process?

Article 27.1 of TRIPs states that both the product and the process of a technology shall be patented.

What is a product and what is a process in a living organism? It seems to me that the way of introducing a gene into an organism is a process. If I want to make a carburettor, I use a combination of human hands, tools and machines. This is analogous to introducing the gene into an organism which did not have it before. Then the transgenic (genetically engineered) organism and the carburettor would both be products. My aim in inventing the product called carburettor is to carry out another process: that of burning fuel efficiently. Similarly, my aim of producing the product called transgenic organism is to have the process of, say, producing a measles vaccine in wheat. Now, the process of living takes over from the transgenic individual and makes it produce many more transgenic individuals through reproduction. This extra process has no mechanical counterpart or analogue. It is not caused by my introduction of the foreign gene. It is something in all life, something I have not influenced by my genetic engineering. This process substitutes in each generation the hand, the tool and the machine needed to make each carburettor. If the introduction of a gene is an invention, each ensuing generation becomes "self inventing" and creates the next generation. Is it then logical or fair, even if we ignore the distinction between inventing and discovering, that I say that I "invent" any generation beyond that particular individual into which I originally introduced the foreign gene? If I had had invented the reproduction process also, then all succeeding generations would have been my invention. The reproduction process, so essential to genetic engineering "products", thus wipes out every "invention".

If I am to insist that I have the right to expropriate the biosphere and claim this "self invention" of my transgenic organism as being my creation, I should also be responsible for whatever happens through that process. In which case, I would be responsible for:

- the "loss of quality" that happens with each generation producing individuals without the gene I have introduced;
- the change that would occur in non-target individual organisms which cross with my "invention" through the usual process of sexual reproduction;
- any unforeseen and unforewarded behaviour of the transgenic variety; and
- any impact, thus becoming absolutely liable in case of any damage or manifestation of any trait or behaviour not specified beforehand.

It is also usual to patent the use of specific biomolecules, which are outcomes of biological processes. For example, if aspirin had been discovered recently, its use would have been patented; there are now literally thousands of patented biomolecules. The extraction of biomolecules from living things is obviously a discovery, not an invention, since the biomolecules existed prior to being extracted. The method of extraction can, however, be an invention and patentable. Since the biomolecule existed before

extraction, its properties also existed before extraction. The extraction process does not add anything to, or decrease anything from its properties unless, of course, it introduces impurities, in which case it would be vandalism rather than invention. The use of a biomolecule is simply the result of recognising one existing useful property of the biomolecule. Patenting that use is, therefore, inconsistent with "invention" as a criterion. When Article 28 of TRIPs gives a monopoly control over the "making, using, offering for sale, selling or importing" a product, therefore, the provision should apply only to molecules constructed by humans, not those extracted. The practice of patenting so far, however, includes also those molecules extracted from living things.

Even a biomolecule "constructed" becomes an invention only if it does not also exist in any organism or part of that organism, be that alive or dead. Otherwise, it becomes merely a synthesis of a biomolecule that is identical with what already exists. Of course the technique for the synthesis could be invented and patentable.

5.2. In Quest of Justice

The use of biomolecules is often the same as that into which the organism or its part has long been put by some local or indigenous communities. Would it then be fair to patent that biomolecule while those who knew its use beforehand give it away free and get no benefit out of it?

Assuming that the use is entirely new, is it fair that those who discover scientific truths, e.g. quarks and charms, cannot patent them, but someone who finds a new use for a naturally occurring enzyme can?

If I patent a gene in an organism, is it fair that that one gene is used to prevent everybody also from getting hold of the thousands of other genes in that organism? In this age of extinction, it could be the sole source of those genes. In any case, even if extinction were not an issue, keeping others out should be possible only when ownership is absolute and complete. I should have the right to keep others out of my own house, but not out of the city I live in!

6. Conclusions

It seems to me that society knows the distinction between discovery and invention. It is greed that makes individuals distort these meanings so that, in the name of invention, they can monopolise discoveries.

But discoveries should also be rewarded. A system for such rewards should be developed. However, distorting the meaning of patenting in order to make it applicable to life only serves to attract the rejection of the whole system. Who ever worried about the legitimacy of patenting before the 1990's, before it became known that the USA was allowing the patenting of living things? But now, opposition is growing all the time, opposition not only to the legitimacy, but also to the legality, of patenting.

The OAU Model Law and Africa's Common Position on the TRIPs Review Process[1]

Prof. J. A. Ekpere[2]

PREAMBLE

The Organization of African Unity (OAU) initiative on the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) in general and Article 27.3(b) in particular has provided the template on which Member States have reacted to the World Trade Organization (WTO) on its review and implementation. The decision of the Council of Ministers and Head of State and Government in Ouagadougou (1998), Africa's Ministers of Trade (Commerce), Algiers (1999), Cairo (2000), and Ministers of the African Economic Community (AEC) (1999 and 2000), targeted the controversy implicit in Article 27.3(b) and the patenting of life forms. The Communication by the Government of Kenya on behalf of Africa to the World Trade Organization in 1999, the submission by Southern Africa Development Commission (SADC) and more recent negotiations by the Africa Trade Representatives in Geneva are all a reflection of the OAU position on TRIPs and the Review of Article 27.3(b) of the Agreement.

It is particularly gratifying to observe that the Assembly of Heads of State and Government at its 37th Ordinary Session (Summit) in Lusaka, Zambia, July, 9-11, 2001, reiterated its commitment and support for the on-going two processes initiated by the General Secretariat of elaborating:

i) an African Model Law for the protection of the rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources.

ii) an African Biosafety Model Law and an Africa-wide Biosafely System.

It calls for a speedy finalization of these two processes and Member States to use these models as a basis for finalizing their national legislation by adapting their provisions to the national context and within the framework of the WTO negotiations (AHG/Dra/t/Dec.5 (XXXVII) Rev. P.2).

This pronouncement raises the TRIPs agenda to a new level of importance. It is for this reason, that any effort to develop a better understanding of Article 27.3(b), the sui generis option, appropriate definitions and key concepts of the Convention on Biological Diversity (CBD) and International Understanding (IU) can only help to expand the space and strengthen the capability of Africa's Trade Representatives in Geneva in the negotiation and review process.

1. INTRODUCTION AND BACKGROUND

The Organization of African Unity OAU) has been an active participant in the Uruguay round as well as the Earth Summit in Rio (1992) which enunciated the CBD. Issues on the implementation of the convention and its protocols, the WTO and its Agreements are listed for discussion in the yearly agenda of the Sessions of Council of Ministers and Summit of Heads of State and government of the OAU.

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[1] Discussion paper presented at the *ICTSD Multistakeholder Policy Dialogue on Trade, Intellectual Property Rights and Biodiversity in Eastern and Southern Africa* in Nairobi, Kenya, 30-31 July 2001.

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In more recent times, the OAU, through its Scientific, Technical and Research Commission identified the problem of ownership, conservation and utilization of Africa's bio-resources as an important area of research and development. The concern for the conservation of and ownership rights over biological resources was first expressed in Kampala, Uganda, during the 5th OAU/STRC Meeting of Experts and Symposium of Traditional African Medicine and Medicinal Plants (1996). In April 1997, the Commission held a joint "Workshop on Medicinal Plants Policy: Issues on Ownership, Access and Utilization"[3] in Nairobi, Kenya. The purpose of the workshop was to chart a course of action and follow-up to the issues raised in Kampala, Uganda. The workshop recommended among others that:

- The OAU/STRC should initiate and coordinate the process of drafting a model law on the protection of indigenous knowledge on medicinal plants (p.35).
- The OAU/STRC should establish a working group of experts to deliberate, coordinate and harmonize existing national policies on medicinal plants and put in place a common policy on sustainable use of medicinal plants (p.30).
- Assist Member State to ensure that policies on ownership, access, utilization and conservation of medicinal plants are drawn up in consultation with other Member States at sub-regional and regional levels, since political boundaries are not necessarily ecological boundaries (p.46).
- Encourage Member States to recognize the urgent need to study the implications of the Trade related Aspects of Intellectual Property rights (IPRs) on pharmaceutical production, Africa's bio-resource heritage and the expected harmonization of Intellectual Property Rights by the year 2000 and 2005 respectively.

The Commission moved very fast on these recommendations and convened a task force (Working Group of experts) in Addis Ababa in April 1998. The task force produced:

- A draft Model Legislation on Community Right and Access to Biological Resources.
- A draft declaration on Community rights and Access to Biological Resources and
- A draft Convention for the Protection, Conservation and Sustainable use of African Biological Diversity, Genetic Resources ad Related knowledge.

The Draft Model Legislation was sponsored by the Government of Ethiopia at the 34th Summit of Heads of State and Government in Ouagadougou, Burkina Faso (June/July 1998) at which it was decided that Governments of Member States should:

- Give due attention as a matter of priority to the need for regulating access to biological resources, community knowledge and technologies and their implication for IPRs as entrenched in the international trade regime of the TRIPs Agreement;
- Adopt the OAU Draft Model Legislation on Access to Biological Resources and call on Member State to initiate the process at national level, involving all stakeholders in accordance with the national interest and enacted into law.
- Initiate a process of negotiation among African Countries to formulate and adopt an African Convention on Biological Diversity (Revised Algiers Convention of 1968) with emphasis on conditions for access to biological resources and protection of community rights.

[3] Mshana, R. N.; Ndoye M; and Ekpere, J. A.; (eds.) Proceedings of the First OAU/STRC/DEPA-KIPO Workshop on Medicinal Plants and Herbal Medicine in Africa: Policy Issues on Ownership, Access and Utilization" Nairobi, Kenya, April 14-17, 1997.

- Develop an African Common Position to Safeguard the sovereign rights of Member State, the vital interests of their local communities and forge alliance with other countries of the South on the revision of the TRIPs Agreement.

The decision and recommendation of the Council of Ministers of the OAU put the TRIPs Agreement in general and its Article 27.3(b) in particular on the national agenda of most Member States. It also legitimized the mandate of the OAU/STRC to proceed with the development of a full-blown legislative instrument on the protection of community rights and new plant varieties.

2. TRIPS, BIODIVERSITY AND TRADITIONAL KNOWLEDGE: ANTECEDENT TO THE OAU MODEL LAW.

The WTO TRIPs Agreement and the imperatives of contemporary jurisprudence have thrown into focus the distinction between the creativity of local communities and indigenous people and the creativity of corporate interest. Only the latter has been accorded value, global recognition and reward through the patent system. This inequity does not only derogate and threaten the validity of the biological resources and knowledge system of local communities and indigenous people, but the value of their technologies, innovation and practices. It is sometimes agued that local biological diversity and knowledge is a universal heritage and resource. For Africa, it represents both a national heritage and a national resource. It should therefore be protected, developed, promoted and where appropriate conserved. This is because biodiversity anywhere is a resource held in trust by the present generation for the service of the present and future generations. The distinction referred to above is therefore inappropriate, irrelevant and spurious.

The biological diversity and knowledge system of local communities, their technologies and practices have sustained them long before the advent of modern science. The world community of today has built on the knowledge and technology base of local communities to achieve current levels of development. The recourse to global trade concepts, setting minimum standards for international commerce on biological resources without regard to valued recognition of the rights of local communities and indigenous people could be interpreted as killing the goose that lays the golden egg.

Perhaps one of the most significant problems in these discussions is the contradiction between the CBD, which recognized the sovereign right of State (local communities) over their biological diversity, and TRIPs, which confers monopoly rights through IPRs (Article 27.3(b)). The definitional constructs of this Article precludes recognition of local technologies, innovations and practices as well as their collective ownership by local communities for common social good. The obvious implication is that the creativity of local communities as represented by indigenous peoples cannot be protected and rewarded under the TRIPs Agreement.

It is this anomaly inherent in the new concept of the world, in trade terms and the IPR system that the OAU Model Legislation attempts to address.

3. SO WHAT IS THE ISSUE AT STAKE

The issue at stake is the appropriation of the knowledge, innovation, technologies and practices of local communities associated with their biodiversity as well as equitable sharing of benefits associated with the sustainable use of these resources.

What was needed as a matter of urgency was an appropriate system to legally secure the rights of local communities and people – especially farmers and traditional medicine practioners – rights over their germplasm. This will enable ownership of the physical resource and the traditional knowledge associated with it.

4. THE OAU MODEL LAW

The OAU Model Law was developed as a direct response to the decision taken and the directive given by the OAU Council of Ministers in 1988. The principal objective was to "ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources as well as associated indigenous knowledge in order to improve their diversity as a means of sustaining the life support systems". Let me indicate here that the model law was developed with specific reference to the CBD and Article 27.3(b) of the TRIPs Agreement. It does not address the various other contentious issues of the TRIPs Agreement. Consequently, it was formulated to:

- Recognize, protect and support the inalienable rights of local communities, including farming communities, over their biological resources, crop varieties, medicinal plants, knowledge, technologies and practices.
- Recognize and protect the rights of breeders over varieties developed by them.
- Provide a mutually acceptable system of access to biological resources community knowledge, technologies and practices subject to the prior informed consent (PIC) of the State and the concerned local communities.
- Provide and promote appropriate mechanisms for the enforcement of the rights of local communities, including farming communities, and breeders and the conditions essential for access to biological resources, community knowledge, technologies and practices.
- Ensure and promote the supply of good quality seed and planting material to farmers and
- Ensure that plant genetic resources are utilized in a sustainable and equitable manner so as to guarantee national food security.

In terms of scope, the OAU Law applies to:

- Biological resources both in-situ and ex-situ conditions.
- The derivatives of the biological resource
- Community knowledge, innovations, technologies and practices
- Local and indigenous farming communities and farmers and
- Plant breeders.

It was developed with a view to:

- Prevent the disruption of African rural life and food production which could result from loss of:
  - Seed and other planting materials which are the foundation of all agricultural production.
  - Traditional medicinal plants, the basis of health care delivery service for majority of African people.
  - Natural fibre and dyes; the basis of African art and crafts etc
- Promote and ensure the sharing of benefits that biodiversity, knowledge, technologies, innovations and practices of African communities provide to Multi-National corporations, mostly from the north.
- Safeguard the vital interests of Africa from the consequences of globalization and trade liberalization.
- Assist OAU Member States who are members of the World Trade Organization (WTO) fulfill their obligations – especially that of Article 27.3(b) of the TRIPs Agreement.

Most African countries have opted for a "*Sui generis*" system instead of patent. They argue that other forms of protection (patent or UPOV) is very similar to that of industrial set up for countries where the agricultural and/or local community represents less than 1.5 percent of the population. In these (industrialized) countries, the selection and development of new plant verities is undertaken by private firms and privately financed. The system of protection is based entirely on the logic of an industrial economy in which the investment and interest of large seed companies with their professional breeders must be rewarded and protected through patents. In developing countries (Africa) where the small farmers hold a capital role, the system is completely alien. It is the small farmer who selects, crosses and breeds new varieties of plants and exchanges them with other farmers. Generally, it is this pre-selected plant material that the plant breeders use in their crop (plant) improvement programme. All these activities are undertaken by public institutions, supported with taxpayers money. They belong in the public domain and therefore should not be subject to monopoly ownership through patent.

5. CORE PECULIARITIES OF THE OAU MODEL LAW

The core peculiarities of the OAU Model Law can be found in the following basic principals as enunciated in the text.

Food Security: Africa's access to food at all times for an active and healthy life is currently provided through small farmers who practice customary rainfed farming of multiple cropping with farm saved seeds and on – farm crop selection. For most communities, locally produced biological resources provided over 95% of their requirement for survival. The argument and need for change may be logical and necessary, but such change must be appropriately planned and carefully implemented consistent with local capacity to absorb it. Biological diversity is essential for sustainable food production and food security. Therefore, the loss of diversity could make the local environment more ecologically unstable, adversely affect sustainable food production, local community control and access to genetic resources.

The Model Law aims at promoting the conservation of local biodiversity – related technologies, innovations and practices, food security as well as community rights over the biological resources and knowledge. It recognizes farmers rights, as counter-balance to breeders rights and thus ensures farmers tradition to save and exchange seeds and where necessary produce farmers tradition to save and exchange seeds and where necessary produce farmer certified seed. The model legislation acknowledges seed security as the foundation for food security in order to improve the region's long term food and livelihood security.

Sovereign and Inalienable Rights: Both the Rio Declaration and CBD recognize the sovereign rights of State, responsibility to sustainably use their biological resources as well access and equitable sharing of benefits derivable from them. National legislation needs to define and guarantee community rights and responsibility over their biological heritage and related traditions. This guarantee is in consonance with the relevant Article of the CBD and the revised section of FAO-IU. It also protects local communities from the vagueness of TRIPs.

The OAU Model Law is based on the principle that the knowledge, technologies and biological resources of local communities are as result of the tried and tested practices of several past generations. They are held in trust by present generations for future generations and no one has the right to create exclusive monopoly rights over them. Community rights are inalienable. The State has a responsibility to protect such rights.

Community Rights: Human existence and development has throughout history been defined in the context of the community. The individual – based system is alien to African culture and lifestyle. Local communities are the custodians of their biological resources, innovations, practices, knowledge

and technologies which are governed completely or partially by their own customary laws, written or orally transmitted.

The United Nation (UN) has recognized community rights and recommended that States do so. It is in this respect that some countries are incorporating collective rights into their national legislation.

The OAU Model Law includes a special section on community rights where the rights of local communities are recognized. These rights are particularly important to protect Africa's abundant multi-ethnic character, rich culture and biological heritage.

The Importance of Community Knowledge and Technology: The CBD recognizes biodiversity as the basis of the livelihood of millions of people around the world. Damage and erosion of biodiversity threaten the very life support system of all human lives and the phenomenon, which provides the ingredients for our food, medicine, shelter and comfort.

The TRIPs Agreement does not recognize the knowledge, technologies, innovations and practices of local communities as subjects for protection under IPRs. However, CBD specifies that innovations and practices of local communities are essential for the conservation of biodiversity and should be so recognized and protected.

The Model Law provides OAU Member States with an opportunity to protect their biodiversity and the associated knowledge and technologies.

Participation in Decision-Making: The International Labour Organization (ILO) Convention 169 adopted June 27, 1989 recognizes the right of indigenous peoples to decide their own development priorities. Interpreted in the context of the local communities of Africa, the model law ensures the effective participation of affected communities in the regulation of access and sharing of benefits accruing from the utilization of their biological resources; knowledge, technologies and practices.

Regulation of Access to Biological Resources: The current trend towards privatization, commercialization, bioprospecting and biotrade promoted through TRIPs could erode the local livelihood systems based on biological resources. In the absence of appropriate regulation local communities will forever be on the losing end. The Model Law provides for a system to regulate access subject to prior informed consent of the state and the concerned local community. They include the requirements to be fulfilled, when applying for access, the information to be provided by the applicant to the National Competent Authority, the procedure for granting access, the types of permits etc.. These conditions are consistent with those prescribed by CBD and the Biosafety Protocol.

Prior Informed Consent: The CBD and the Protocol on Biosafety both require prior informed consent as a condition for granting access. Consequently, the Model Law requires the prior informed consent of both the State and the Local Community before granting access to biological resources. It specifies provision for consultation with the concerned communities on applications being made for access. The responsibility to ensure appropriate consultation rests with the National Competent Authority.

Fair and Equitable Sharing of Benefits: The Model Law recognizes benefit sharing as a right of local communities consistent with the basic tenets of CBD. The Model Law stipulates that a specific percentage of any financial or non-financial benefit be shared with the local community.

One of the proposed mechanism for benefit sharing is the establishment of a community gene fund. The fund shall be used to finance development projects in the local community.

The Legislation is unique in terms of its enunciation and amplification of the African Common Position of "No Patents on Life Form". It acknowledges the pivotal role of women in the conservation of biological diversity and gender equality in decision making.

6. AFRICA'S COMMON POSITION ON THE REVIEW OF ARTICLE 27.3(b)

Africa's predominant position and response to Article 27.3(b) of the TRIPs Agreement and patent on life is predicated on its commitment to the spirit, principles and relevant provisions of the Convention on Biological Diversity (CBD). There provisions include:

- Sovereign right of State to the ownership of its biological and natural resources.
- Authority to regulate access to biological and genetic resources.
- Authority to maintain knowledge, innovations, and practices of indigenous people.
- Equitable sharing of benefits arising from the use of such knowledge, technologies, innovations and practices.

Africa is a multi-ethnic continent with a deep sense of moral, religious and cultural values. Its population consists of a large array of indigenous people whose environment comprising trees (including sacred forests), crops, animals, birds, fish, soil, mico-organisims etc. are an integral component of their total life style in fellowship with others. Its long history and political existence has survived centuries of careful growth and development consistent with available benefits of Western Civilisation. These values and the future of African Society are currently being threatened by privatization, multi-national corporations' drive for profit, unethical Science and technology research outcomes, and corporate monopoly through IPRs and patent on life forms. Africa's reaction suggests that these incursions are totally at variance with its culture and tradition and therefore unacceptable.

Africa recognizes its obligation to a World driven by science and technology, international agreements and the concept of free trade based on the free flow of knowledge and information. It, however, has difficulty accepting concepts and principles which are detrimental to its development and survival as a people and continent. The development of new technologies and the dissemination of innovation is indeed a desirable on-going process that must be supported by Governments and Nations with appropriate accompanying rewards, rights and incentives. But the types of rights Africa needs are not those monopolized through patent and privatization, but rewards which support local communities, farmers, indigenous peoples and their efforts over the past millennia to conserve and enhance biodiversity for the benefit of all human kind. It is against this backdrop that Africa has rejected the option for patent on life. The ownership of knowledge, individual or corporate should be in the interest of the overall public good. This is hardly guaranteed by the patent system as entrenched in the TRIPs Agreement.

Members of the Africna Regional Industrial Property Organization (ARIPO) meeting in Kampala, Uganda (March 4-9, 1999) criticized the TRIPs Agreement, calling attention to fundamental imbalances inimical to the development of Africa. They cited several adverse effects, which include constraint on domestic technology development, barriers to technology transfer and monopolistic high prices (including cost of medical products, seeds and software). As far as Africa is concerned, they concluded that the most serious problem with TRIPs is its failure to recognize the rights of local communities, their knowledge, innovation and practices. This may lead to unjustified patenting of their knowledge and biological resources by foreign corporations. In this context, they suggested the exclusion of all life forms from patentability. They recommended that African Countries should develop an appropriate "*sui generis*" systems of protection of plant varieties, indigenous knowledge, technologies and community rights consistent with their national priorities and ensure that the TRIPs Agreement conforms with the aims of the CBD. Similar discussion at other fora have led to the

African common position on the TRIPs Agreement in general, Article 27.3(b) and NO patent on life forms in particular.

A recent submission by the African Group in Geneva to the TRIPs Council has raised the same outstanding issues on Article 27.3(b) over which they had earlier presented a common position. These issues include:

- technical issues relating to patent protection under Article 27.3(b).
- technical issues relating to *"sui generis"* protection of plant varieties.
- Ethical issues relating to the patentability of life forms
- The relationship of the conservation and sustainable use of genetic materials (resources);
- The relationship between the concept of traditional knowledge and farmers rights and
- Access to essential medicines and HIV-Aids drugs.

With respect to technical issues related to patent protection under Article 27.3(b), "the African Group has highlighted the incongruencies raised by the artificial distinction made between plants and animals (which may be excluded from patentability) and micro-organisms (which may not excluded), as well as between essentially biological processes for making plants and animals (which may be excluded) and micro-biological processes (which may not be excluded)." They contend that these distinctions are spurious and challenge the basic tenets of intellectual property law.

On the issue relating to the patentability of life forms, Africa's concern is predicated on ethical, moral, religious and cultural values. The commodification and market transaction of life structures violate the fundamental moral principles of some cultures of a large number of Member States and societies.

7. FUTURE AGENDA

The African common position is rational, valid and has profound merit. However, it needs widespread common understanding, commitment and support to sustain under pressure from the developed economies. A small group of interested scientists, government functionaries and NGOs within a network of active monitors have good ideas which need political support and concerted action at National Capitals and in the Trade Missions in Geneva if Africa has to succeed with future negotiations of the African common position. The following follow-up agenda is proposed.

I. Elaboration of a strategy to document and disseminate the potential implications of TRIPs and patent on life forms to stakeholders at national, sub-regional and regional levels. There is a need to undertake a rapid assessment of the work of various ministries and national institutions on TRIPs and other related international agreements with a view to harmonization.

   There is a need for technical support for the conceptualization and drafting of submission documents, preparation of briefing materials and organizing of national, sub-regional and regional pre-negotiation meetings to discuss and coordinate strategies, presentation and procedures for on-coming negotiations and review sessions.

II. There is need to undertake empirical studies and generate evidence on the impact of TRIPs and/or IPRs on:

   - Biodiversity and agro-biodiversity
   - Farmers access to germplasm and plant varieties as well as technology transfer.
   - Local biological-resource based production systems.

- Indigenous (traditional) knowledge, innovation and practices as well as local community rights systems.
- Economic loses due to patenting of life forms (royalty payment, biopiracy and total absence of benefit sharing etc) should be investigated to substantiate the harmful impact of IPRs on the agricultural systems, economies and environment of African countries. Some of these studies already exist and could be synthesized by an expert group of consultants. These studies would add legitimacy to the African common position and strengthen the bargaining power of its negotiators.

III. There is need for technical assistance and capacity building at national, sub-regional, and regional levels as well as in the Trade Missions in Geneva on key issues of TRIPs and up-coming negotiations. Implementing strategies to promote and popularize the OAU *Model Legislation on the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources* will greatly enhance the capacity of African Governments and civil society to better understand and contribute to the debate on TRIPs and NO patent on life. It will also help African Countries that have not done so, to commence action on developing strong national positions, teams of international negotiators and enact appropriate enabling legislation at national level.

Mr. Chairman, Ladies and Gentlemen, it is my hope that my presentation to you today and humble suggestions will assist in crafting a strategic plan of action to support the African common position on the TRIPs Agreement and NO patent on life.

8. CONCLUSION

Africa's position on the TRIPs Agreement and NO patenting of life forms is unequivocally clear. TRIPs and its accompanying criteria for the granting of patents do not provide an appropriate system for the protection of Africa's biological resources. Africa insists that there should be no patent on plants, animals and other life forms. The envisaged review process of Article 27.3(b) should be a substantive review with due consideration for broader issues related to biodiversity management and conservation. In essence, Africa is of the view that Article 27.3(b) should be amended to read: Countries must exclude plants, animals, micro-organisms and parts thereof and any processes making use thereof or related thereto from patentability".

Communication from Kenya on behalf of the African Group: Preparations For the 1999 Ministerial Conference

29 July 1999

The following communication, dated 29 July 1999, has been received from the Permanent Mission of Kenya (WT/GC/W/302).

I. INTRODUCTION

1.The TRIPS Council is carrying out work on the review of various provisions contained in the TRIPS Agreement. Some parts of this work create difficulties for members of the African Group. This paper sets out some of the key issues of interest to the Group, highlights difficulties facing the Group on these issues and makes proposals on how these difficulties should be redressed.

II. OVERLAPS AND SEQUENCING

2.The WTO work programme on intellectual property issues is made up of three components, namely; implementation, built-in agenda, and preparations for future negotiations. Whilst in conceptual terms these components are simple to categorize, at operational level they are dealt with in a complex tapestry of overlaps, characterized by lack of proper sequencing. This poses serious difficulties to the African Group.

- First, whilst developed countries underwent legislative reviews unencumbered by other work, developing countries will undergo this exercise concurrently with work on the built-in reviews of TRIPS provisions;

- Second, the current built-in reviews of TRIPS provisions are likely to continue into 2000 at which time the overall review of the TRIPS Agreement will be conducted pursuant to Article 71.1 of the Agreement.

- Third, the overall Article 71.1 review of the Agreement is scheduled to coincide with the next set of multilateral trade negotiations in which TRIPS issues are likely to form part of the agenda.

3.This concurrency of work poses three sets of difficulties for the Group: first, institutional capacity problems; second, lack of national experiences on the impacts of implementation of the Agreement; and third, undermining of the ability of developing countries to identify their interests.

Proposal

4.The African Group considers it appropriate that the work of the TRIPS Council should be staggered and sequenced in a manner that enables developing countries with meagre resources to participate effectively in its work. This can be achieved by inter alia delaying some of the reviews or speeding up those on which conclusion is nearing such as the one on non-violation complaints.

III. ARTICLE 64.3 - NON-VIOLATION COMPLAINTS

5.Article 64.3 provides for the non-violation remedy in the TRIPS Agreement. However, this Article also contains a built-in moratorium on application, due to expire on 1 January 2000 unless otherwise decided by Members - by virtue of a Ministerial Decision - after reviewing the scope and modalities of non-violation disputes in the context of TRIPS.

6.A number of factors need to be considered before this decision can be taken. First, there is currently no sufficient experience with the application of the DSU provisions to the TRIPS Agreement. Furthermore, developing countries have as yet not implemented their obligations under the Agreement and as such have not as yet had the benefit of direct experience on the scope and modalities of the non-violation remedy as foreseen in the provisions. More important is the fact that the non-violation provisions contained in the GATT 1994 were crafted for trade in goods. The TRIPS Agreement seeks to establish minimum standards of protection and not liberalization.

Proposal

7.That the moratorium on the application of the non-violation remedy under the TRIPS Agreement be maintained indefinitely until Members agree by consensus that sufficient experience has been gained with the application of the Agreement and that the remedy if adopted will not increase Members' level of obligations.

IV. ARTICLE 66.2 - INCENTIVES FOR TRANSFER OF TECHNOLOGY TO LDCs

8.This Article calls on developed countries to provide incentives to their enterprises and institutions to encourage them to transfer technology to LDCs.

9.The provisions of this Article are couched in "best endeavour" terms. Best endeavour provisions are fundamentally flawed in that they are neither enforceable nor do they constitute a real benefit for developing and least-developed countries. Consequently many developed countries have as yet not demonstrated how they are fulfilling the provisions of this Article.

Proposal

10.Need for a regular full review of the implementation of the provisions of Article 66.2 by developed countries.

V. ARTICLE 27.3(b) - PROTECTION OF PLANT VARIETIES

11.The review of Article 27.3(b) is complex both in the way it is being dealt with and in its very substance. First, there are issues of procedure and interpretation of the scope and mandate of the TRIPS Council on the review process. Second, there are issues relating to the review of the substantive provisions of the Article itself. For the African Group, these issues need to be resolved speedily for there to be progress in the light of the up-coming Seattle Ministerial Conference.

Part 1 - On procedures and interpretation

Nature and scope of review

12.The question of interpretation of the nature and scope of the review of Article 27.3(b) still remains to be resolved. The debate is about whether Article 27.3(b) provides for the review of the implementation of the provisions therein, or for the review of the substantive provisions of the Article itself. It is our view that the review mandated and meant is a review of the substance of the subparagraph itself, and is not meant to be confined to the implementation of the subparagraph. This is clear from the wording of the last sentence of Article 27.3(b): "The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."
Proposal

13.Members will need to clarify the mandate of the TRIPS Council on this issue. It is the firm understanding of the African Group that the mandate of the Council is to review the substantive provisions of Article 27.3(b). Since no provision is made for review of implementation of this specific

Article (except implicitly in the context of the overall review scheduled for 2000 in Article 71.1) members of the African Group consider it appropriate that any information (to be) submitted under the current review will not be used for the purpose of reviewing the implementation of the provisions of this Article.

Timing for implementation of Article 27.3(b) provisions

14.The review of the provisions of Article 27.3(b) scheduled for 1999 has been ongoing since the beginning of the year. On the other hand, the deadline for implementation of the obligations by developing countries of the TRIPS Agreement is January 2000.

15.In effect, the review is scheduled to precede the implementation of obligations undertaken by developing countries. Developing countries have as yet not had sufficient experience with the operation of the Agreement and hence no prior opportunity to conduct impact assessment studies of implications resulting therefrom.

16.Furthermore, the review, if undertaken in 1999 will pre-empt the outcome of deliberations in other related fora such as CBD, UPOV, FAO, International Undertaking on Plant Genetic Resources, and the development of an OAU model law on Community Rights and Control of Access to Biological Resources. These are important fora dealing with Article 27.3(b) issues (from a developmental perspective) which the TRIPS Council cannot afford to ignore.

17.The process of reviewing the substantive provisions of Article 27.3(b) could well extend to beyond 2000, and it could result in changes to the provisions. It would thus be premature for developing countries to implement the subparagraph by January 2000.

Proposals

18.Members of the African Group consider it appropriate that the implementation deadline should be extended to take place after the completion of the substantive review of Article 27.3(b). The period given for implementation of the provisions should be the same as that allowed in Article 65(1) and (2), namely, five years from the date the review is completed. This period is provided to allow developing countries to set up the necessary infrastructure entailed by the implementation.

Part 2 - On substantive provisions

Artificial distinctions between biological and microbiological organisms and processes

19.There is lack of clarity on the criteria/rationale used to decide what can and cannot be excluded from patentability in Article 27.3(b). This relates to the artificial distinction made between plants and animals (which may be excluded) and micro-organisms (which may not be excluded); and also between "essentially biological" processes for making plants and animals (which may be excluded) and microbiological processes.

20.By stipulating compulsory patenting of micro-organisms (which are natural living things) and microbiological processes (which are natural processes), the provisions of Article 27.3 contravene the basic tenets on which patent laws are based: that substances and processes that exist in nature are a discovery and not an invention and thus are not patentable. Moreover, by giving Members the option whether or not to exclude the patentability of plants and animals, Article 27.3(b) allows for life forms to be patented.

Proposals

21.(a) The review of the substantive provisions of Article 27.3(b) should clarify the following:

- Why the option of exclusion of patentability of plants and animals does not extend to micro-organisms as there is no scientific basis for the distinction.

- Why the option of exclusion of patentability of "essentially biological processes" does not extend to "microbiological processes" as the latter are also biological processes.

(b) The review process should clarify that plants and animals as well as microorganisms and all other living organisms and their parts cannot be patented, and that natural processes that produce plants, animals and other living organisms should also not be patentable.

Clarifying the option of a sui generis system for plant varieties

22.Article 27.3(b) provides for protection of plant varieties by either a patent, a sui generis system or a combination of both. The implementation of the provision in respect of plant varieties needs to be clarified to allow developing countries to:

- Meet their international obligations, for example under the Convention on Biological Diversity, and the FAO International Undertaking for Plant Genetic Resources;

- Satisfy their need to protect the knowledge and innovations in farming, agriculture and health and medical care of indigenous people and local communities. The resolution of this issue affects the food security, social and economic welfare, and public health of people in developing countries. These concerns are central and can be taken into account under Articles 7 and 8 of the TRIPS Agreement, when Members take measures to implement TRIPS.

- To protect human, animal and plant life and to avoid serious prejudice to the environment. Exclusions from patentability for these purposes are permitted under Article 27(2) of the TRIPS Agreement.

Proposal

23.After the sentence on plant variety protection in Article 27.3(b), a footnote should be inserted stating that any sui generis law for plant variety protection can provide for:

(i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;

(ii) the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest;

(iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement.

Relation between Article 27.3(b) and CBD and the International Undertaking on Plant Genetic Resources

24.The CBD aims to protect the rights of indigenous people and local farming communities and to protect and promote biological diversity. The International Undertaking on Plant Genetic Resources (under the FAO) seeks to protect and promote farmers' rights and to conserve plant genetic resources. These are international obligations undertaken by States, including most of the Members of the WTO. It is therefore imperative that Article 27.3(b) recognize the principles, objectives and measures planned and proposed under the CBD and the International Undertaking. By mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b) is likely to lead to appropriation of the knowledge and resources of indigenous and local communities.

Proposal

25.The review process should seek to harmonize Article 27.3(b) with the provisions of the CBD and the International Undertaking, in which the conservation and sustainable use of biological diversity, the protection of the rights and knowledge of indigenous and local communities, and the promotion of farmers' rights, are fully taken into account.

VI. ARTICLE 23.4 OF THE TRIPS AGREEMENT - ESTABLISHMENT OF A MULTILATERAL SYSTEM OF NOTIFICATION AND REGISTRATION OF GEOGRAPHICAL INDICATIONS

26.With the objective of facilitating the protection of geographical indications for wines, Article 23.4 of the TRIPS Agreements requires the Council for TRIPS to undertake negotiations concerning the establishment of a multilateral system of notification and registration of geographical indications. At Singapore in 1990, Ministers declared themselves in favour of the extension of these negotiations to spirits.

Proposal

27.Considering that Ministers made no distinction between the two above-mentioned products, the African Group is of the view that the negotiations envisaged under Article 23.4 should be extended to other categories, and requests, in this regard, that the scope of the system of notification and registration be expanded to other products recognizable by their geographical origins (handicrafts, agro-food products).

Communication from Mauritius on behalf of the African Group: Review of the Provisions of Article 27.3(B)

20 September 2000

The following communication has been received from the Permanent Mission of Mauritius on 18 September 2000 (IP/C/W/206).

At the meeting of the Council for TRIPS held on 21 March 2000, the Chair set out the issues that had arisen under the review of the provisions of Article 27.3(b) of the TRIPs Agreement, as follows:

- the link between the provisions of Article 27.3(b) and development;
- technical issues relating to patent protection under Article 27.3(b);
- technical issues relating to *sui generis* protection of plant varieties;
- ethical issues relating to the patentability of life forms;
- the relationship to the conservation and sustainable use of genetic material; and
- the relationship with the concepts of traditional knowledge and farmers' rights.

He arrived at this list on the basis of proceedings in the Council for TRIPS and informal consultations. These issues are of fundamental importance to us and should be seen in line with our submission contained in document WT/GC/W/302.

1. Link between Article 27.3(b) and development

1.1 The link between Article 27.3(b) and development is important to the African Group because, apart from being mandated by the General Council decision agreed at the meeting of 7 and 8 February 2000 (WT/GC/M/53), it is fundamental to the review itself.

1.2 The topic is timely because of ever increasing concerns over the expropriationary effects of bio-patenting over genetic resources.

1.3 The review should be seen in the context of broad socio-economic development expectations among members of the African Group. The promise of benefits from globalization and joining the multilateral trading system and from the revolution in biotechnology as well as the mutuality of benefits that the TRIPS Agreement has been based on, are yet to be duly evaluated.

1.4 The review of the link between Article 27.3(b) and development must address specific issues of:

- whether and how intellectual property rights such as patents and plant breeders' rights lead to relocation of investment to natural resource endowed countries, transfer and dissemination of technology, research and development, and innovation in developing countries;
- whether the appropriate balance has been struck between the protection of intellectual property rights and the protection of key socio-economic interests such as food security, health and the conservation and sustainable use of genetic resources; and

- whether protection of intellectual property rights has or is leading to equitable sharing of benefits between producers and consumers of technology and natural resources.

2. Technical issues relating to patent protection under Article 27.3(b)

2.1 Our domestic laws are based on internationally recognized regimes of intellectual property law that distinguish discoveries (which are not patentable) from inventions (which are patentable).

2.2 The African Group has highlighted the incogruencies raised by the artificial distinction made between plants and animals (which may be excluded from patentability) and micro-organisms (which may not be excluded); and also between essentially biological processes for the production of plants and animals (which may be excluded) and non- or micro-biological processes (which may not be excluded).

2.3 These distinctions violate the basic principles of intellectual property law. These questions, raised in our submission for the Seattle Third Ministerial Meeting, are yet to elicit specific responses.

3. Technical issues relating to *sui generis* protection of plant varieties

3.1 The obligation to protect plant varieties, in requiring protection of plant breeders' rights, raises the vital and parallel question of protecting farmers' rights. The latter entail the right to save, share and replant seeds.

3.2 The obligation also raises the question of the exemption for other breeders to innovate around protected varieties, without overly restrictive or prohibitive compensatory conditions in favour of breeders of protected varieties.

3.3 These rights and exemption directly have an impact on the national goals of African countries for food security, health, rural development and equity for local communities whose traditional knowledge systems have produced staple varieties, including varieties that have medicinal and biodiversity value.

3.4 These local communities have not benefited from patents granted in developed countries, either in the form of effective benefit-sharing schemes or transfer of technology.

3.5 It is the objective of the African Group to ensure that the obligation to protect plant varieties by effective *sui generis* systems for purposes of Article 27.3(b), is consistent with the provisions of the Convention on Biological Diversity (CBD) and the FAO International Undertaking on Plant Genetic Resources.

3.6 It is on this basis that the African Group considers this subject particularly relevant in the review.

4. Ethical issues relating to the patentability of life forms

4.1 The grounds for concerns over the patentability of life forms, obtaining in societies far and wide, are ethical, religious and cultural. The co-modification and marketing of life structures violate the cultural principles of quite a number of societies.

4.2 The concerns also arise from the fact that patents over research material may restrict further research, that discoveries do no amount to inventions, that the cost of medicines keeps escalating due to the required systems of patent protection, and that research increasingly targets products for the affluent rather than for the general public health.

5. Conservation and sustainable use of genetic material

5.1 Africa, like other developing countries, is rich in biological diversity, a resource that holds great potential for its economic development. At the same time African biological diversity greatly benefits the entire world and possesses intrinsic value that merits its conservation and sustainable use.

5.2 On this basis, Africa expects its development partners to support the condition of access to genetic resources on the basis of mutually agreed terms, the requirements for prior informed consent and benefit sharing.

5.3 However, Article 27.3(b) of the TRIPS Agreement, though making provision for the protection of plant varieties through patents and *sui generis* systems, does not provide the condition of access to genetic resources on the basis of mutually agreed terms, as well as the requirements for prior informed consent and benefit sharing. Consequently, compliance with its provisions does not require compliance with these condition and requirements.

5.4 The African Group is of the view that the TRIPS Agreement should contain provisions to promote and not undermine the conservation and sustainable use of genetic material, and to prevent the associated biopiracy.

5.5 To ensure benefit sharing and authorization of access to genetic material, contractual arrangements between developing country governments and entities seeking genetic material, require an enforcement mechanism at the WTO level.

6. <u>The relationship with the concepts of traditional knowledge and farmers' rights</u>

6.1 Local and farming communities have over the years developed knowledge systems for the conservation and sustainable use of biological diversity. This includes the selection and breeding of plant varieties for agricultural and medicinal purposes. The well-established practices of saving, sharing and replanting seeds, fundamentally sustain these communities and ensure their food security.

6.2 *Sui generis* systems for protecting plant varieties have related laws that deal with traditional knowledge and farmers' rights. The knowledge and the rights, in many instances, take the form of selecting, breeding, using and sustaining plant varieties.

6.3 Domestic laws and measures on plant varieties therefore directly affect the traditional knowledge and farmers' rights, and may support or harm these, depending on whether or not the laws and measures strike a balance between the various key interests; and whether or not farmers' rights and traditional knowledge are duly recognized and provided for.

6.4 At the international and regional level, these knowledge systems and traditions have been duly recognized:

- the Convention on Biological Diversity provides (under Articles 8j and 10) for the protection and promotion of rights of communities, farmers and indigenous peoples vis-à-vis their customary use of biological resources and traditional knowledge;

- the FAO International Undertaking on Plant Genetic Resources provides for regulated access to genetic resources to ensure that both providers and users of these resources enjoy mutual benefit, and directly recognizes farmers' rights; and

- the OAU model law protects the rights of local communities, farmers and breeders, and regulates access to biological resources.

6.5 It is important, therefore, to recognize that there exists a variety of international instruments which may be used complimentarily to pursue national goals for development and the conservation and sustainable use of genetic resources, while ensuring the development of commercial agriculture.

6.6 The last recital of the preamble to the TRIPS Agreement recognizes the desire to establish a mutually supportive relationship between the WTO and the WIPO as well as other relevant international organizations.

6.7 The African Group is of the view that the flexibility allowed by Article 27.3(b) should be retained and construed consistently with the instruments referred to above.

Declaration of the African Group at the 5th Conference of the Parties of the Convention on Biological Diversity

15-26 May 2000, NAIROBI, KENYA

The African Group,

Reaffirming that the conservation of biological diversity is a common concern of humankind,

Recognizing that Africa is dependent on its biological resources,

Further recognizing that unless biological resources continue to contribute to human survival and prosperity in a tangible way, the prospects for ensuring the measures for biodiversity conservation and sustainable use in Africa are dismal,

Calls upon all Parties, Governments and international organisations to:

Give priority attention to capacity development and poverty eradication,

Enhance public awareness and education on environmental issues,

Adopt a holistic approach to sectoral development,

Examine the appropriate opportunities among MEAs to strengthen their complementarities and explore linkages to avoid duplication, especially with regard to the Convention on Biological Diversity (CBD), Convention to Combat Desertification (CCD) and the United Nations Framework Convention on Climate Change (UNFCCC),

Encourage the fostering of leadership of local communities in the continued conservation and sustainable use of biodiversity as well as their full participation in all decision making,

Further encourage the enactment of national laws consistent with the *African Model Legislation for the Protection of Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources* (OAU, 1998),

Protect community and farmers' rights from piracy through coordinated efforts in the relevant fora dealing with these issues,

Oppose the patenting of life forms,

Push for a global enabling condition for forest biodiversity, conservation and sustainable use in the relevant fora,

Promote sustainable farming community agriculture using both traditional and modern techniques to increase the use of agro-biodiversity and to harness ecological dynamics to boost and protect production,

Address as a matter of priority the issue of repatriation of Africa's genetic resources abroad, access to, and the sharing of benefits accruing from the use of Africa's genetic resources in terms of the CBD,

Cooperate to prevent the unregulated introduction of alien species as well as the eradication of alien invasive species,

Sign and ratify the Cartagena Protocol on Biosafety as a matter of urgency,

Enhance the capacity of Parties in Africa to regulate, monitor and control genetically modified organisms (GMOs),

Develop and harmonise liability and redress measures at the regional level, in relation to damage arising from the transboundary movement of living modified organisms;

Enact national laws based on the Biosafety Model Law developed by the OAU as soon as possible,

Promote taxonomic research and capacity building and use the Global Taxonomy Initiative as well as other cooperative agreements and encourage partnerships for the conservation and sustainable use of the continent's biodiversity; and

Recognise the particular circumstances, challenges and limitations faced by Small Island States and assist such Parties to implement the requirements of the Convention on Biological Diversity.

The African Group appeals to all development and funding agencies, in the spirit of Agenda 21, to provide technical and financial support to African countries and initiatives with regard to capacity building in priority areas of the CBD.

Communique of the African Group in the Meeting of the 5th Conference of the Parties of the Convention on Biological Diversity

15-26 May 2000, Nairobi, Kenya

Preamble

Bearing in mind that almost 90% of the economic life of Africa is based on biological resources;

Noting that approximately 90% of the biodiversity in Africa lies outside protected areas;

Recognising that the sustainability of use of natural resources is a precondition for the continuation of life in all its diversity of genes, species and ecosystems;

Further recognising that unless biological resources continue to contribute to human survival and prosperity in a tangible way, the prospects for taking the measures necessary for biodiversity conservation and sustainable use in Africa are bleak;

Recognising that the use of biodiversity must become sustainable in all of its consumptive, non-consumptive as well as commercial components;

Mindful of the fact that the farming communities of rural Africa are the generators and managers of its agro-biodiversity wealth, that its local communities are the managers of its biodiversity wealth, and the generators of the knowledge and technologies that have sustained, and continue to sustain, Africa;

Aware that all this wealth of biodiversity, knowledge and technologies is now being unfairly appropriated by external private agents, depriving Africa of immense benefits that could contribute to its development;

The African Group at the Fifth Meeting of the Conference of the Parties of the Convention on Biological Diversity, held in Nairobi, Kenya 15-26 May 2000, calls upon all Parties, Governments and international organisations to:

11. Give priority attention to the development in terms of trained human, institutional and infrastructural capacity to conserve and sustainably use biodiversity for its development;

12. Give priority attention to

(a) poverty eradication, since the sustainable use of biodiversity and the environment is impossible in conditions of abject poverty; and

(b) environmental education and awareness raising, especially among the policy makers and technocrats, since uninformed decision-taking is the main cause for policies, laws and management systems that are not conducive to the conservation and sustainable use of biodiversity and the environment for accelerated development;

13. Reorient sectoral policies and programmes to become components of a holistic system for the sustainability of both accelerated development and improved environment;

14. Further examine appropriate opportunities and measures within the Convention on Biological Diversity, the Convention to Combat Desertification and the United Nations Framework

Convention on Climate Change, to strengthen their complementarities and improve scientific assessments of ecological linkages between the three conventions and their combined implications for Africa's sustainable economic and social development;

Access and Equitable Sharing of Benefits, and Protection of Community Rights and Farmers' Rights

15. Foster the leadership of local communities in the effective management of biodiversity and, in general, the environment, by ensuring their participation in all decision-making on the conservation and sustainable use of biodiversity and the environment as integral components of development, starting from the household level all the way up to the national level;

16. Enact national laws, which will put into effect the *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources*, endorsed by the OAU in its Summit of 1998 in Ouagadougou, the provisions of which are designed to

    (a) recognise Community Rights and Farmers Rights over their biodiversity, knowledge and technologies; and

    (b) ensure that access to biological resources and the equitable sharing of benefits arising from the use of such resources are in accordance with the fundamental principles and objectives of the Convention on Biological Diversity;

17. Congruent with the recognition of Community Rights, build upon the richness of Africa's existing socio-economically useful biodiversity, knowledge and technologies to contribute to sustainable development and not to look for complete *de novo* importation of all components of development;

18. For enhancing the effectiveness and fairness of service from the wealth of community biodiversity, knowledge and technologies, ensure that the benefits derived from the sustainable use of this wealth accrue to the local communities who have generated and conserved that wealth, and who still continue to generate, conserve, manage and sustainably use it;

Patenting of life and the TRIPS Agreement

19. Protect the rights of the local communities and their wealth of biodiversity, knowledge and technologies from piracy by through continuing to fight to have Community and Farmers' Rights internationally recognised, *inter alia*, by:

(a) continuing with, and supporting, the good work begun by the African Group, the Like-Minded Group and the Least Developed Countries in the WTO to have TRIPS, and in particular, its Article 27.3(b), revised (see attached document), to the effect that:

    (i) the patenting of life forms, including plants, animals, microorganisms and biological processes, shall be prohibited; and

    (ii) any *sui generis* law can provide for the protection of the innovations of indigenous and local farming communities, consistent with the Convention on Biological Diversity and the FAO International Undertaking on Plant Genetic Resources;

(b) further strengthening the position of the African Group, the Like-Minded Group and the Least Developed Countries in the WTO, with regard to their proposals for harmonising the provisions

of the TRIPS Agreement with that of the Convention on Biological Diversity (see attached document); and

(c) examining carefully, and carrying out consultations, especially with local communities, on existing and proposed laws on intellectual property rights, especially those aimed at implementing TRIPS so as to maximise room for national development, as well as, the expression and implementation of Community and Farmers' Rights;

[… Provisions on Arid, Semi-arid and dry sub-humid areas; coral reefs and forest biodiversity; Agro-biodiversity; Alien Species; Biosafety and Taxonomy]

Financial and Technical Support

In light of the above, the African Group:

27. Appeals to the United Nations system, to international organisations and to bilateral donors to support, in the spirit of Agenda 21, countries, to be generous in their technical and financial support to African countries, especially with regard to capacity building; and

28. Appeals to the GEF to support African countries financially to have better coordination through the office of their GEF Councillor, and to develop and implement programmes and projects to operationalise the decisions in this communique.

TRIPS, Public Health and Access to Medicines

In the grey landscape of *déjà vu* that characterises the run-up to the WTO's Ministerial Conference next November, the issue of poor countries' access to medicines looks set to provide a bright exception. On 20 June, WTO Member governments for the first time addressed this high-profile problem head-on. In a rare show of unanimity, none of the more than 40 delegates who spoke at the meeting disputed the right of developing country governments to use compulsory licensing of patented medicines to cope with public health emergencies. While interpretations of the latitude offered by the Agreement of Trade-related Aspects of Intellectual Property Rights (TRIPs) varied considerably, all speakers agreed that the HIV/AIDS epidemic in Sub-Saharan Africa, and perhaps other countries, was a "national emergency" or "situation of extreme urgency", which could justify the granting of licenses even without seeking the patent-holder's consent.

Two papers provided the backbone for the TRIPs Council's June special discussion. One was submitted by the 30-nation Africa Group together with 26 other developing countries on *TRIPs and Public Health* (IP/C/W/296, see pp. 51) and the other by the European Union on the *Relationship between the Provisions of the TRIPs Agreement and Access to Medicines* (IP/C/W/280).

Intellectual Property Rights and Public Health

Developing countries seek a formal confirmation at the Doha Ministerial that "nothing in the TRIPs Agreement reduces the range of options available to governments to promote and protect public health, as well as other overarching public policy objectives." While such a confirmation would not necessarily require any changes in the Agreement, it would provide certainty that measures taken under existing provisions will not be subjected to dispute settlement challenges based on a narrow reading of the Agreement or other forms of coercion. Many of the points in the Africa Group's submission are drafted in language that could be used in such a ministerial affirmation.

The Group's statement that "each provision of the TRIPs Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8" led other speakers to comment on how those provisions related to the overall interpretation of the treaty. Article 7 states that intellectual property rights protection "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology [...] in a manner conducive to social and economic welfare, and to balance rights and obligations." According to Article 8.1, "Members may, in formulating or amending their laws and regulations, adopt measures to protect public health 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* (editors italics)."

The Africa Group, supported by the many developing country delegates who took the floor at the meeting, focused on the *rights* conferred by these articles: "When intellectual property rights are properly granted and exercised, they may meet their objective of contributing to the development of new medicines. However, there should be a common understanding that confirms the right of governments to ensure access to medications at affordable prices and to make use of the provisions in the Agreement whenever the scope or exercise of IPRs result in barriers to access to medicines."

The United States, the sturdiest champion of intellectual property protection, emphasised the *obligation* that any measures pursuant to Article 7 or 8, including those to protect public health, must be consistent with other TRIPs provisions. Stressing the importance of patent protection, it argued that, rather than the simple possibility of a royalty, the market exclusivity conferred by patents provided "the necessary incentive for companies to invest in research to discover, develop and commercialise new products". Furthermore, because local innovators stood to benefit from the technical details that patent applicants

must disclose, the US concluded that, instead of impeding research and development or discouraging competition, patent systems "actually promote the objective of TRIPs Article 7 by contributing to the promotion of technological innovation and to the transfer and dissemination of technology." The US also strongly emphasised the role of other factors, such as poor public health infrastructure, in impeding access to medicines.

"Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by Members to meet health objectives, "the EU wrote. The European Union also stated that intellectual property protection provided "an essential stimulus for creativity and innovation". While the TRIPs Agreement had been criticised as "limiting policy options in relation to public health concerns", the EU maintained that Articles 7 and 8, special transitional arrangements and other provisions gave Members "a sufficiently wide margin of discretion in implementing it".

Compulsory Licensing

Article 31 of the TRIPs Agreement on the use of patented matter without the authorisation of the rights holder sets out a number of conditions that Members must fulfil if they have recourse to such use, but does not itemise the purposes for which compulsory licenses may be granted. Among the most important requirements regarding compulsory licenses are the obligation to have -unsuccessfully - sought the patent holder's authorisation "on reasonable commercial terms and conditions" prior to issuing a compulsory license, and the obligation to provide the rights holder with adequate remuneration if his patent is infringed. However, in cases of "national emergency or other circumstances of extreme urgency", the requirement to seek prior consent may be waived.

"Members should take the view that the TRIPs Agreement in no way stands in the way of public health protection, and therefore that it should provide the broadest flexibility for the use of compulsory licenses," developing countries averred. According to the Africa Group's submission, compulsory licenses "are an essential tool for governments to carry out public health policies, as they may facilitate access to medicines through prevention of abuses of rights, encouragement of domestic capacities for manufacturing pharmaceuticals and in cases of national emergency or other circumstances of extreme urgency, or of public non-commercial use. Nothing in the TRIPs Agreement limits the grounds for governments to issue compulsory licenses." The EU agreed that Article 7 and 8 justified Members' invoking public health concerns as a reason for compulsory licensing, although Article 31 makes to explicit reference to it.

Despite its general aversion regarding measures that may weaken patent protection, the US recognised that Article 31(b) allowed countries to issue compulsory licences without seeking the right holder's consent in cases of "national emergency or other circumstances of extreme urgency", but stressed that Article 31 must be read in light of the other provisions of the TRIPs Agreement, including Article 27.1 (obligation to provide patents without discrimination as to the place of invention, the field technology and whether products are imported or locally produced). The US also took issue with the claim that compulsory licenses could be granted to encourage domestic capacities for manufacturing pharmaceuticals: "Contrary to what some have asserted, compulsory licenses under TRIPs 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."

Foreign Compulsory Licensing

One of the questions that is likely to be the subject of intense political debate, as well as technical scrutiny of TRIPs language, concerns the possibility to award a compulsory license to a manufacturer in a third country. While the châpeau of Article 31 allows governments to authorise "third parties" to produce goods under compulsory licensing, it does not specify where those third parties should be

located. However, Article 31(f) provides that compulsory licensing "shall be authorised predominantly for the supply of the domestic market".

Because many developing countries - particularly least developed countries and smaller economies -have limited industrial capacities and very small domestic markets to manufacture medicines locally, the African Group urged a reading of Article 31(f) confirming that "nothing in the TRIPs Agreement will prevent Members from granting compulsory licenses to supply foreign markets."

The EU noted that the Agreement did not appear to offer any legal certainty on the issue. "What can be said is that a WTO Member is free to grant a compulsory licence for the importation of goods which are under patent in its own territory, as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired." The US concurred up to this point, but added that if a drug was protected by a patent in the foreign licencee's home country and the compulsory licensee chose to manufacture it there for export to the licensing country "a problem [would be] created."

This arcane-sounding point has wide implications. For instance, at this moment it is possible even for a country that extends patent protection to medicines - South Africa, say - to grant a compulsory license to a manufacturer in another country, such as India, which does not. That manufacturer would produce a generic version of a patented brandname drug and export it to the country that granted the license. However, India and the few other developing countries allowed to postpone full patent patent protection in some fields of technology under Article 64.4, must extend such protection to all fields, medicines included, as of January 2005. Under a narrow reading of the Article 31(f) requirement that compulsory licenses should be authorised *predominantly for the supply of the domestic marke*t, it could then become "TRIPs-illegal" to manufacture generics under a foreign license for export. This would in turn affect the "client country's" access to affordable drugs.

The EU's submission offered "another possible interpretation of the Agreement that would allow a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that other country recognised the licence (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the licence were exported to the country granting the licence." The EU added that it was "far from certain whether such a 'permissive' reading of the Agreement would stand scrutiny by a panel or the Appellate Body".

The US commented that the EU's "possible interpretation" of the Agreement raised questions that should be addressed in case of "further discussion of this concept".

The Special Case of AIDS

While the TRIPs Council discussions on access to medicines are not limited to any particular disease, most speakers at the June meeting singled out the HIV/AIDS pandemic. Whatever their more general views or reservations concerning compulsory licensing, industrialised countries concurred that the proportions that the AIDS epidemic had reached in certain countries could be considered as "a national emergency or a circumstance of extreme urgency" that would dispense them from seeking the patent holder's consent prior to granting a license to a third party (Article 31(b)). The US put epidemics such as HIV/AIDS within a Member's territory on par with "war, civil strife or natural disasters for purposes of exercising the waiver authority," and the EU said that the level of HIV/AIDS infection reported in some developing countries appeared to be a "very good reason for describing it as a national emergency or as a circumstance of extreme urgency."

The Next Steps

WTO Members continued the June discussion at an informal meeting of the TRIPs Council on 25 July 2001 in preparation for the next formal TRIPs Council meeting on 19-21 September 2001 and the WTO Ministerial Conference in Doha, Qatar, in November. Following a suggestion by Chair Ambassador

Chidyausiku from Zimbabwe, the agenda of the September TRIPs Council meeting will focus in particular on principles and objectives of the TRIPs Agreement as set out in Articles 7 and 8; issues related to compulsory licensing, and parallel importation measures.

The Africa Group noted the "willingness to move forward on this issue [access to medicines]" and the "goodwill" that has been exhibited by Members. In a joint statement on its behalf and on behalf of several other developing countries, the Group addressed some of the questions raised at the June meeting related to the mandate of the TRIPs Council, compulsory licenses and parallel import. Furthermore, the statement included suggestions for the Doha preparations, calling on the Chair to begin initiating the necessary processes to identify possible elements of the Ministerial Declaration.

In particular, the Africa Group proposed a number of "vital elements" for the Doha Declaration, including the use of Articles 7 and 8 in the interpretation of all TRIPs provisions; countries' right to determine the grounds for issuing compulsory licenses; recognition of compulsory licences issued for a foreign manufacturer; a moratorium on all dispute actions aimed at preventing or limiting Members' capacity to promote access to medicines and protect public health; and the extension of transition periods for developing and least-developed Countries.

The debate on access to medicines at the WTO has barely begun. In addition to the topics above, Members will need to address in more depth the difficult issues of parallel imports and the protection of undisclosed test data against "unfair commercial use", both key concerns for the pharmaceutical lobby in industrialised countries. Developing countries, supported by Norway, are also seeking a moratorium on dispute settlement cases against their health-related IPR measures until all the open questions have been answered.

While it is already certain that ministers will address access to medicines, the format and wording are still under intense discussion. These will now follow two parallel tracks: the General Council special sessions on Doha preparations will focus on the "political dimension", i.e. Ministerial Declaration language, while the TRIPs Council will continue to explore the legal interpretation of the relevant provisions, such as the meaning or relevance of "predominantly domestic" or "anti-competitive practices"

Essential Drugs in Southern Africa Need Protection from Public Health Safeguards under TRIPs

René Loewenson[1]

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"The question that arises is what intervention can the developing countries make to ensure that a process which, by its nature, will favour the rich, addresses also what are clearly the more urgent needs of our people, millions of whom lack the most basic things that a human being needs."

South African President Thabo Mbeki, speaking on globalisation (opening address of the Non Aligned Movement Summit, Durban, August 31, 1998)

This article investigates the consequences of the WTO TRIPs Agreement on drug access for Southern African Development Community (SADC) countries[2]. It outlines the key content of the essential drug policies needed to manage the public health problems in the region, and explores the impact of the TRIPs Agreement on these policies. It highlights the options that SADC governments have to address these impacts and the current policy measures which SADC governments and other institutions are pursuing to sustain essential drug access and meet public health obligations.

The Health Challenges

The health context for these policy measures is important. Human poverty affects more than a quarter of the population in all SADC countries, and most poor people depend on public sector provision for health care. The burden of disease is equally high. Nearly a third of children are underweight, one in ten infants dies in their first year of life and one in 200 women dies due to pregnancy or childbirth complications. Southern Africa is the worst affected region in the world for HIV/AIDS, drastically reducing life expectancy to amongst the lowest in the world. The region also has a high prevalence of tuberculosis, pneumonia, malaria, other communicable diseases and malnutrition.

What Role for Essential Drugs?

The Essential Drug Concept, developed by WHO in 1977, aims to prioritise a limited list of vital and essential drugs that are effective, safe, good quality and affordable for treating the priority health problems of the majority of the population[3]. The concept has been embraced by all SADC member states. WHO regularly updates its Model Essential Drug List, but countries have to make their own Essential Drug Lists for the various levels (primary care, hospital care) based on their own morbidity patterns, treatment guidelines and available human and financial resources[4].

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[2] The Southern African Development Community (SADC) comprises Angola, Botswana, DRC, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. It is an economic, political and social community of nations, covering 193 million people. SADC's Health Sector Desk is co-ordinated by South Africa, as well the SADC Trade and Investment Sector Desk.

[3] WHO's strategy to achieve access to Essential Drugs is based on four pillars: rational selection; affordable prices; sustainable financing, and reliable health and supply systems. See http://www.who.int/medicines

[4] For example, Zimbabwe just published its 4th Essential Drugs List and Standard Treatment Guidelines. Info: ndtpac@healthnet.zw South Africa's Treatment Guidelines for PHC and Hospitals (December 1998) are available at http://www.sadap.org.za/edl

Affordability is one of the criteria for becoming an Essential Drug. Some new, life-saving but expensive (mostly patented) drugs are therefore excluded from the current Essential Drug Lists. Consequently, these drugs do not benefit from tax exemption and fast-track registration procedures, and are not seen as priorities in many countries. A new category of "life-saving, not-yet-affordable" essential drugs needs to be considered, on which efforts to reduce prices can be concentrated.

The WHO estimates that 33 percent of the world's population does not yet have regular access to essential drugs. Barriers to access include poor health care infrastructure, inadequate financing, irrational drug use and non-affordability of new drugs. Poor drug availability increases the ill health burden and reduces confidence in and use of public health services, the major source of care for the poor.

In relation to essential drugs, SADC Health Ministers have:

- made a commitment to ensure that all SADC citizens have access to them;
- initiated a review of bulk purchasing of TB drugs and harmonisation of drug registration;
- begun negotiating with the pharmaceutical industry to drastically lower their prices for essential drugs that are currently not affordable, e.g., drugs for HIV/AIDS, resistant TB, malaria and sexually transmitted diseases;
- begun investigating the use of public health safeguards under TRIPs, such as compulsory licensing, parallel importing and an "early working" for generics or "Bolar" clause.

How Will TRIPs Affect Peoples'Access to Essential Drugs?

The TRIPs Agreement has relevance to drug policies in those articles that protect public health and patentable subject matter[5]. These articles protect intellectual property rights through patent arrangements that exclude third party use, offering for sale, selling or importing of such products for a minimum of 20 years from the date the patent application is filed. Civil claims around breach of patents put the burden of proof on the defendant.

Pre-TRIPs, many developing countries did not recognise patents for pharmaceuticals, or only for processes (and not for products). This allowed copies of new drugs to be made through reverse engineering and patenting another pathway. TRIPs obliges all WTO member states to implement product patent protection for all drugs patented after 1995. This will make it impossible to produce generic copies for at least 20 years, and will thus raise prices.

Currently, most essential drugs are not patented. In South Africa, less than five percent of the 693 essential drugs are patent-protected. TRIPs is thus less of an issue for the vast share of *existing* essential drugs than it is for *new and future* essential drugs, patented after 1995. The increased costs of patented drugs will put a significant burden on public health budgets. These include new drugs for HIV/AIDS, resistant tuberculosis, malaria and reserve antibiotics. SADC will thus face a challenge in accessing these new essential drugs at affordable prices. The price differences can be substantial, as exemplified in the table below:

[5] TRIPs Articles 1, 27.1, 27.2, 27.3, 28, 28.1(b), 33, 34, 65 and 70

Table 1: Best price found for drugs from reliable manufacturers[6]

Medicine (price in USD)	South Africa (patented)	India (generic)	Brazil (generic)
Zidovudine 100mg	0.4	0.2	0.2
Lamivudine 150mg	1.1	0.5	0.8
Didanosine 100mg	0.7		0.5
Stavudine 40mg	2.5	0.6	0.3
Nevirapine 200mg	3.0	2.1	2.5
Fluconazole 200mg	4.1	0.6	0.2
Ceftriaxone 1g	10.9	1.8	

Least-developed countries must make their patent laws TRIPs compliant by 2006. They can continue to import or produce generic copies of drugs patented before 1995 if they had no patent protection, but from 2006 they will have to honour drug patents filed in their country after 1995[7]. SADC countries that do not qualify for LDC status (e.g., Botswana, South Africa, Zimbabwe, Mauritius) had to be TRIPs compliant on 1st January 2000.

South Africa voluntarily became TRIPs compliant in 1997. Its experience is instructive for other SADC countries. The 1996 South African National Drug Policy led to legislation in 1997 to enable parallel import and compulsory licenses. Although these remedies are permitted in TRIPs under certain circumstances, the Act was legally challenged by the South African Pharmaceutical Manufacturers Association on grounds of conflict with TRIPs and alleged failure to protect registration information from unfair commercial use. The US Government threatened trade sanctions over the same Act, and put South Africa on its 301 "watch list". Pressure also came from the European Union[8].

The case signalled the response that SADC countries would need to deal with, should they attempt to invoke provisions that, in principle, exist within TRIPs. At the same time these disputes strain relations between governments and their pharmaceutical industries, and make drug policies more difficult to implement. With the public health burden and resource limits of most SADC countries, a more sustainable solution is required to ensure drug access, including new drugs needed for priority public health actions.

Options for SADC Countries

Signatories to TRIPs have flexibility in how they implement the Agreement, as TRIPs only defines the *minimum* requirements. SADC countries are now studying how to formulate or adapt their legislation to widen their options to access essential drugs. This means using the provisions in TRIPS Article 30 to provide for limited exceptions to the exclusive rights conferred by a patent, provided that they are limited, justified, and do not unreasonably affect the patent owner. The exceptions enable countries to parallel import the drugs or to compulsorily license them, provided their national laws provide for this.

The strongest grounds for such exceptions are in the interests of public health, given that TRIPs enables members to give the highest possible priority to protecting the public interest[9]. SADC countries are thus challenged to define an acceptable and evidence-based definition of public health interests that can justify the exceptions they seek to impose on patent owners.

[6] MSF. 2000. HIV/AIDS medicines pricing report. Available at: http://msf.org/advocacy/accessmed/reports/2000/07/aidspricing/

[7] Patent protection for drugs before 1995 was available in South Africa and Zimbabwe.

[8] Patrick Bond. *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with US Firms and Politician*s. International Journal of Health Services Vol. 29, No.4, 1999.

[9] TRIPs Articles 7 and 8.

In SADC countries that currently do not have patent laws, or in cases where drug companies have not sought patent protection, generic copies of drugs can be imported. TRIPs allows certain public health "safeguards" for patented drugs:

When a patented product is marketed at a lower cost in another country, countries may revert to "parallel import" of that drug from the country where the same manufacturer sells it at a lower price, but only if they have enabled the principle of "exhaustion" in their national patent act[10].

Countries may insert *"compulsory licens*e" clauses in their national legislation. Such licences would allow a government, under certain circumstances, to import or produce a more affordable generic copy of the patented product, and pay a royalty to the patent holder. These exceptions are, however, time-limited, and conditional.

In order to benefit from lower priced generic drugs immediately after patent expiry, governments could insert *"Bolar*" or "early working" clauses in the patent act. These would allow generic companies to develop and test (but not stockpile for sale) generic drugs in the last years of a patented drug.

SADC countries need to fulfil all of the above conditions. This means they must have the expertise and institutions necessary for the appropriate laws, patent registration and health registration data provisions, as well as the capacity to defend themselves in legal battles in case of disputes within WTO around their actions.

Countries can also seek remedies not regulated under TRIPs, such as:

- voluntary price reductions / donations from industry
- price controls
- voluntary license from patent holders for local production / transfer of technology, emergency use.

Some of these remedies have been more widely raised in recent months. Five multinational drug companies offered on 12 May 2000 to make AIDS-related drugs cheaper by 60-85 percent for developing countries, in collaboration with UNAIDS. Boehringer Ingelheim offered its nevirapine free for five years to mother-to-child transmission prevention programmes in developing countries. Pfizer offered fluconazole free until end 2002 to South African public sector patients with cryptococcus meningitis.

In August 2000, SADC health ministers developed a joint strategy on how to deal with these offers. They insisted that donations be equitable (i.e. available to all citizens in all SADC countries), as well as affordable, accessible, appropriate, acceptable and sustainable (at least five years)[11].

It would appear that legal remedies that use the leeway offered within TRIPs on public health grounds offer a more sustainable approach within the control of SADC health authorities than current price measures. This is exemplified for example in the table below, which compares price reductions or donations with compulsory licensing.

[10] Although TRIPs seems to prevent parallel import in Article 28.1, this is subject to the exhaustion Article 6, where it is stated that countries cannot be taken to dispute settlement if their patent legislation allows exhaustion.
[11] SADC Principles to guide negotiations with pharmaceutical companies on provision of drugs for the treatment of HIV/AIDS related conditions in SADC countries. August 2000.

Table 2: Price reductions/donations and compulsory licensing

Compulsory Licenses	Reduced Price Offers
Patents Act decides	Voluntary offers
National controls	Patent holders in control
Non-exclusive	Exclusive
Allow generics	Brandname only
Clear procedure	Terms not (yet) clear
Prices probably cheaper	Prices lower, but not as low as with compulsory licenses
Conditions listed in TRIPS, royalties	Conditions unclear

These considerations are probably one reason why SADC ministers of health have rejected offers through media for price reductions in the search for more sustainable longer-term measures. It is also doubtful whether even an 85-90 percent price reduction is enough for the huge cost burden implied in making these drugs equitably accessible in HIV/AIDS therapy, given the scale of the epidemic.

The South African experience cited above signals further the investments and areas of potential dispute that will need to be addressed if SADC countries are to ensure access to new essential drugs, even within the TRIPs framework.

SADC member states will need to implement legal and institutional measures to take up the "public health safeguards" permitted under the TRIPs Agreement. SADC offers an important framework for organising and channelling such support to member states. The World Health Organisation (WHO) also has a mandate to provide such support[12].

The pharmaceutical industry will need to balance considerations of property rights and cost returns against public health interests, and the potentially wide market for new drug products if prices are put at more affordable levels. At a deeper level, the deep disconnect between current drug price structures and the needs of the majority of people within regions such as SADC should be a stimulus to the industry to review its policies and to participate in a wider public review of drug access policies. The current proposals for price subsidies and tiered pricing arrangements themselves signal that the present situation is not tenable.

Clients, particularly low income communities, and the civic organisations that represent them, face pressure to become more informed and involved in the negotiations around health service and drug access. Organisations such as Doctors without Borders (MSF) and Health Action International have taken a proactive role in raising awareness on complex WTO issues at community level, and in taking up issues of drug access and cost at global level. So too have local civic networks such as the Treatment Action Campaign in South Africa and the Community Working Group on Health in Zimbabwe. Such civil input is important for strengthening state actions in public health interest. It is also important that clients know their options in terms of generic drugs, and become more informed consumers of health products. This implies greater and more proactive public information dissemination on drugs and drug use.

The challenge of ensuring equitable and affordable access to new essential drugs under TRIPs in SADC countries once again highlights the agility that states must develop in the uneven WTO playing field, particularly if they are to make trade integrate public health and equity considerations. This is not simply an issue for SADC - it goes back to how the WTO takes account of such issues in framing trade agreements. This pressure for a more proactive integration of such issues within WTO was found for example in the 1999 World Health Assembly, when countries raised a wider global concern that trade agreements be more sensitive to public health considerations.

[12] WHO Assembly resolution WHA52/19. May 1999.

References

Equinet. 2000. *WTO Agreements: Implications for Equity and Health in Southern Africa.* Equinet Policy Series No. 4. Harare. Soon available at: http://www.equinet.org.zw

Equinet Steering Committee. 2000. *Equity in Health in Southern Africa: Turning values into practic*e. Paper presented at the Equinet conference on Equity in Health in Southern Africa, September 2000.

WHO/EDM. 1999. *Globalization, Patents and Drugs - an annotated bibliograph*y. Health Economics and Drugs EDM Series No. 9. Geneva: World Health Organization; (WHO/EDM/PAR/99.6). Available on-line, see URL below.

WHO/EDM. 1999. *Globalization and Access to Drugs - Perspectives on the WTO TRIPs Agreement.* Health Economics and Drugs EDM Series No.7. Geneva: World Health Organization; (WHO/EDM/98.9 Revised). Available from: http://www.who.int/medicines/docs/pagespublications/economicspub.htm

Velasquez/Boulet. *Essential Drugs in the New InternationalEconomic Environmen*t. Bulletin of the WHO, Vol. 77, No.3, 1999.

South Centre (2000; in press). *Integrating Public Health Concerns into Patent Legislation in Developing Countrie*s. Info:south@southcentre.org

Health Action International. 1997. *Power, Patents and Pills - an examination of GATT/WTO policies and essential drug policies. Seminar Repor*t. Amsterdam. Info: hai@hai.antenna.nl

HAI/MSF. 2000. *Improving Access to Essential Medicines in East Africa Œ patents and prices in a global economy*. Report of 15-16 June 2000 meeting in Nairobi, Kenya. Available from: http://www.accessmed.msf.org

MSF. 2000. Access to Essential Medicines Report. Available from: http://msf.org/advocacy/accessmed/reports/2000/07/aidspricing/

Africa Group Statement on TRIPS, Access to Medicines and Public Health
20 June 2001

Presented by the Delegation of Zimbabwe

1.0 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.

2.0 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. Patients in developing countries also deserve access to medicines at affordable prices, to treat AIDS and other diseases.

3.0 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.

4.0 Members should reach a common understanding that asserts and confirms the balance in the TRIPs Agreement that recognises 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 Africa 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.

5.0 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.

6.0 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 4th WTO Ministerial Conference will provide an ideal opportunity for Members to affirm this common understanding.

7.0 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 6 years since the Agreement was established provides clear evidence of this.

8.0 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.

9.0 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.

10.0 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.

11.0 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.

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

13.0 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 or 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 licence 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.

14.0 In the light of Articles 7 and 8, 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.

15.0 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 recognise 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.

16.0 Parallel importation is also an important tool to ensure adequate access to medicines. It should be recalled that the Preamble and Part 1 sets 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.

17.0 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.

18.0 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:

- 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.
- undertaking, through a Ministerial Declaration, to adopt a moratorium in the dispute settlement mechanism to allow Members to take measures to protect public health.
- 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 license and parallel import) measures.

19.0 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.

20.0 The issue 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 dispute settlement procedures.

Thank you!!!

20 June 2001

Submission by 47 Developing Countries to the WTO's TRIPS Council on "TRIPS and Public Health"

29 June 2001

Submission by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (IP/C/W/296).

- 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 the TRIPs Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health.

- The TRIPs Agreement allows for implementation of public health policy measures. Nevertheless, where the provisions of the Agreement may be considered insufficient to protect public health, Members may wish to bring further proposals for modifications in the Agreement, with a view to increase its flexibility.

- Nothing in the TRIPs Agreement should prevent Members from taking measures to protect public health.

- Each provision of the TRIPs Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. The 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 medications.

- Compulsory licenses are an essential tool for Governments to carry out public health policies, as they may facilitate access to medicines through prevention of abuses of rights, encouragement of domestic capacities for manufacturing pharmaceuticals and in cases of national emergency or other circumstances of extreme urgency, or of public non-commercial use. Nothing in the TRIPs Agreement limits the grounds for Governments to issue compulsory licenses.

- Parallel imports can also be an important tool to ensure adequate access to medications. In light of TRIPs Article 6, the TRIPs Council should confirm the unconditional right of Members to determine the way in which exhaustion of rights regimes are applied in their jurisdiction.

- While we favor discussions on differential pricing arrangements, they are only part of a broader set of initiatives to improve access to medications. Differential pricing should in no way be used to limit the flexibility of the TRIPs Agreement in any of its provisions. Given that the issue is not within the sphere of discussions on intellectual property rights, it should not be covered by the TRIPs Council, but rather by other intergovernmental international organizations, such as the World Health Organization.

- Other issues related to the provisions of the TRIPs Agreement also deserve further discussion by Members, such as the extension of transitional arrangements.

- Finally, the Ministerial Conference in Qatar in November 2001 will be the best opportunity to take such action as will ensure that the TRIPs Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health.

I. INTRODUCTION

1.At the TRIPS Council meeting held on 2 to 6 April 2001, Members agreed to hold a special session of the TRIPS Council in June 2001 to initiate discussions on the interpretation and application of the relevant provisions of the TRIPS Agreement with a view to clarifying the flexibilities to which Members are entitled to and, in particular, to establish the relationship between intellectual property rights (IPRs) and access to medicines. The decision to hold such a discussion was based on a proposal by the African Group, which was supported by virtually all Members.

2.The main purpose of this paper is to address the relationship between the TRIPS Agreement and public health. Clearly, the World Trade Organization has no mandate to establish public health policies, which should remain within the mandate of other international bodies, such as the World Health Organization. In this sense, the purpose of the discussions on TRIPS and public health at the TRIPS Council should be to ensure that the TRIPS Agreement does not undermine the implementation of public health policies by Members.

3.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 the TRIPS Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health.

4.Our commitment to the TRIPS Agreement stems from our expectation that the protection and enforcement of IPRs, in accordance with the objectives of the Agreement (Article 7), "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". With a view to fulfilling these objectives, we remain committed to implementation of the TRIPS Agreement based on its proper and flexible interpretation and in accordance with the objectives and principles contained in Articles 7 and 8 of the Agreement.

5.Some provisions of the TRIPS Agreement may elicit different interpretations. This "room to manoeuvre" served the purpose of accommodating different positions held by Members at the time of negotiations of the Agreement. We strongly believe that nothing in the TRIPS Agreement reduces the range of options available to Governments to promote and protect public health, as well as other overarching public policy objectives. The TRIPS Council must confirm this understanding as early as possible.

6.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 dispute settlement procedures.

II. CONTEXT OF THE DISCUSSIONS ON TRIPS AND PUBLIC HEALTH

7.Although the TRIPS Council has only recently begun to discuss the implications of the TRIPS Agreement to public health, other intergovernmental organizations and civil society have already been paying careful attention to such implications for some time.

8.A number of recent events have illustrated the effects of the TRIPS Agreement on public health policies. In this respect, one landmark case was the **lawsuit brought by a Pharmaceutical Industry Association and 39 of its affiliate pharmaceutical companies against the Government of South Africa** regarding provisions of its Medicines and Related Substances Control Amendment Act. The South Africa Government's resolve on the correctness of its policy, serious weakness in the technical arguments of the plaintiffs together with strong pressure from domestic and international public opinion

resulted in the withdrawal of these companies from the case. The case also signalled that public opinion is seriously concerned that intellectual property rights may be interpreted and implemented in a manner that runs counter to the promotion of public health policies by governments.

9.Further, in April 2001, the 57th Session of the United Nations Commission on Human Rights adopted **Resolution 2001/33, on "Access to Medication in the Context of Pandemics such as HIV/AIDS"**, which was approved by the overwhelming majority of its Members. The Resolution recognizes access to medicines in the context of pandemics as an essential human right. The United Nations Commission on Human Rights, in this Resolution, "calls upon States, at the national level, on a non discriminatory basis for all, to: (i) refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them; (ii) adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties; (iii) adopt all appropriate positive measures to the maximum of the resources allocated for this purpose so as to promote effective access to such preventive, curative or palliative pharmaceuticals or medical technologies". Among other actions, the Human Rights Commission "also calls upon States, at the international level, to take steps individually and/or through international co-operation, in accordance with applicable international law, including international agreements acceded to, such as: (i) to facilitate access in other countries to essential preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them wherever possible as well as to extend the necessary cooperation wherever possible, especially in times of emergency; and (ii) to ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, efficient and affordable preventive, curative or palliative pharmaceuticals and medical technologies".

10.In 21 May 2001, the 54th World Health Assembly also approved two Resolutions that are relevant for the discussions at the TRIPS Council: the **Resolution "Scaling Up the Response to HIV/AIDS" and the Resolution "WHO Medicines Strategy"**. In the Resolution "Scaling Up the Response to HIV/AIDS" (WHA54.10), the World Health Assembly recalls "efforts to make drugs available at lower prices for those in need" and urges Members "in order to increase access to medicines, to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries consistent with national law".

11.The **Resolution "WHO Medicines Strategy"** (WHA54.11) also contains several important elements for discussion at the TRIPS Council. The World Health Assembly notes that "the impact of international trade agreements on access to, or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated". Further, the Resolution urges Members to "cooperate with respect to resolution 2001/33 of the United Nations Commission on Human Rights" and "in order to increase access to medicines, and in accordance with the health needs of people, especially those who can least afford the costs, and recognizing the efforts of Members to expand access to drugs and promote domestic industry, cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes in order further to promote innovation and the development of domestic industries, consistent with applicable international law". The WHA also requests the Director-General "to continue and to enhance efforts to study and report on existing and future health implications of international trade agreements in close cooperation with relevant intergovernmental organizations".

12.In June 2001, the **General Assembly of the United Nations** will hold a **Special Session on HIV/AIDS**. The TRIPS Council could take into consideration some of the important conclusions of the Report of the Secretary General to this meeting (document A/55/779, issued on 16 February 2001). In paragraph 48, for instance, the UN Secretary General notes that "[g]lobally trade policy provisions need

to be used more effectively to increase access to care. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with a guarantee of their quality. The relevance of compulsory licensing and the development of national manufacturing capacities need further expansion". In paragraph 101, the Report also remarks that "[w]e need to find ways of more effectively using trade policy provisions, such as compulsory licensing or parallel importation, to increase access to care. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with guarantees of their quality".

13.At the **XI Summit of the Heads of State and Government of the Group of Fifteen** (G-15), in Jakarta (30-31 May 2001), the Heads of State and Government stressed the "urgent need to address pandemic and endemic diseases such as HIV/AIDS, Tuberculosis and Malaria" and stated that "the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) should in no way prevent developing countries from taking measures, such as compulsory licensing and parallel imports to ensure access to life-saving drugs at affordable prices to overcome hazards to public health and nutrition caused by HIV/AIDS and other diseases". They also considered "the forthcoming Special Discussion in the Council for TRIPS of the WTO as an opportunity for promoting a convergence of views in this regard".

14.Finally, in civil society, a number of important non-governmental organizations, such as **"Médecins Sans Frontières"**, **Oxfam** and **Consumers International** also have emphasized their concern that the TRIPS Agreement may be applied in detriment to health policies.

III. TRIPS AND PUBLIC HEALTH

15.There are different elements that relate the TRIPS Agreement to public health issues. In particular, provisions related to patents on pharmaceutical products have an obvious effect on national policies on access to medications. In the Preamble of the TRIPS Agreement, Members recognize "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives". They also recognize "the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base. In this context, patent rights cannot be paramount to overarching public policies, in particular health policies". Whenever governments deem it appropriate, a number of the provisions of the TRIPS Agreement can be applied in order to ensure access to medications.

16.Adequate access to medications at affordable prices is recognized as one of the most effective elements of public health policies to reduce mortality and infection rates. In the case of HIV/AIDS, for instance, some of the most successful policies have been possible through provision of increased access to generic and patented medicines to those in need. Access can be limited by a number of factors, such as financial hurdles; physical and infrastructure barriers; and information gaps, among others. When IPRs are properly granted and exercised, they may meet their objective of contributing to the development of new medicines. However, there should be a common understanding that confirms the right of governments to ensure access to medications at affordable prices and to make use of the provisions in the Agreement whenever the scope or exercise of IPRs result in barriers to access to medicines.

(a) Objectives and Principles of the TRIPS Agreement

17.**Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8.** Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23 May 1969), which establishes, in Article 31, that *"[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".*

18.**Article 7** is a key provision that defines the objectives of the TRIPS Agreement. It clearly establishes that **the protection and enforcement of intellectual property rights do not exist in a vacuum**. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights. Some of the elements in Article 7 are particularly relevant, in order to ensure that the provisions of the TRIPS Agreement do not conflict with health policies: the promotion of technological innovation and the transfer and dissemination of technology; the mutual advantage of producers and users of technological knowledge; social and economic welfare; and the balance of rights and obligations.

19.Article 7 states that the protection and enforcement of intellectual property rights "should" contribute to the aforementioned objectives. **Such language stems from a recognition by Members that the mere existence and the exercise of IPRs, such as patents, do not necessarily result in the fulfilment of the objectives of the Agreement.** In the context of health policies, for instance, patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to a balance of rights and obligations. **Where confronted with specific situations where the patent rights over medicines are not exercised in a way that meets the objectives of Article 7, Members may take measures to ensure that they will be achieved - such as the granting of compulsory licences.**

20.The objective of the **promotion of technological innovation and the transfer and dissemination of technology** places the protection and enforcement of IPRs in the context of the interests of society. Such an objective is essential for the promotion of health policies, as it **encourages the development of domestic production of pharmaceutical products.** Whenever economically feasible, local production of pharmaceutical products is extremely important to ensure that medications are more readily available in the market, and at more 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. As mentioned above, these objectives can be obtained by the normal exercise of patent rights. **Where the patent holder fails to meet the objectives of the TRIPS Agreement and of public health policies, however, Members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals.**

21.Also regarding patent protection of pharmaceutical products, the concept of "balance of rights and obligations" and of "mutual advantage of producers and users of technological knowledge" are relevant to ensure that the exercise of the exclusive rights provided by patent rights is subject to limitations, which are expressed in different provisions of the TRIPS Agreement, such as those relating to compulsory licences and parallel imports.

22.In **Article 8**, the TRIPS Agreement affirms that Members may adopt measures to protect public health, among other overarching public policy objectives, such as nutrition and socio-economic and technological development. Any interpretation of the provisions of the Agreement should take into account the principles set forth in Article 8. The reading of such provision should confirm that **nothing in the TRIPS Agreement will prevent Members from adopting measures to protect public health, as well as from pursuing the overarching policies defined in Article 8.**

23.Article 8.2 allows Members to take measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. In the implementation of public health objectives, one situation of abuse of rights could be, for instance, the practice of excessively high prices of patented pharmaceutical products. Under normal circumstances, the exercise of patent rights can encourage the creation of new drugs and promote sustainable availability to society, as part of the "balance of interests" foreseen in the objectives of Article 7. Nevertheless, in many instances, the owners of patented pharmaceutical products may abuse their exclusive rights, by selling or offering for sale drugs at prices beyond reasonable margins of profit, which prevents adequate access to medications by the general public. Another situation of abuse of rights could occur when the owners of patented pharmaceutical products do not offer their products in sufficient amounts to meet the demands of the market. In such non-exhaustive

situations, patent rights are exercised in a way that conflicts with public health policies as they prevent adequate access to medicines.

(b) Parallel Imports

24.Article 6 of the TRIPS Agreement is extremely relevant for Members, especially developing countries, and particularly the least-developed and smaller economies among them. Article 6 provides that Members are free to incorporate the principle of international exhaustion of rights in national legislation. Consequently, any Member can determine the extent to which the principle of exhaustion of rights is applied in its own jurisdiction, without breaching any obligation under the TRIPS Agreement.

25.Whenever governments deem it appropriate, adoption of the principle of international exhaustion of rights can be a useful tool for health policies. Where the prices of pharmaceutical products are lower in a foreign market, for instance, a government may decide to allow importation of such products into the national market, so as to allow offer of drugs at more affordable prices. Such measures may be beneficial to prevent anti-competitive practices on behalf of patent owners who offer their patented products at unreasonably high prices in the domestic market. In this case, patent owners would compete with other legitimate products: given that their exclusive rights would be exhausted, the interests of the patent owner would not be damaged.

26.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. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licences may be ineffective, parallel importation may be a relevant tool to ensure access to drugs.

27.In light of the importance of Article 6 as an instrument for health policies, we consider that Article 6 should be implemented in such a way as to ensure the broadest flexibility for Members to resort to parallel imports. **Members should therefore confirm their right of applying regimes of exhaustion of rights in their jurisdiction.**

(c) Compulsory Licences

28.Compulsory licences are important instruments to protect public health. Obviously, compulsory licences alone will not address all the problems related to public health, as other structural factors can also contribute to limiting access to pharmaceuticals. The TRIPS Council, however, is called to consider the extent to which intellectual property rights, on particular patents, may impose a barrier to access to medicines. Members should take the view that **the TRIPS Agreement in no way stands in the way of public health protection, and therefore that it should provide the broadest flexibility for the use of compulsory licences.**

29.Empirical evidence demonstrates that many Members have extensive experience in resorting to compulsory licences, without damaging the patent protection system. Some developed countries, for instance, are not only among of the main users of the patent system, but also seem to be great users of compulsory licences. [13] The national legislation of several Members also provides for compulsory licences on different grounds, such as refusal to deal, failure to work, public interest, inadequate supply and health.

[13]"In the United States under anti-trust laws, from August 1941 to January 1959 there were 107 judgements (13 in litigated cases and 94 by consent) in which patent rights were restricted. The use of compulsory licences continued after that date: 'literally tens of thousands of patents' have been compulsorily licensed in the United States (Scherer, 1998, p.106), in more than a hundred cases. In one single case (US Manufacturers Aircraft Associations Inc.), about 1,500 patents were compulsorily licensed (Finnegan 1997, p. 139; Goldestein, 1977, p. 123)" – in *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, by Carlos Correa (Geneva: South Center, October 1999).

30.Compulsory licences can represent a significant tool for governments to ensure access to pharmaceuticals. Normally, patent owners are expected to provide access of their patented medicines to the market. In specific circumstances, however, governments may deem it necessary to grant compulsory licences to allow interested third persons to produce the medicine, in order to ensure that it will be more readily available, or more affordable to the general public.

31.Some of the most relevant provisions of the TRIPS Agreement with respect to compulsory licences are Articles 31, 7, 8 and 40 of the TRIPS Agreement and Article 5 of the Paris Convention. When read together, such provisions allow scope for Members to ensure that regulatory policies can be exercised by governments to promote public health policies. Based on Article 5A of the Paris Convention and Article 31 of the TRIPS Agreement, governments may issue compulsory licences as a way of ensuring that medicines will be available at more affordable prices.

32.Clearly, Article 31 of the TRIPS Agreement does not define the grounds upon which to issue compulsory licences, but merely establishes procedural requirements to be followed by Members. Therefore, **Members are free to determine the grounds upon which to issue compulsory licences**.

33.As regards the relationship of the provisions related to compulsory licenses with Articles 27.1 and 28 of the TRIPS Agreement, we believe that both set of provisions address different matters and circumstances. In no way Articles 27.1 and 28 limit the right of Members to issue compulsory licences.

34.In many cases, developing countries - particularly least-developed countries and smaller economies - have limited industrial capacities and very small domestic market to manufacture medicines locally in order to ensure adequate access to drugs. In this regard, it should be noted that nothing in the TRIPS Agreement prevents Members from granting compulsory licences for foreign suppliers to provide medicines in the domestic market. In addition, Members may adopt regimes of international exhaustion of rights in national legislation to allow parallel imports into the domestic market. In this respect, the reading of Article 31(f) should confirm that **nothing in the TRIPS Agreement will prevent Members to grant compulsory licences to supply foreign markets**.

(d) Differential Pricing

35.Given that differential pricing (or tiered pricing) is not an intellectual property issue, we believe that it should not be covered by the TRIPS Agreement, although Members might be interested in following the development of discussions in other competent international fora, such as the World Health Organization.
36.We believe that differential pricing arrangements can play a relevant role in providing better access to affordable medicines. Governments should also consider the establishment of global data bases on drug prices, which would facilitate decisions by governments related to the establishment of price controls, authorization of parallel imports and granting of compulsory licences.

37.**In no way should discussions on differential pricing be prejudicial to the right of Members to make use of the provisions of the TRIPS Agreement, such as parallel imports and compulsory licences.**

(e) Other Issues

38.Nature and scope of obligations in the TRIPS Agreement (Article 1.1): Article 1.1 is important to ensure the freedom of governments on the means of implementation of the minimum standards of the TRIPS Agreement in national legislation. In many cases, more extensive protection in national legislation than is required by the TRIPS Agreement may result in limitations for the implementation of health policies. **We consider that Members should be free to implement the TRIPS Agreement in ways that best accommodate the protection of health policies in national legislation.**

39.Protection of Test Data (Article 39.3 of the TRIPS Agreement): Article 39.3 of the TRIPS Agreement leaves considerable room for Member countries to implement the obligation to protect test data against unfair competition practices. The Agreement provides that "undisclosed information" is regulated under the discipline of unfair competition, as contained in Article 10bis of the Paris Convention. With this provision, the Agreement clearly avoids the treatment of undisclosed information as a "property" and does not require granting "exclusive" rights to the owner of the data.

40.The TRIPS Agreement requires Members to grant this protection only in respect of *new chemical* entities. There is no need to provide it for a new dosage form or for new use of a known product. The protection is to be granted against "unfair commercial use" of confidential data. This means that a third party could be prevented from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the data had been acquired through dishonest commercial practices. However, Article 39.3 does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, since this would not imply any "unfair commercial use".

41.Transitional arrangements (Articles 65.4 and 66.1 of the TRIPS Agreement): The TRIPS Council could consider extending the transitional periods foreseen in Article 65.4 and 66.1 of the TRIPS Agreement.

42. Non-violation (Article 64.3 of the TRIPS Agreement): There is no consensus on the scope of non-violation complaints made pursuant to the TRIPS Agreement. It seems inconceivable that a non-violation complaint could be applied to measures to protect public health, in particular measures for providing access to essential medicines.

Statement by the Africa Group:
TRIPS and Public Health Informal Session of the WTO TRIPS Council
25 July 2001

The Special Discussion of the TRIPS Council on June 20 has demonstrated the high level of interest and commitment of the WTO Membership to address the concerns raised by developing countries on the issue of the TRIPS Agreement and Public Health. Indeed, we are very encouraged by the degree of agreement, as indicated in the Members' statements, on the need to ensure that the implementation of the TRIPS Agreement does not prevent Members from adopting appropriate measures to protect public health and ensure to affordable medicines. There was general support for concrete measures to be taken at the Doha Ministerial Conference to this effect. We look forward to furthering the discussions along these lines.

On June 20, more than a third of the WTO Membership co-sponsored a paper that sets out their common understanding of the provisions of TRIPS Agreement related to public health issues. A large number of Members have also added their support to several elements contained in the joint developing country paper. However, we take note of some questions raised by a number of delegations, and we look forward to reaching agreement on those points, so that we may proceed swiftly towards achieving a tangible result for our discussions, in time for Doha.

In the interest of maintaining the momentum of our important discussions, we take the opportunity of this meeting to do the following

- address those substantive issues and questions raised by some delegations during our formal session on June 20, with a view to achieving a convergence of views;
- offer procedural suggestions with regard to on-going preparations for the Ministerial Conference in Qatar, regarding the issue of the TRIPS Agreement and Public Health; and
- provide our recommendations for some of the elements to be included in the Ministerial Declaration on this issue.

WTO Secretariat Checklist

Before we address the substantive issues raised, we wish to take note of the Secretariat's document; the "Checklist of Articles of the TRIPs Agreement and matters raised in relation to them at the Council's special discussion on intellectual property and access to medicines" (document JOB 01/113)

We thank the Secretariat for its efforts in preparing this document. Although the Checklist does not adequately reflect the high degree of convergence amongst the WTO Membership on key issues raised during the Special Discussion, we nonetheless understand the need for the Secretariat to maintain its position of neutrality on matters related to the interpretation of WTO Agreements. In this connection, we refer to the US statement on June 20, which invited other Members to refer to some documents prepared by the Secretariat for "explanations" on the provisions of the TRIPS Agreement We do not consider it appropriate for the WTO Secretariat to provide interpretations of the provisions of the TRIPS Agreement, and would strongly suggest that the Secretariat strives to maintain its objectivity in such matters.

Substantive issues

We have read with particular interest the interventions made by a number of delegations, including the United States, the European Communities and Switzerland. We would like to provide some preliminary comments on their respective interventions, in the interests of moving forward.

Mandate of TRIPS Council

In its statement on June 20, the US urged the adoption of a "comprehensive approach" to deal with serious health problems. Certainly, in other international fora and at the national level, our respective governments are engaged in the serious work of identifying and implementing various solutions to address public health issues. It is not within the mandate of the TRIPS Council to talk of the infrastructure in different countries, in terms of hospitals, doctors and nurses. Nor will be useful for this forum to discuss the global funds and other initiatives for the purchase and distribution medicines. These issues are belong and are being addressed in their appropriate fora and institutions.

Insofar as our present work in the TRIPS Council concerned, it is to address the impact of the TRIPS Agreement on public health and access to affordable medicines. We must be clear about the mandate and objective of our exercise in this forum; that is, to examine the relationship between the various provisions of the TRIPS Agreement and issues of public health and access to medicines, and most importantly, to ensure that the implementation of the TRIPS Agreement does not amount to an obstacle to the promotion of access to affordable medicines and the protection of public health

Compulsory licences

Members have the right under the TRIPS Agreement to determine the grounds on which compulsory licences can be issued. The US has said that Article 31 of the TRIPS Agreement does not "itemize the purposes for which compulsory licenses may be granted", rather it establishes the conditions to be met with respect to compulsory licences. The EC and Switzerland have also said that, "compulsory licenses can be issued for any reason, including of course public health".

Under the TRIPS Agreement, Members are free to determine the grounds upon which to issue compulsory licenses. In addition, Members are free to determine and implement in national law the meaning of terms in the TRIPS Agreement.

Regarding the relationship between Article 31 and Article 27.1, we reiterate that both sets of provisions address different matters and circumstances. As stated in the paper co-sponsored by developing countries, Articles 27.1 and 28 do not limit the right of Members to issue compulsory licenses. We do not believe that these provisions prohibit the grant of compulsory licences in cases where the patent fails to be worked or is insufficiently worked. As with all other provisions of the TRIPs Agreement, Articles 31 and 27.1 should certainly be read in light of the objectives and principles of the TRIPs Agreement.

Under Article 31(b), requirement to obtain authorization from the patent holder can be waived in cases of national emergency, extreme urgency and for public non-commercial use. The US reading of this provision seems to suggest that the application of the waiver depends on the time element. It is clear that Article 31(b) is not limited to a question of time, but rather is dependent on situations of critical and extreme importance in which governments deem it necessary to issue compulsory licenses. In this respect, governments have the prerogative to determine when a situation constitutes one of national emergency or extreme urgency.

The Africa Group has already stated its understanding that legitimate grounds for the issuance of a compulsory license may include the following: (1) where there is non-working or insufficient working of a patent; (2) for the importation of a product under patent protection; (3) for the export of a product produced under compulsory licence; and (4) for a foreign manufacturer to produce goods intended for the market of the Member issuing the license. We also said that with respect to item (4), Members should undertake to recognize and give due effect to such compulsory licenses. We note that the EC has referred to such an interpretation and we look forward to discussing this issue to secure consensus on this point.

Parallel import

As regards "parallel imports", we believe that a restrictive view of Article 6 will only work towards limiting access to affordable medicines. Article 6 confers upon Members the right to adopt the principle of international exhaustion of rights in their national legislation. Article 6 is a crucial element in the balance of rights and obligations in the TRIPS Agreement, and should be regarded as an essential tool in a country's arsenal of national health policies. This fact is evidenced in the practice of certain developed countries.
We further wish to clarify that parallel importing is allowed under the TRIPS Agreement in several circumstances including the following: (1) where the patented product has been marketed in another country, by the patent holder or with his consent, or (2) where the product is sold in another country under a compulsory license, or (3) where the product is marketed in another country through other legitimate means without the authorization of the patent holder (such as where the product is not patent protected in the exporting country).

The Africa Group also wishes to reiterate its position that on-going discussions and initiatives in other fora should not prejudice the rights of governments to adopt policy options available under the TRIPS Agreement. Therefore, the discussions on the global tiered pricing scheme should not affect the affect the right of Members to adopt parallel import measures.

Preparatory work for Doha

In view of the wide support for the TRIPS and public health issue to be addressed at the Doha Ministerial Conference, we believe that it will be appropriate for Members to consider the course of action to be pursued. In our opinion, we think that our work in the TRIPS Council should be co-ordinated with that of the preparatory process for the Doha Ministerial Conference.

Mr Chairman, for this purpose, we would recommend that you begin to initiate the necessary processes to identify the elements for inclusion into the Doha Ministerial Declaration. From our perspective, the vital elements would include the following:

- Recognition of the paramount importance of the objectives and principles of the TRIPs Agreement, set out in Articles 7 and 8, in the interpretation of provisions in the Agreement. All provisions of the TRIPS Agreement must be clarified and interpreted in the context of and against the background of Articles 7 and 8 of the TRIPS Agreement.
- Reaffirmation of Members' right to determine the grounds on which compulsory licenses may be issued, including that of protection of public health and nutrition.
- Undertaking to recognize and give due effect to a compulsory license issued by another Member to a manufacturer in their territory for the production of drugs or medicine intended for the market of the Member issuing the license.
- Reaffirmation of the fact that nothing in the TRIPS Agreement prevents WTO Members from resort to parallel imports.
- Agreement to observe a moratorium on all dispute actions that are aimed at preventing or limiting Members' capacity to promote access to medicines and protect public health.

Extension of transition periods for developing and least developed countries.

We note again, Mr Chairman that Members have shown a lot of willingness to move forward on this issue. A lot of goodwill has been exhibited. We feel it is time that all delegations set out in specific terms what they would want to see done in the period leading up to Doha, and at Doha, regarding the TRIPS Agreement and its impact on access to affordable medicines. The Africa Group is more than prepared to work with all delegations in a constructive manner on this issue.

Joint NGO Statement on Patents and Medicines

Presented at Media Conference organised by TWN, Oxfam and Medicins Sans Frontiers
19 June 2001

PATENTS AND MEDICINES: THE WTO MUST ACT NOW!

Joint NGO Statement on the Special Discussion in the WTO TRIPS Council on Patents and Access to Affordable Medicines.

The deepening health crisis in many developing countries has raised public concern about the lack of access of poor people to affordable medicines. Public outrage over the exorbitant prices of HIV/AIDS drugs has also put the spotlight on the negative effects of global patent rules on the price and affordability of essential and vitally-needed medicines. Each year about 11 million people die from preventable infectious diseases. The AIDS epidemic is claiming millions of lives, to the extent that in some countries over a quarter of the population is affected.

Around the world, public concern is mounting at how the introduction of strict patent regimes in developing countries required by the WTO's TRIPS Agreement is causing the price of patented drugs to be set at high, often exorbitant levels. The effective monopolies granted by TRIPS allow pharmaceutical giants to suppress competition from alternative, low-cost producers and to charge prices far above what is reasonable. This is done at the expense of many ordinary consumers who are too poor to afford treatment.

Before the establishment of the TRIPS Agreement in 1994, countries were allowed more options to exclude sectors from patent rules in their national laws. Approximately 50 countries (both developed and developing) excluded pharmaceutical products from patenting. However, with the implementation of the TRIPS Agreement, member countries are no longer allowed to do this.

The Agreement does allow member countries to take compensatory measures to counter the effective monopolies of companies owning patents. Two of the most important measures are the issuing of compulsory licences, whereby a government can give permission to other parties to produce or import products on which patents had been given without the permission of the patent holder, and the practice of parallel imports. Since TRIPS does not limit the grounds on which compulsory licences can be given, a country should not be prevented from issuing compulsory licenses on other grounds that it may consider necessary to meet public health and other public interest objectives.

However, pressures have been put on many developing countries by governments and companies in some developed countries not to exercise their rights to compulsory licensing or parallel importation. Recent examples of harassment faced by developing countries include the case brought by 39 pharmaceutical companies against the South African government over its Medicines and Related Substances Control Amendment Act, and the dispute settlement case lodged by the USA against Brazil in the WTO in relation to its Industrial Property Law. People everywhere, in developing and developed countries, are outraged at these kinds of pressures imposed on poor countries to prevent them from using the flexibility of TRIPS to improve the access of ordinary people, particularly the poorest, to medicines.

Growing public reaction to the scandal of patents and high medicine prices provides the background to a one-day Special Discussion on patents and access to medicines, which will be held by the TRIPS Council at the WTO in Geneva on 20 June. This special discussion was proposed by the Africa Group of countries in the WTO and supported by many others.

We, the undersigned NGOs, welcome this decision and regard the Special Discussion as an important opportunity for the urgent consideration and resolution of the negative impacts of the TRIPS Agreement on health and access to medicines.

In agreeing to the Special Discussion, WTO member countries have taken the first step towards clarifying the role of intellectual property rights and interpreting the TRIPS Agreement in such a way that intellectual property protection does not hinder access to vitally needed medicines. This meeting represents an opportunity to shift the balance of global patent rules in favour of the public interest and the protection of public health.

In developing countries, the TRIPS Agreement has exacerbated conflicts between private corporate interests, and the public interest including public health. The controversy over access to medicines has highlighted just one aspect of the imbalances within the TRIPS Agreement, which is too heavily tilted in favour of private right holders and against the public interest. There is growing evidence of social and economic problems caused by the introduction and enforcement of stricter intellectual property rights, which developing countries are obliged to implement as part of their obligations under TRIPS. This has resulted in calls for a re-assessment of the Agreement itself.

The key principle that should guide the discussions in the WTO is that access to essential and vitally-needed medicines is a fundamental human right. Poor people have the right to good health, and therefore to medicines for the treatment of poverty-related diseases. Protecting people's health and saving their lives must take precedence over the strict protection of intellectual property and the very high profits which drug companies derive from this. Governments need a permanent guarantee that they can put public health and the welfare of their citizens before patent rights, without having to face the kind of legal pressures or threat of trade sanctions experienced by South Africa and Brazil.

We therefore call on WTO member countries, during the Special Discussion, to:

- Strengthen the existing public-health safeguards within TRIPS to ensure that governments have the unambiguous right to override patents in the interests of public health;
- Adopt a pro-public health interpretation of the Agreement through the flexible use of existing safeguards and exceptions. These include upholding the right of countries to grant compulsory licences for local manufacturing, import and export, and their right to implement parallel importation measures;
- Remove the burdensome conditions that governments have to fulfil in the issuing of compulsory licences, so that licences can be granted on a 'fast track' basis for public-health purposes;
- Extend the implementation deadlines within TRIPS for developing countries in relation to patent protection (both product and process) for medicines;
- Agree not to exert bilateral or regional pressure on developing countries which take measures to exercise their rights under TRIPS to protect public health and promote access to medicines, nor to pressure them to implement unnecessarily strict and potentially harmful intellectual property protection standards or 'TRIPS-plus' measures.
- Observe, with immediate effect, a moratorium on dispute settlement action against developing countries which hinders their ability to promote access to medicines and protect public health (including the use of compulsory licence and parallel importation measures).
- Allow developing countries the option of excluding medicines from patenting on humanitarian or public-health grounds, in order to meet the objectives of saving lives, countering and controlling epidemics, and ensuring that the poor obtain access to essential medicines for the treatment of poverty-related diseases.

The NGOs signing this statement will use the above recommendations as the yardstick to judge the decisions and actions taken by the WTO TRIPS Council and higher bodies of the WTO, and whether the process initiated by the Special Discussion on TRIPS and medicines has been a success or a failure.

People all over the world will be watching whether WTO member countries meet the challenge of tackling the global health crisis, and demonstrate their commitment and contribution to the prevention of further unnecessary deaths.

We also call on governments in developed countries not to be influenced by any attempts by multinational drug companies to block clarifications of, or changes to, the TRIPS Agreement which are needed to make medicines affordable to the poor. We also call on the governments of developing countries to stand firm in putting forward proposals that affirm and strengthen their rights under TRIPS (especially in relation to compulsory licensing and parallel importation). Discussions on schemes such as 'differential pricing', or a global fund for AIDS, should not distract from, or be a substitute for, the need for action on patents and the TRIPS Agreement.

Checklist of Articles of the TRIPs Agreement and Matters Raised in Relation to them at the Council's Special Discussion on Intellectual Property and Access to Medicines of 20 June 2001

WTO Secretariat, Council for TRIPS, 16 July 2001 (JOB(01)/113)

At the Council's meeting of 18-22 June 2001, the Council agreed that the Secretariat should prepare a checklist of all provisions of the TRIPS Agreement to which Members had made reference in their interventions in the Special Discussion on Intellectual Property and Access to Medicines held on 20 June 2001 and of the matters that delegations raised in relation thereto.

In order to respond to this request, the Secretariat has prepared the attached checklist. This contains, in its first column, the various provisions of the TRIPS Agreement to which reference was made and, in its second column, against each such provision the issues that were identified.

The checklist seeks to identify the issues, rather than to indicate the positions taken by each Member on the issue in question. For that, reference should be made to the minutes of the discussion (IP/C/M/31) and the two papers submitted by Members in advance of that discussion (IP/C/W/280 and IP/C/W/296). On some issues, there appeared to be a large measure of agreement on how the TRIPS Agreement should be understood, while on others different positions were taken.

TRIPS PROVISION	ISSUE IN BRIEF
Preamble, 1st consideration	Significance of desire "...to reduce distortions and impediments to international trade." for treatment of parallel imports
Preamble, 5th consideration	Significance of the recognition of the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives, for the interpretation of other provisions of TRIPS
Article 1.1	Significance for freedom of Members to implement the TRIPS Agreement in ways that best accommodate the protection of health policies in national legislation
Article 2.1	Relevance of Articles 5 and 5A of the Paris Convention for the grounds on which compulsory licences can be granted, including as a way of ensuring that medicines will be available at affordable prices
Article 6	- Extent to which Members are free to adopt their own exhaustion regimes, including international exhaustion, and implications for treatment of parallel imports - Relation of Article 6 to other provisions of the TRIPS Agreement, notably those in Part II - Definition of parallel imports permitted under an international exhaustion regime. Extent to which they cover products produced under a compulsory licence in another country or put on the market in any other legitimate manner - Action to prevent re-importation as a complementary measure to a global tiered pricing system - Non-prejudicing of rights of Members under the TRIPS Agreement by tiered pricing arrangements
Article 7	The scope of this provision and its significance for the interpretation of other TRIPS provisions, including those that provide for flexibility

Article 8.1	- The scope of this provision and its significance for the interpretation of other provisions of the TRIPS Agreement, including those that provide for flexibility. Extent to which this provision allows Members to adopt any measure necessary to protect public health. What is meant by "consistent with the provisions of this Agreement"? Significance of difference compared to Article XX of GATT - Implications for price and reimbursement policies, including differential pricing
Article 8.2	- The scope of this provision and its significance for the interpretation of other provisions of the TRIPS Agreement - Extent to which this provision allows Members to take measures against abuses of IPRs, anti-competitive practices or practices which unjustifiably limit trade or are detrimental to the international transfer of technology
Article 27.1	- Significance for providing incentives for research and development - Importance of the criteria of novelty, inventive step and industrial applicability for the balance in the patent system - Distinction between discovery and invention, especially in the field of biotechnology - Impact of over-broad patents, patents for inventions that do not involve a sufficiently inventive step, sleeping patents, and selection patents - Need to take into account knowledge of traditional communities in examining patent applications - Relevance for the use of compulsory licensing, including the extent to which Article 27.1 restricts the grounds for the grant of compulsory licences, the possibility to grant compulsory licences because of importation rather than local production, and the possibility to grant compulsory licences for importation
Article 27.2	Extent to which this provision can be used to exclude from patentability medicines that are vital for saving human lives
Article 27.3	Exclusion of essential drugs as identified by WHO from patentability
Article 27.3(a)	Scope of the exclusion under this provision and significance for public health. Extent to which use, including new use of a known substance, is covered by this exclusion
Article 27.3(b)	- Extent to which the exclusion allowed in this provision can be used to promote public health objectives - Proposed disclosure requirement relating to the source of genetic material and traditional knowledge, prior informed consent and benefit-sharing
Article 28.1	- Significance for providing incentives for R&D - Relationship with Article 6: extent to which the exclusive right to prevent importation allows objections by right holders to parallel imports - Significance of footnote - Relevance of this provision for the right of Members to issue compulsory licences. Significance of importation right for local working requirements in compulsory licensing systems
Article 28.2	Issue not specified
Article 29.1	- Extent to which disclosure promotes flow of information to the public, including competing manufacturers - Significance for the balance in the TRIPS Agreement

Article 30	- Nature and scope of the exceptions allowed under this provision (prior user rights, acts done privately and for non-commercial purposes, research/ experimental/ scientific/ academic use, acts necessary to meet governmental or regulatory requirements, public non-commercial activity) - Significance for facilitating generic competition, including "Bolar" or regulatory exception and panel report on Canada - Patent Protection of Pharmaceutical Products (WT/DS114/R) - Does the term "third parties" include the general public? Should the legitimate interests of consumers be taken into account? - Extent to which Article 27 affects the interpretation of Article 30
Article 31	- Extent to which Members are free to determine the grounds including public health, for the grant of compulsory licences. Relevance of abuse by the patent owner. Extent to which use of Article 31 should be a last resort. Extent to which compulsory licences can be granted on grounds of non-working or insufficient working of a patent? - Extent to which compulsory licences can be issued for importation
Article 31(a)	- Extent to which this provision requires the grant of compulsory licences on a case by case basis? - Impact of this provision on the non-discrimination requirements of Article 27.1
Article 31(b)	- What constitutes a national emergency? Is the HIV/AIDS crisis in some countries a case of "a national emergency or other circumstances of extreme urgency"? Can a national emergency encompass a continuous crisis (such as the HIV/AIDS epidemic in some African countries) as well as sudden or unforeseen events? - Extent to which the phrases "reasonable commercial terms and conditions" and "reasonable period of time" should be interpreted flexibly and in the light of practices prevailing in the Member in question, taking into account the level of development and socio-economic priorities - Should the concept of "reasonable commercial terms and conditions" be understood to require the interests of both the patent holder and those of the applicant and the consumer to be taken into account? - Extent to which licensing rates should be lower in developing countries and graduated according to a country's ability to pay - Significance of waiver from requirement to seek first a voluntary licence in cases of public non-commercial use. Extent to which it covers governmental health care for the poor and free of charge distribution of drugs by the government
Article 31(c)	Application of this provision in cases of extreme urgency
Article 31(f)	- Extent to which a compulsory licence can be issued to supply foreign markets, in particular on grounds of public health - Extent of exports possible by virtue of the use of the word "predominantly" - Extent to which Members have the right to confer compulsory licences on a manufacturer of a third country. Extent to which this would require recognition of the licence by the government in the country of production and that all the goods manufactured under the licence are exported to the country granting the licence. Extent to which eligibility for compulsory licences should be limited to those parties that can assure the government

	granting the licence that they will be able to supply the market without the interruption that might result from infringement of a patent in their own country - Relevance of nationality of a recipient of a compulsory licence
Article 31(g)	Application of this provision in cases of extreme urgency
Article 31(h)	- Interpretation of this provision - Extent to which remuneration can be less than the "reasonable commercial terms and conditions" under Article 31(b) - Extent to which licensing rates should be lower in developing countries and graduated according to a country's ability to pay - Extent to which the nature of the products (e.g. urgently needed life-saving drugs) may influence the level of remuneration
Article 31(i)	Extent to which a compulsory licence can be provisionally applied before any review is completed
Article 32	Issue not specified
Article 33	- Significance for the balance in TRIPS Agreement - Commercial rational of this provision. Appropriateness for developing countries. Extent to which possible drug resistance and obsolescence, or the possible development of more effective drugs superseding earlier ones, has been taken into account
Article 34	Issue not specified
Article 39.2	Relevance for the interpretation of Article 39.3
Article 39.3	- Nature of the obligation to protect test and other data, including implications for generic competition and extent to which this matter is to be regulated under the discipline of unfair competition, as contained in Article 10bis of the Paris Convention, and the extent to which undisclosed information should be regarded as a form of property and the subject of exclusive rights. Extent to which protection against "unfair commercial use" requires regulatory authorities not to rely on such data for a reasonable period of time for the purposes of providing marketing approval for the drugs of competitors. Relevance of whether the data has been acquired through dishonest commercial practices - Extent to which this provision applies to marketing approval procedures that do not require the submission of the data in question - Extent to which Article 39.3 requires marketing approval procedures or prescribes their nature - Extent to which this provision applies to new dosage forms or new uses of a known product - Extent to which whether the product in question is protected by a patent or not is relevant for the protection required by this provision - Extent to which this provision may weaken or nullify Members' rights under other provisions of the Agreement, including the "fast track" compulsory licensing procedure in case of emergency under Article 31(b)
Article 40	Issue not specified
Article 64	- Moratorium/due restraint on the use of WTO dispute settlement procedures in regard to measures for the protection of public health - Non-applicability of/extension of moratorium on non-violation complaints, especially in regard to measures to protect public health

Article 65.2	- Significance for the flexibility available - Sufficiency of transition period for developing countries in relation to patent protection (product and process) regarding pharmaceuticals. Consistency with Article 7 and development needs
Article 65.4	- Significance for the flexibility available - Sufficiency of transition period for developing countries, in particular in relation to patent protection (product and process) regarding pharmaceuticals. Consistency with Article 7 and development needs
Article 66.1	- Significance for the flexibility available - Sufficiency of transition period for LDCs
Article 66.2	Incentives for the transfer of technology. Relevance for facilitating generic competition
Article 67	Enhancing the provision of technical cooperation, especially in regard to the use of the flexibility in the TRIPS Agreement. Relevance for facilitating generic competition
Article 70.8 and 70.9	Issue not specified

Appendix - List of Participants

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The Inappropriateness of the Patent System for Life Forms and Processes
By Dr. Tewolde Egziabhe, Environmental Protection Authority, Ethiopia

The OAU Model Law and Africa's Common Position on the TRIPS Review Process
By Prof. Johnson Ekpere, University of Ibadan, Nigeria

REFERENCE DOCUMENTS

Communication from Kenya on behalf of the African Group: Preparation for the 1999 ministerial Conference, 29 July 1999

Communication from Mauritius on behalf of the African Group: Review of the Provisions of Article 27.3(b), 20 September 2000

Declaration of the African Group at the 5th Conference of the Parties of the Convention on Biological Diversity

Communiqué of the African Group in the meeting of the 5th Conference of the Parties of the Convention on Biological Diversity

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By ICTSD, BRIDGES, Year 5 No 5, June 2001

Essential Drugs in Southern Africa Need Protection fro Public Health Safeguards under TRIPS
By René Loeweneson, Training and Research Support Centre, Zimbabwe

REFERENCE DOCUMENTS

African Group Statement on TRIPS, Access to Medicines and Public Health, 20 June 2001

Submission by 47 Developing Countries to the WTO TRIPS Council on "TRIPS and Public Health", 29 June 2001

Statement by the African Group: TRIPS and Public Health Informal Session of the WTO TRIPS Council, 25 July 2001

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